UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number 001-38205

ZAI LAB LIMITED

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Cayman Islands
(Jurisdiction of incorporation or organization)

4560 Jinke Road
Bldg. 1, Fourth Floor
Pudong
Shanghai, China 201210
(Address of principal executive offices)

Samantha Du
Chief Executive Officer
Zai Lab Limited
4560 Jinke Road
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Shanghai, China 201210
Telephone: +86 21 6163 2588
(Name, telephone, email and/or facsimile number and address of Company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American depositary shares, each representing one ordinary share, par value $0.00006 per share	ZLAB	Nasdaq Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the Annual Report:

68,375,511 ordinary shares were issued and outstanding as of December 31, 2019

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☒ Yes ☐ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Note—checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "accelerated filer and large accelerated filer" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated Filer	☐
Non-Accelerated Filer	☐	Emerging Growth Company	☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP	☒	International Financial Reporting Standards as issued by the International Accounting Standards Board	☐	Other	☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an Annual Report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

Zai Lab Limited
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Industry and Market Data

Although we are responsible for all disclosure contained in this Annual Report on Form 20-F, in some cases we have relied on certain market and industry data obtained from third-party sources that we believe to be reliable. Market estimates are calculated by using independent industry publications, government publications and third-party forecasts in conjunction with our assumptions about our markets. While we are not aware of any misstatements regarding any market, industry or similar data presented herein, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the headings "Cautionary Statement Regarding Forward-Looking Statements" and "Item 3.D. Risk Factors" in this Annual Report on Form 20-F.

Trademarks and Service Marks

We own or have rights to trademarks and service marks for use in connection with the operation of our business, including, but not limited to, ZAI LAB and □□□□. All other trademarks or service marks appearing in this Annual Report on Form 20-F that are not identified as marks owned by us are the property of their respective owners.

Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 20-F are listed without the ®, (TM) and (sm) symbols, but we will assert, to the fullest extent under applicable law, our applicable rights in these trademarks, service marks and trade names.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our operational results and other future conditions. Forward-looking statements can be identified by words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "seek," "target," "potential," "will," "would," "could," "should," "continue," "contemplate" and other similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this Annual Report on Form 20-F and include statements regarding our intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth, strategies and the industry in which we operate.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We believe that these risks and uncertainties include, but are not limited to, those described in the "Item 3.D. Risk Factors" section of this Annual Report on Form 20-F, which include, but are not limited to, the following:

- our ability to successfully commercialize ZEJULA, Optune and any other products and drug candidates that we may obtain regulatory approval for;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- the timing or likelihood of regulatory filings and approvals;
- our ability to continue to develop our commercial team and our sales and marketing capabilities;
- our ability to contract on commercially reasonable terms with contract research organizations, or CROs, third-party suppliers and manufacturers;
- the pricing and reimbursement of our drug candidates, if approved;
- our ability to contract on commercially reasonable terms with CROs;
- the disruption of our business relationships with our licensors;

- our ability to operate our business without breaching our licenses or other intellectual property-related agreements;
- cost associated with defending against intellectual property infringement, product liability and other claims;
- regulatory developments in China, the United States and other jurisdictions;
- the ability to obtain additional funding for our operations;
- the rate and degree of market acceptance of our products and drug candidates;
- developments relating to our competitors and our industry;
- our ability to effectively manage our growth; and
- our ability to retain key executives and to attract, retain and motivate personnel.

These factors should not be construed as exhaustive and should be read with the other cautionary statements in this Annual Report on Form 20-F.

Although we base these forward-looking statements on assumptions that we believe are reasonable when made, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this Annual Report on Form 20-F. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate, are consistent with the forward-looking statements contained in this Annual Report on Form 20-F, those results or developments may not be indicative of results or developments in subsequent periods.

Given these risks and uncertainties, you are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statement that we make in this Annual Report on Form 20-F speaks only as of the date of such statement, and we undertake no obligation to update any forward-looking statements or to publicly announce the results of any revisions to any of those statements to reflect future events or developments. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless specifically expressed as such, and should only be viewed as historical data.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. SELECTED FINANCIAL DATA

Our Selected Consolidated Financial Data

The following selected consolidated statement of operations data for the years ended December 31, 2019, 2018 and 2017 and the selected balance sheet data as of December 31, 2019 and 2018 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. Our historical results for any period are not necessarily indicative of results to be expected for any future period. The selected consolidated financial data should be read in conjunction with, and are qualified in their entirety by reference to, our audited consolidated financial statements and related notes and "Item 5. Operating and Financial Review and Prospects" below. Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP.

	Year Ended December 31,		
	2019	2018	2017
	(in thousands, except share and per share data)		
Revenue	$ 12,985	$ 129	$ —
Expenses:			
Cost of sales	(3,749)	(43)	—
Research and development expenses	(142,221)	(120,278)	(39,342)
Selling, general and administrative expenses	(70,211)	(21,576)	(12,049)
Loss from operations	$ (203,196)	$ (141,768)	$ (51,391)
Interest income	8,232	3,261	527
Interest expenses	(293)	(40)	—
Changes in fair value of warrants	—	—	200
Other income, net	938	59	530
Loss before income taxes and share of loss from equity method investment	$ (194,319)	$ (138,488)	$ (50,134)
Income tax expense	—	—	—
Share of loss from equity method investment	(752)	(587)	(250)
Net loss	$ (195,071)	$ (139,075)	$ (50,384)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted (1)	64,369,490	52,609,810	21,752,757
Net loss per share, basic and diluted (1)	(3.03)	(2.64)	(2.32)

(1) See Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 20-F for a description of the method used to calculate basic and diluted net loss per share.

	As of December 31,	
	2019	2018
	(in thousands)	
Consolidated balance sheet data:		
Cash, cash equivalents and restricted cash	$ 76,442	$ 62,952
Short-term investments (1)	$ 200,000	$ 200,350
Total assets	$ 355,153	$ 301,987
Total shareholders' equity	$ 294,660	$ 251,082
Total current liabilities	$ 46,635	$ 48,842
Total non-current liabilities	$ 13,858	$ 2,064

(1) The short-term investments primarily comprise of the time deposits with original maturities between three months and one year.

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future and may never achieve or maintain profitability.

The Hong Kong Department of Health approved ZEJULA in October 2018 and we launched ZEJULA in Hong Kong in December 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. The China National Medical Products Administration, or NMPA, approved ZEJULA in December 2019 as a maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy and we launched ZEJULA in the People's Republic of China, or PRC or China, in January 2020. In December 2018, we announced the launch of Optune (Tumor Treating Fields) for the treatment of glioblastoma multiforme, or GBM, in Hong Kong. Although we launched ZEJULA in China in January 2020 for recurrent ovarian cancer, in Macau in June 2019 for recurrent ovarian cancer, and in Hong Kong in December 2018 for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy and we launched Optune (Tumor Treating Fields) in Hong Kong in December 2018, it will take some time to attain profitability and we may never do so. We have also obtained the rights to commercialize many clinical-stage drug candidates. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through private placements, our initial public offering in September 2017 and multiple follow-on offerings. For the year ended December 31, 2019, we generated revenue of $13.0 million from product sales, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2013. For the years ended December 31, 2019 and 2018, we reported a net loss of $195.1 million and $139.1 million, respectively.

We expect to continue to incur losses in the foreseeable future, and we expect these losses to increase as we:

- continue to commercialize ZEJULA, Optune and any other products for which we may obtain regulatory approval;
- maintain and expand sales, marketing and commercialization infrastructure for ZEJULA, Optune and any other products for which we may obtain regulatory approval;

- maintain and expand regulatory approvals for our products and drug candidates that successfully complete clinical trials;
- continue our development and commence clinical trials of our drug candidates;
- maintain our manufacturing facilities;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- seek to identify additional drug candidates;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend intellectual property-related claims; and
- acquire or in-license other intellectual property, drug candidates and technologies.

To become and remain profitable, we must continue commercialization efforts of ZEJULA and Optune and develop and eventually commercialize other drug candidates with significant market potential. This will require us to be successful in a range of challenging activities, including manufacturing, marketing and selling approved products such as ZEJULA, Optune and other products for which we may obtain marketing approval as well as completing pre-clinical testing and clinical trials of and obtaining marketing approval for our clinical and pre-clinical stage drug candidates. We will also need to be successful in satisfying any post-marketing requirements with respect to all of our products and drug candidates. We may not succeed in any or all of these activities and, even if we do, we may never generate product revenues that are significant or large enough to achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts and commercialization efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will continue to require substantial additional funding for our drug development programs and for our commercialization efforts for ZEJULA, Optune and other products for which we may obtain regulatory approval, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.

To date, we have financed our activities primarily through private placements, our initial public offering in September 2017 and three rounds of follow-on offerings. In January 2020, we raised $280.6 million in net proceeds from our subsequent follow-on offering of 6,300,000 of our American depositary shares, or ADSs. As of April 2020, through these offerings, we have raised $958.6 million. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $191.0 million and $97.5 million for the years ended December 31, 2019 and 2018, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue to commercialize ZEJULA and Optune, research and develop our pre-clinical-stage drug candidates and initiate additional clinical trials of, and seek and/or expand regulatory approval for, ZEJULA, Optune and our other drug assets. In addition, if we obtain regulatory approval for any additional drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, if more of our drug candidates are approved, additional costs may be substantial as we may have to modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers. We have, and may continue to, incur expenses as we create additional infrastructure to support our operations. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts.

We believe our cash and cash equivalents and short-term investments as of December 31, 2019 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution for ZEJULA, Optune and any other products for which we receive regulatory approval;
- the cash received, if any, from future commercial sales of ZEJULA, Optune and any other products for which we receive regulatory approval;
- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;
- the number and characteristics of other product candidates that we may pursue;
- the cost, timing and outcome of seeking, obtaining, maintaining and expanding regulatory approval of our products and drug candidates;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangement and the financial terms of such arrangements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property related claims;
- the extent to which we acquire or in-license other drug candidates and technologies;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and our partners' business arrangements with third parties comply with applicable healthcare laws and regulations;
- our headcount growth and associated costs; and
- the costs of operating as a public company in the United States.

Raising additional capital or entering into certain other arrangements may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Identifying and acquiring rights to develop potential drug candidates, conducting pre-clinical testing and clinical trials and commercializing products for which we receive regulatory approval is a time-consuming, expensive and uncertain process that may take years to complete. Our near-term commercial revenue, if any, will be derived from sales of ZEJULA and Optune. Any additional commercial revenue, if any, will be derived from sales of drug candidates that we do not expect to be commercially available until we receive regulatory approval, if at all. We may never generate the necessary data or results required to obtain regulatory approval and achieve product sales of some of our drug candidates, and even if we obtain regulatory approval, our products may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect rights of our security holders. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to

incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our ADSs to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Risks Related to Our Business and Industry

Even though we have launched ZEJULA in China, Hong Kong and Macau and Optune (Tumor Treating Fields) in Hong Kong, we may never obtain approval of or commercialize Optune outside of Hong Kong and we may never obtain approval of ZEJULA for other indications outside of the regulatory approvals we have already obtained, which would limit our ability to realize its full market potential.

In order to market products in any given jurisdiction, we must comply with numerous and varying regulatory requirements of such jurisdiction regarding safety, efficacy and quality. The Hong Kong Department of Health approved ZEJULA in October 2018 and we launched ZEJULA in Hong Kong in December 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. The NMPA approved ZEJULA in December 2019 as a maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy and we launched ZEJULA in China in January 2020. In December 2018, we announced the launch of Optune (Tumor Treating Fields) for the treatment of GBM in Hong Kong. The approval of Optune for commercialization in Hong Kong does not mean that the NMPA will approve Optune. The approval of ZEJULA for certain indications does not mean that the NMPA will approve ZEJULA for other indications. Approval procedures vary among jurisdictions and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other jurisdiction.

We are invested in the commercial success of ZEJULA and Optune and our ability to generate product revenues in the near future is highly dependent on the commercial success of ZEJULA in China and Hong Kong and Optune in Hong Kong.

A substantial portion of our time, resources and effort are focused on the commercialization of our approved product ZEJULA in China, Hong Kong, and Macau, and our approved product Optune in Hong Kong. Our ability to generate product revenues will depend heavily on the successful commercialization of ZEJULA in China, Hong Kong and Macau and Optune in Hong Kong. Our ability to successfully commercialize ZEJULA and Optune will depend on, among other things, our ability to:

- maintain commercial manufacturing or supply arrangements with third-party manufacturers for ZEJULA and Optune;
- produce, through a validated process or procure, from third-party manufacturers sufficient quantities and inventory of ZEJULA and Optune to meet demand;
- build and maintain internal sales, distribution and marketing capabilities sufficient to generate commercial sales of ZEJULA and Optune;
- secure widespread acceptance of our product from physicians, healthcare payors, patients and the medical community;
- properly price and obtain coverage and adequate reimbursement of ZEJULA and of Optune by governmental authorities, private health insurers, managed care organizations and other third-party payors;
- maintain compliance with ongoing regulatory labeling, packaging, storage, advertising, promotion, recordkeeping, safety and other post-market requirements;

- manage our growth and spending as costs and expenses increase due to commercialization; and
- manage business interruptions resulting from the occurrence of any pandemic, epidemic, including from the outbreak of the novel coronavirus, COVID-19, or any other public health crises, natural catastrophe or other disasters.

There are no guarantees that we will be successful in completing these tasks. In addition, we have invested, and will continue to invest, substantial financial and management resources to build out our commercial infrastructure and to recruit and train sufficient additional qualified marketing, sales and other personnel in support of our sales of ZEJULA and Optune.

Sales of ZEJULA and Optune may be slow or limited for a variety of reasons including competing therapies or safety issues. If ZEJULA or Optune is not successful in gaining broad commercial acceptance, our business would be harmed.

Any sales of ZEJULA and Optune will be dependent on several factors, including our and our partners' ability to educate and increase physician awareness of the benefits, safety and cost-effectiveness of ZEJULA and Optune relative to competing therapies. The degree of market acceptance of ZEJULA and Optune among physicians, patients, healthcare payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing, cost effectiveness and value propositions;
- effectiveness of our sales and marketing capabilities and strategies;
- ability to obtain sufficient third-party coverage and reimbursement;
- the clinical indications for which ZEJULA and Optune are approved, as well as changes in the standard of care for their targeted indications;
- the continuing effectiveness of manufacturing and supply chain;
- warnings and limitations contained in the approved labeling for ZEJULA and for Optune;
- safety concerns with similar products marketed by others;
- the prevalence and severity of any side effects as a result of treatment with ZEJULA or Optune;
- our ability to comply with regulatory post-marketing requirements associated with the approval of ZEJULA or Optune;
- the actual market-size for ZEJULA and Optune, which may be larger or smaller than expected; and
- our ability to manage complications or barriers that inhibit our commercial team from reaching the appropriate audience to promote our product(s) because of the outbreak of COVID-19 or any other public health crises, natural catastrophe or other disasters.

For example, due to business interruptions to hospitals and treatment centers in China arising in connection with the outbreak of COVID-19, some patients have experienced difficulties in accessing hospital care and, as a result, our commercial team has had fewer opportunities to reach patients who could benefit from ZEJULA or Optune (Tumor Treating Fields). Although the outbreak of COVID-19 has largely been contained in China and we have experienced

only minimal disruption to our commercialization of ZEJULA and Optune (Tumor Treating Fields), outbreaks may occur again and may result in similar business interruptions in the future.

We have a very limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced our operations in 2014. Our operations to date have been limited to organizing and staffing our company, identifying potential partnerships and drug candidates, acquiring product and technology rights, conducting research and development activities for our drug candidates and, more recently, commercializing products for which we have obtained regulatory approval. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials. Additionally, we have limited experience in the sale, marketing or distribution of pharmaceutical and medical device products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate, may make it difficult to evaluate our current business and prospects for future performance. Our short history makes any assessment of our future performance or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by companies in rapidly evolving fields as we continue to expand our commercial activities. In addition, as a new business, we may be more likely to encounter unforeseen expenses, difficulties, complications and delays due to limited experience. If we do not address these risks and difficulties successfully, our business will suffer.

Many of our drug candidates are still in clinical development. If we are unable to obtain regulatory approval and ultimately commercialize these drug candidates or experience significant delays in doing so, our business, financial condition, results of operations and prospects may be materially adversely harmed.

Many of our drug candidates are in clinical development and various others are in pre-clinical development. Our ability to generate revenue from our drug candidates is dependent on receipt of regulatory approval and successful commercialization of such products, which may never occur. Each of our drug candidates will require additional pre-clinical and/or clinical development, regulatory approval in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales. The success of our drug candidates will depend on several factors, including the following:

- successful completion of pre-clinical and/or clinical studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;
- successful completion of all safety studies required to obtain regulatory approval in China, the United States and other jurisdictions for our drug candidates;
- adapting our commercial manufacturing capabilities to the specifications for our drug candidates for clinical supply and commercial manufacturing;
- making and maintain arrangements with third-party manufacturers;
- obtaining and maintaining patent, trade secret and other intellectual property protection and/or regulatory exclusivity for our drug candidates;
- launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and alternative drugs;

- obtaining and maintaining healthcare coverage and adequate reimbursement;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the drug candidates following regulatory approval.

The success of our business is substantially dependent on our ability to successfully commercialize ZEJULA and Optune as well as complete the development of, maintain, expand or obtain regulatory approval for, and successfully commercialize our drug candidates in a timely manner.

We cannot commercialize drug candidates in China without first obtaining regulatory approval from the NMPA. Similarly, we cannot commercialize drug candidates in the United States or another jurisdiction outside of China without obtaining regulatory approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities. The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside of China and approval may not be granted. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Even after obtaining regulatory approval from the FDA and comparable foreign regulatory authorities, we would still need to seek approval in China and any other jurisdictions where we plan to market the product. For example, we will need to conduct clinical trials of each of our drug candidates in patients in China prior to seeking regulatory approval in China. Even if our drug candidates have successfully completed clinical trials outside of China, there is no assurance that clinical trials conducted with Chinese patients will be successful. Any safety issues, product recalls or other incidents related to products approved and marketed in other jurisdictions may impact approval of those products by the NMPA. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, or are imposed on certain drug candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the commercialization of our products and the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

We may allocate our limited resources to pursue a particular product, drug candidate or indication and fail to capitalize on products, drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must limit our licensing, research, development and commercialization programs to specific products and drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other products or drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

Our products and drug candidates are subject to extensive regulation, and we cannot give any assurance that any of our drug candidates will receive any, or that any of our products will receive any additional, regulatory approval or be successfully commercialized.

Our products and drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the NMPA, FDA and European Medicines Agency, or EMA, and other regulatory agencies in China and the United States and by comparable authorities in other countries. We are not permitted to market any of our products or drug candidates in China, the United States and other jurisdictions unless and until we receive regulatory approval from the NMPA, FDA and EMA and other comparable authorities, respectively. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product's or drug candidate's safety and efficacy. Securing regulatory approval may also require the submission of information about the product or drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our products and drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. Although Optune was approved for commercialization in Hong Kong, the United States and the European Union, we cannot provide any

assurance that we will ever obtain regulatory approval for Optune in China or for any of our other drug candidates in any jurisdiction or that any of our drug candidates will be successfully commercialized even if we receive regulatory approval.

The process of obtaining regulatory approvals in China, the United States and other countries is expensive, may take many years of additional clinical trials and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product or drug candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted New Drug Application, or NDA, pre-market approval or equivalent application type, may cause delays in the approval or rejection of an application. The NMPA, FDA and EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies. Our products and drug candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- disagreement with the NMPA, FDA and EMA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the NMPA, FDA and EMA or comparable regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- failure of CROs, clinical study sites or investigators to comply with the ICH-good clinical practice, or GCP, requirements imposed by the NMPA, FDA and EMA or comparable regulatory authorities;
- failure of the clinical trial results to meet the level of statistical significance required by the NMPA, FDA and EMA or comparable regulatory authorities for approval;
- failure to demonstrate that a product's or drug candidate's clinical and other benefits outweigh its safety risks;
- the NMPA, FDA and EMA or comparable regulatory authorities disagreeing with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA or other submission or to obtain regulatory approval in China, the United States or elsewhere;
- the NMPA, FDA and EMA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the NMPA, FDA or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the NMPA, FDA or comparable regulatory authorities restricting the use of our products to a narrow population; and
- our CROs or licensors taking actions that materially and adversely impact the clinical trials.

In addition, even if we were to obtain approval, regulatory authorities may revoke approval, may approve any of our products or drug candidates for fewer or more limited indications than we request, may monitor the price we intend to charge for our products or drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product or drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product or drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our products or drug candidates.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect the approval and commercialization of our drugs and drug candidates.

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, manufacturing, distribution, and marketing of new drugs. In recent years, the pharmaceutical regulatory framework in China has undergone significant changes, and we expect that the transformation will continue. For instance, in June 2019, the State Council promulgated the Regulation on the Administration of PRC Human Genetic Resources, which became effective in July 2019. The Regulation on the Administration of PRC Human Genetic Resources replaced the advance approval requirement for clinical studies involving the collection of patient human genetic resources with a record-filing process, except for those involving the export of patient human genetic resources out of China. In August 2019, the PRC Drug Administration Law was amended by the Standing Committee of the National People's Congress, and became effective in December 2019. The new Drug Administration Law codifies the marketing authorization holder system and enhances the compliance standards throughout the product life cycle. In January 2020, the SAMR released the amended Administrative Measures for Supervision and Administration for Drug Registration, or the Drug Registration Measures Regulation, and the amended Measures for Supervision and Administration for Drug Manufacturing, or Drug Manufacturing Regulation, both of which will come into effect in July 2020. In April 2020, the NMPA and the NHC released the amended Good Clinical Practice for Pharmaceutical Product, or the Amended GCP, which will come into effect in July 2020. The amended Drug Registration Regulations omits the provisions that provide an administrative exclusivity of the new drug monitoring period up to five years. Detailed implementation rules on the Drug Registration Regulation and Drug Manufacturing Regulation are still pending, thus uncertainties exist as to whether other intellectual property protection systems, such as patent linkage and patent term extension, would be available.

Any changes or amendments with respect to government regulation and supervision of the pharmaceutical industry in China may result in uncertainties with respect to the interpretation and implementation of the relevant laws and regulations or adversely impact the development or commercialization of our drugs and drug candidates in China.

For further information regarding government regulation in China and other jurisdictions, see "Regulation—Government Regulation of Pharmaceutical Product Development and Approval," "Regulation—Coverage and Reimbursement" and "Regulation—Other Healthcare Laws."

If safety, efficacy, manufacturing or supply issues arise with any therapeutic that we use in combination with our products and drug candidates, we may be unable to market such products or drug candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our products and drug candidates for use as a combination therapy. For example, GlaxoSmithKline, or GSK, is currently developing, and we also plan to develop, ZEJULA as both a monotherapy and in combination with any potential anti-VEGF or PD-1/PD-L1 treatments. However, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any anti-VEGF or PD-1/PD-L1 treatments or any other therapeutic we use in combination with our drug candidates. We may also seek to develop our drug candidates in combination with other therapeutics in the future.

If the NMPA, FDA or another regulatory agency revokes its approval of any anti-VEGF or PD-1/PD-L1 treatments or another therapeutic we use in combination with our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any anti-VEGF or PD-1/PD-L1 treatments or any other combination therapeutics, we may not be able to successfully commercialize ZEJULA on our current timeline or at all.

Even after obtaining regulatory approval for use in combination with any anti-VEGF or PD-1/PD-L1 treatments, as applicable, or another therapeutic, we would continue to be subject to the risk that the NMPA, FDA or another regulatory agency could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with one of these combination therapeutics. This could result in ZEJULA or one of our other products being removed from the market or being less successful commercially.

Additionally, although we have not experienced material supply disruptions due to the outbreak of COVID-19, we cannot guarantee that we will not experience supply disruptions in the future due to COVID-19 or any other pandemic, epidemic or other public health crises, natural catastrophe or other disasters.

We face substantial competition, which may result in our competitors discovering, developing or commercializing drugs before or more successfully than we do, or developing products or therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our products and drug candidates.

The development and commercialization of new medical device products and drugs is highly competitive. We face competition with respect to our current products and drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies and medical device companies worldwide. For example, there are a number of large pharmaceutical and biotechnology companies that currently market drugs or are pursuing the development of therapies in the field of poly ADP ribose polymerase, or PARP, inhibition to treat cancer. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to that of our drug candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Specifically, there are a large number of companies developing or marketing treatments for oncology, autoimmune and infectious diseases including many major pharmaceutical and biotechnology companies.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products or drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products or drugs that we may develop. Our competitors also may obtain NMPA, FDA or other regulatory approval for their products or drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our products or potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our products or drug candidates against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Clinical development involves a lengthy and expensive process with an uncertain outcome.

There is a risk of failure for each of our drug candidates. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any drug candidate, our drug candidates must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete.

The outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Future clinical trials of our drug candidates may not be successful. For

example, brivanib (ZL-2301) failed to meet its primary endpoint of overall survival, or OS, noninferiority for brivanib (ZL-2301) versus sorafenib in Phase III trials in patients with HCC conducted by Bristol-Myers Squibb Company, or BMS, before we licensed the development rights from them. In addition, brivanib (ZL-2301) showed no difference when compared to placebo in the primary efficacy endpoint. Although we believe that brivanib (ZL-2301) has the potential to be an effective treatment for Chinese patients and merits further clinical trials patients, we cannot guarantee that our future clinical trials of brivanib (ZL-2301) in Chinese patients will be successful.

Commencement of clinical trials is subject to finalizing the trial design based on ongoing discussions with the NMPA, FDA and/or other regulatory authorities. The NMPA, FDA and other regulatory authorities could change their position on the acceptability of trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not currently expect. Successful completion of our clinical trials is a prerequisite to submitting an NDA (or analogous filing) to the NMPA, FDA and/or other regulatory authorities for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. We do not know whether the clinical trials for our drug candidates will begin or be completed on schedule, if at all.

We may incur additional costs or experience delays in completing pre-clinical or clinical trials, or ultimately be unable to complete the development and commercialization of our products and drug candidates.

We may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, future clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us or them, to conduct additional clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our products and drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- the ability to conduct a companion diagnostic test to identify patients who are likely to benefit from our products and drug candidates;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our products and drug candidates may be greater than we anticipate;
- the supply or quality of our products and drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our products and drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our products and drug candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or the ethics committee of the institutions in which such trials are being conducted, by the data safety monitoring

board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the NMPA, FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, a failure to obtain the regulatory approval and/or complete record filings with respect to the collection, preservation, use and export of China's human genetic resources, inspection of the clinical trial operations or trial site by the NMPA, FDA or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the NMPA, FDA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

If we are required to conduct additional clinical trials or other testing of our products or drug candidates beyond those that are currently contemplated, if we are unable to successfully complete clinical trials of our products or drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our products and drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements;
- encounter difficulties obtaining or be unable to obtain reimbursement for use of our products and drug candidates;
- be subject to restrictions on the distribution and/or commercialization of our products and drug candidates; or
- have our products and drug candidates removed from the market after obtaining regulatory approval.

Our product and drug development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our products and drug candidates and may harm our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and prospects significantly.

If we experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our products and drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, FDA or similar regulatory authorities. In particular, we have designed many of our clinical trials, and expect to design future trials, to include some patients with the applicable genomic mutation with a view to assessing possible early evidence of potential therapeutic effect. Genomically defined diseases, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genomic mutation. The inability to enroll a sufficient number of patients with the applicable genomic alteration or that meet other applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

In addition, some of our competitors have ongoing clinical trials for products or drug candidates that treat the same indications as our products or drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors’ products or drug candidates.

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the product or drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability of competing therapies also undergoing clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the occurrence of any pandemic, epidemic, including from the outbreak of COVID-19, or any other public health crises, natural catastrophe or other disasters may cause a delay in enrollment of patients in clinical trials; and

For example, we have experienced delays in the enrollment of patients in our clinical trials due to the outbreak of COVID-19. Although the outbreak of COVID-19 has largely been contained in China and we have experienced only minimal disruption to our planned clinical trials, outbreaks may occur again and may result in delays and interruptions to our clinical trials in the future. Additionally, our commercial partners and licensors have similarly experienced and may continue to experience delays in enrollment of patients to their clinical trials due to the outbreak of COVID-19 in their respective territories. Such delays may result in increased development costs for our products and drug candidates, which could cause the value of our company to decline and limit our ability to obtain additional financing.

Our products and drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects caused by our products or drug candidates could cause us to interrupt, delay or halt clinical trials or could cause regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA or other regulatory authorities. In particular, as is the case with all oncology products and drugs, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology products or drug candidates. For example, the known adverse events for ZEJULA include thrombocytopenia, anemia and neutropenia and for brivanib (ZL-2301), the known adverse events include hyponatremia, AST elevation, fatigue, hand-foot skin reaction and hypertension. The results of our products' or drug candidates' trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, trials of our products or drug candidates could be suspended or terminated and the NMPA, FDA or comparable regulatory authorities could order us to cease further development of or deny approval of our products or drug candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, our products and drug candidates could cause undesirable side effects related to off-target toxicity. For example, many of the currently approved PARP inhibitors have been associated with off-target toxicities. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our products or drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. Even after a product or drug candidate receives regulatory approval, if we, our partners or others identify undesirable side effects caused by such drug candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- the NMPA, FDA or other comparable regulatory authorities may withdraw or limit their approval of such products or drug candidates;
- the NMPA, FDA or other comparable regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such products or drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of our products or drug candidates;
- the NMPA, FDA or other comparable regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS (or analogous requirement), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such products or drug candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products or drug candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected products or drug candidates and could substantially increase the costs of commercializing our products and drug candidates, if approved, and significantly impact our ability to successfully commercialize our products and drug candidates and generate revenue.

If we are unable to obtain NMPA approval for our products and drug candidates to be eligible for an expedited registration pathway as Category 1 drug candidates, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive such Category 1 designation, it may not lead to a faster development, review or approval process.

The NMPA categorizes domestically-manufactured innovative drug applications as Category 1, provided such drug has a new and clearly defined structure, pharmacological property and apparent clinical value and has not been marketed anywhere in the world. Domestically developed and manufactured innovative drugs will be attributed to Category 1 for their clinical trial application, or CTA, and NDA applications. While some multinational pharmaceutical companies may file CTAs with the NMPA prior to approval of a drug in another country in order to take advantage of Category 1 classification, such drug will most likely be assigned to Category 5, a class designated for drugs that were approved outside China before the NMPA approval for NDA approval purposes. This is because, based on historical observations, multinational pharmaceutical companies would typically not prioritize China as the first market for product launch, hence subjecting the drug to the Category 5 status. Because margetuximab and durlobactam (ETX2514) are imported drug products, they will be subject to Category 5 status if they are approved by the NMPA. Our CTAs for ZEJULA and omadacycline (ZL-2401) were approved as Category 1 drugs by the NMPA. A Category 1 designation by the NMPA may not be granted for any of our other drug candidates that will not be first approved in China or, if granted, such designation may not lead to faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our product or drug candidates will receive regulatory approval. Optune is a medical device and does not follow the NMPA drug categorization.

Furthermore, despite positive regulatory changes introduced since 2015 which significantly accelerated time to market for innovative drugs, the regulatory process in China is still relatively ambiguous and unpredictable. The NMPA might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

Even if we receive regulatory approval for our products or any drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our products or drug candidates, we may be subject to penalties.

Even after obtaining regulatory approval, our products and drug candidates will be subject to, among other things, ongoing regulatory requirements governing the labeling, packaging, promotion, recordkeeping, data management and submission of safety, efficacy and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and GCPs. For example, ZEJULA and Optune will continue to be subject to post-approval development and regulatory requirements, which may limit how they are manufactured and marketed, and could materially impair our ability to generate revenue. As such, we and our partners and any of our and their respective contract manufacturers will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. Additionally, to the extent we want to make certain changes to the approved products, product labeling, or manufacturing processes, we will need to submit new applications or supplements to the Hong Kong Department of Health and the NMPA and obtain the agencies' approval.

Additionally, any additional regulatory approvals that we receive for our products or drug candidates may also be subject to limitations on the approved indicated uses for which the products or drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV studies for the surveillance and monitoring the safety and efficacy of the products or drug.

In addition, once a product or drug is approved by the NMPA, FDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the product or drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our products or drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the product or drug, withdrawal of the product or drug from the market, or voluntary or mandatory product or drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the NMPA, FDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product or drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of the product or drug; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products or drug candidates. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which may harm our business, financial condition and prospects significantly.

The incidence and prevalence for target patient populations of our products and drug candidates are based on estimates and third-party sources. If the market opportunities for our products and drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our product and drug development strategy, including acquiring or in-licensing products or drug candidates and determining indications on which to focus in pre-clinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, their acceptance by the medical community and patient access, product and drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

The recent restructure of the drug regulatory authorities may delay approval of our products or drug candidates.

On March 17, 2018, China's highest legislative body, the National People's Congress, approved a sweeping government restructuring plan. This is generally considered to be the most comprehensive government restructuring that China has undertaken since its "Open Door" policy in the late 1970s. As part of the new plan, China has established a State Market Regulatory Administration, or SMRA, which merges and undertakes the responsibilities previously held by the China State Food and Drug Administration, or SFDA, the State Administration for Industry and Commerce, or SAIC, General Administration of Quality Supervision, Inspection and Quarantine, or AQSIQ, price supervision and antitrust enforcement responsibilities previously held by the National Development and Reform Commission, or NDRC, the antitrust enforcement responsibilities previously held by the Ministry of Commerce, or MOFCOM, and the Antimonopoly and Anti-Unfair Competition Bureau of State Council, as well as the responsibilities previously held by the Certification and Accreditation Administration, or CAC, and the Standardization Administration of China, or SAC.

The new NMPA reports to the SMRA, is responsible for the review and approval of drugs, medical devices and cosmetics, and maintains its own branches at the provincial level and leave the post-approval enforcement authorities at the local level to the consolidated SMRA branches.

Although the NMPA is fully functional as of 2019 and the restructuring at the state, municipal and county level authorities has been mostly completed as of July 2019, there could still be delays in the NMPA's implementation of the new reform initiatives and disruption in the NMPA's routine operations due to personnel reshuffling post-restructuring.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the expertise of the members of our research and development team, as well as the other principal members of our management, including Samantha Du, our founder, Chairman and Chief Executive Officer. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time with one months' prior written notice. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of certain of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing certain of our executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our management will be required to devote significant time to new compliance initiatives from our status as a U.S. public company, which may require us to recruit more management personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of drug development, drug commercialization, regulatory affairs and business development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and have a materially adverse effect on our business.

In addition to in-licensing or acquiring drug candidates, we may engage in future business acquisitions that could disrupt our business, cause dilution to our ADS holders and harm our financial condition and operating results.

We have, from time to time, evaluated partnership opportunities or investments and may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current drug candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

- issue stock that would dilute our ADS holders' percentage of ownership;
- incur debt and assume liabilities; and
- incur amortization expenses related to intangible assets or incur large and immediate write-offs.

We also may be unable to find suitable acquisition candidates and we may not be able to complete partnership opportunities or investments on favorable terms, if at all. If we do enter into partnership opportunities or investments, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future partnership opportunities or investments could also pose numerous additional risks to our operations, including:

- problems integrating the purchased business, products or technologies;
- increases to our expenses;
- the failure to have discovered undisclosed liabilities of the acquired asset or company;
- diversion of management's attention from their day-to-day responsibilities;
- harm to our operating results or financial condition;
- entrance into markets in which we have limited or no prior experience; and
- potential loss of key employees, particularly those of the acquired entity.

We may not be able to complete one or more partnership opportunities or investments or effectively integrate the operations, products or personnel gained through any such partnership opportunities or investments without a material adverse effect on our business, financial condition and results of operations.

We may need to significantly concede on prices for ZEJULA, Optune or our other drug candidates and devices for which we may receive regulatory approval in China and face uncertainty of reimbursement, which could diminish our sales or affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceutical drugs and devices vary widely from country to country. In China, the newly created National Healthcare Security Administration, or NHSA, an agency responsible for administering China's social security system, organized a price negotiation with drug companies for 119 new drugs that had not been included in the National Reimbursable Drug List, or the NRDL, at the time of the

negotiation in November 2019, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation. NHSA, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the NRDL, or provincial or local medical insurance catalogues for the national medical insurance program regularly, and the tier under which a drug or device will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. In November 2019, the NRDL was expanded to include 70 new drugs.

We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in China, but we will likely need to significantly reduce our prices, and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. If we were to successfully launch commercial sales of our oncology-based product and drug candidates, including ZEJULA and Optune, our revenue from such sales is largely expected to be self-paid by patients, which may make our drug candidates and devices less desirable. On the other hand, if the NHSA or any of its local counterpart includes our drugs and devices in the NRDL or provincial RDL, which may increase the demand for our drug candidates and devices, our potential revenue from the sales of our drug candidates and devices may still decrease as a result of lower prices.

Moreover, eligibility for reimbursement in China does not imply that any drug or device will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution.

Companies in China that manufacture or sell drugs and medical devices are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our drug candidates.

The life sciences industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including approval, registration, production, distribution, packaging, labelling, storage and shipment, advertising, licensing and certification requirements and procedures, periodic renewal and reassessment processes, registration of new products and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. In order to manufacture and distribute drug and medical device products in China, we are required to:

- obtain a manufacturing permit for each production facility from the NMPA and its relevant branches for the manufacture of drug and device products;
- obtain a marketing authorization, which includes an approval number, from the NMPA for each drug or device manufactured by us;
- obtain a distribution permit (or record filing) from the NMPA and its relevant branches; and
- renew the manufacturing permits, the distribution permits (or record-filing) and marketing authorizations every five years, among other requirements.

If we are unable to obtain or renew such permits or any other permits or licenses required for our operations, will not be able to engage in the commercialization, manufacture and distribution of our products and drug candidates and our business may be adversely affected.

The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. China government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services without incurring significant fiscal burden. The specific regulatory changes under the reform still remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the level we expect, if at all. Moreover, the reform could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

For further information regarding government regulation in China and other jurisdictions, see "Regulation—Government Regulation of Pharmaceutical Product Development and Approval," "Regulation—Coverage and Reimbursement" and "Regulation—Other Healthcare Laws."

If we breach our license or other intellectual property-related agreements for our products or drug candidates or otherwise experience disruptions to our business relationships with our licensors and collaboration partners, we could lose the ability to continue the development and commercialization of our products and drug candidates.

Our business relies, in large part, on our ability to develop and commercialize products and drug candidates from third parties including ZEJULA from GSK; Optune from Novocure Limited, or Novocure; omadacycline (ZL-2401) from Paratek Pharmaceuticals, or Paratek; bemarituzumab (FPA144) from Five Prime Therapeutics, Inc., or Five Prime; durlobactam from Entasis Therapeutics Holdings, Inc., or Entasis; margetuximab, MGD-013 and a pre-clinical multi-specific TRIDENT molecule from MacroGenics Inc., or MacroGenics; ripretinib from Deciphera Pharmaceuticals, LLC, or Deciphera; INCMGA0012 (PD-1) from Incyte Corporation, or Incyte; and REGN1979 from Regeneron Pharmaceuticals, Inc., or Regeneron. If we have not obtained a license to all intellectual property rights that are relevant to our products and drug candidates and that are owned or controlled by our licensors and collaboration partners or owned or controlled by affiliates of such licensors and collaboration partners, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors and collaboration partners breach such agreements, we may not be able to enforce such agreements against our licensors' parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable drug candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such drug candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and other intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such drug candidates and/or maintaining the confidentiality of information we receive from our licensors. For example, we are also obligated to use commercially reasonable efforts to develop and commercialize Optune, margetuximab, MGD-013, a pre-clinical multi-specific TRIDENT molecule, omadacycline (ZL-2401), bemarituzumab (FPA144), durlobactam, ripretinib, INCMGA0012 (PD-1) and REGN1979 in certain of their respective territories, in each case, under their respective agreements.

If we fail to meet any of our obligations under our license and other intellectual property-related agreements, our licensors have the right to terminate our licenses and sublicenses and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses or sublicenses, we will lose the right to develop and commercialize our applicable products and drug candidates and other third parties may be able to market products or drug candidates similar or identical to ours. In such case, we may be required to provide a grant back license or expand an existing license to the licensors under our own intellectual property with respect to the terminated products. In addition, if our agreements with GSK for ZEJULA terminate for any reason, we are required to grant GSK an exclusive license to certain of our intellectual property rights that relate to ZEJULA, as applicable. Furthermore, if our agreement with MacroGenics for margetuximab, MGD-013 and a pre-clinical multi-specific TRIDENT molecule is terminated by MacroGenics for certain reasons, we are required to grant MacroGenics an option to convert the non-exclusive license granted to MacroGenics to use certain of our intellectual property rights that relate to margetuximab, MGD-013 and a pre-clinical multi-specific TRIDENT molecule in China, Hong Kong, Macau and Taiwan to an exclusive license. If our agreement with Entasis for durlobactam is terminated for certain reasons, we are required to grant Entasis an exclusive, fully paid, royalty free, perpetual irrevocable and sublicenseable (through multiple tiers) license to use certain of our intellectual property rights that relate to EXT2514 in the licensed territory. If our agreement with Incyte for INCMGA0012 (PD-1) is terminated for certain reasons, we are required to assign to Incyte certain trademarks and certain other business premises, data and regulatory materials that relate to INCMGA0012 (PD-1). If our agreement with Deciphera for ripretinib is terminated for certain reasons, we are required to grant Deciphera a worldwide, perpetual and irrevocable license to use certain of our intellectual property rights that relate to ripretinib in China, Hong Kong, Macau and Taiwan. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our drug candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such drug candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable drug candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, disputes may further arise regarding intellectual property subject to a license and/or collaboration agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe, misappropriate or otherwise violate on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party, and have granted us a sub-license. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. For example, our licenses from GSK, Paratek, MacroGenics and Incyte comprise sublicenses to us of certain intellectual property rights owned by third parties that are not our direct licensors. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our rights to the applicable licensed intellectual property may be terminated or narrowed, our exclusive licenses may be converted to non-exclusive licenses, and our ability to produce and sell our products and drug candidates may be materially harmed. In addition, our license from Paratek is limited to intellectual property rights under the control of Paratek Bermuda, Ltd. To the extent Paratek Bermuda, Ltd. loses control over any of the licensed intellectual property rights for any reason, we will no longer be licensed to such intellectual property rights to use, develop and otherwise commercialize omadacycline (ZL-2401). Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In addition, the agreements under which we currently license or have rights to use intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed, sublicensed or obtained rights to use prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products or drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Product liability claims or lawsuits could cause us to incur substantial liabilities.

We face an inherent risk of product liability exposure related to the use of our products and drug candidates in clinical trials or any products or drug candidates we may decide to commercialize and manufacture. If we cannot successfully defend against claims that the use of such products or drug candidates in our clinical trials or any products that we procure from third-party manufacturers, or that we may choose to manufacture at our production facilities in the future, including any of our products or drug candidates which receive regulatory approval, caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- significant negative media attention and reputational damage;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;

- the inability to commercialize any products or drug candidates that we may develop;
- initiation of investigations by regulators;
- a diversion of management's time and our resources; and
- a decline in the ADS price.

Any litigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), product liability insurance to cover our product liability claims and general liability insurance to cover other commercial liability claims, these insurances may not fully cover our potential liabilities. Additionally, inability to obtain sufficient insurance coverage at an acceptable cost could prevent or inhibit the successful commercialization of products or drugs we develop, alone or with our collaborators.

The research and development projects under our internal discovery programs are at an early stage of development. As a result, we are unable to predict if or when we will successfully develop or commercialize any drug candidates under such programs.

Our internal discovery programs are at an early stage of development and will require significant investment and regulatory approvals prior to commercialization. Each of our drug candidates will require additional clinical and pre-clinical development, management of clinical, pre-clinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before they generate any revenue from product sales. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the NMPA, the FDA or comparable regulatory authorities, and we may never receive such regulatory approval for any such drug candidates.

We cannot be certain that clinical development of any drug candidates from our internal discovery programs will be successful or that we will obtain regulatory approval or be able to successfully commercialize any of our drug candidates and generate revenue. Success in pre-clinical testing does not ensure that clinical trials will be successful, and the clinical trial process may fail to demonstrate that our drug candidates are safe and effective for their proposed uses. Any such failure could cause us to abandon further development of any one or more of our drug candidates and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any NDAs with the NMPA, the FDA or comparable regulatory authorities and, ultimately, our ability to commercialize our drug candidates and generate product revenue.

If our manufacturing facilities are not approved by regulators, are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

In 2017, we built a small molecule facility capable of supporting clinical and commercial production, and in 2018, we built a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. We intend to rely on these facilities for the manufacture of clinical and commercial supply of some of our products or drug candidates. Prior to being permitted to sell any products or drugs produced at these facilities, the facilities will need to be inspected and approved by regulatory authorities. If either facility is not approved by regulators or is damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace our manufacturing capabilities. In such event, we would be forced to identify and rely partially or entirely on third-party contract manufacturers for an indefinite period of time. Any new facility needed to replace an existing production facility would need to comply with the necessary regulatory requirements and be tailored to our production requirements and processes. We also would need regulatory approvals before using any products or drugs manufactured at a new facility in clinical trials or selling any products or drugs that are ultimately approved. Any disruptions or delays at our facility or its failure to meet regulatory compliance would impair our ability to develop and commercialize our products or drug candidates, which would adversely affect our business and results of operations.

We may become involved in lawsuits to protect or enforce our intellectual property.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. We may not be able to prevent third parties from infringing upon or misappropriating our intellectual property, particularly in countries where the laws may not protect intellectual property rights as fully as in the United States. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, nondisclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

The data privacy regime in China and in the United States are evolving and there may be more stringent compliance requirements for the collection, processing, use, and transfer of personal information and important data. In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including

research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues, and invite regulator's scrutiny. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We are subject to laws and government regulations relating to privacy and data protection that have required us to modify certain of our policies and procedures with respect to the collection and processing of personal data, and future laws and regulations may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the United States, our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, collectively, HIPAA, which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although we believe that we currently are neither a "covered entity" nor a "business associate" under the legislation, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA may affect our interactions with customers who are covered entities or their business associates because HIPAA affects the ability of these entities to disclose patient health information to us. The federal government, various states and localities also have laws that regulate the privacy and security of personal information and so may affect our business operations. For example, we are subject to the California Consumer Privacy Act, or CCPA, that became effective on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose details about the personal information they collect, as well as other rights such as the right to ask companies to delete a consumer's personal information and opt out of the sale of personal information.

We could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims under the laws described, as well as for alleged unfair or deceptive practices. If our operations are found to be in violation of any of the privacy laws, rules or regulations that apply to us, we could be subject to penalties, including civil penalties, damages, injunctive relief, and other penalties, which could adversely affect our ability to operate our business and our financial results. We will continue to review these and all future privacy and other laws and regulations to assess whether additional procedural safeguards are warranted, which may cause us to incur additional expenses or otherwise limit our ability to collect and process personal data.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our pre-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products or drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for some of our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our pre-clinical studies in accordance with Good Laboratory Practices, or GLP, and the Administrative Regulations on Experimental Animals or the Animal Welfare Act requirements. We and our CROs are required to comply with GCP regulations and guidelines enforced by the NMPA, and comparable foreign regulatory authorities for all of our products or drug candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with products or drugs produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and pre-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our products or drug candidates. As a result, our results of operations and the commercial prospects for our products and drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or compromised.

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we lose our relationships with CROs, our product or drug development efforts could be delayed.

We rely on third-party vendors and CROs for some of our pre-clinical studies and clinical trials related to our product or drug development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and

managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

We have limited experience manufacturing our products and drug candidates on a large clinical or commercial scale. We are or will be dependent on third party manufacturers for the manufacture of certain of our products and drug candidates as well as on third parties for our supply chain, and if we experience problems with any of these third parties, the manufacture of our products or drug candidates or products could be delayed, which could harm our results of operations.

If our two manufacturing facilities are unable to meet our intended production capacity in a timely fashion, we may have to engage a contract manufacturing organization, or CMO, for the production of clinical supplies of our products or drug candidates.

Additionally, in order to successfully commercialize our products and drug candidates, we will need to identify qualified CMOs for the scaled production of a commercial supply of certain of our products and drug candidates. The CMOs should be drug manufacturers holding manufacturing permits with a scope that can cover our drug registration candidates, and such CMO arrangement should be approved by the NMPA's provincial level branches. We have not yet identified suppliers to support scaled production. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, or to obtain the NMPA approval for our CMO arrangement in a timely manner, we may not be able to complete development of our products or drug candidates, or market or distribute them.

We rely on third-party manufacturers to manufacture at least some of our products and drug candidates. For example, we rely on MacroGenics to manufacture and supply margetuximab, MGD-013, and a pre-clinical multi-specific TRIDENT molecule, Entasis to manufacture and supply durlobactam, Novocure to manufacture and supply Optune, Deciphera to manufacture and supply ripretinib, Incyte to manufacture and supply INCMGA0012 (PD-1) and, as of April 2020, Regeneron to manufacture and supply REGN1979.

Such reliance entails risks to which we would not be subject to if we manufactured drug candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing or supply agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our drug candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the NMPA and other regulatory authorities require that our drug candidates and any products that we may eventually commercialize be manufactured according to cGMP standards. Any failure by our third-party manufacturers to comply with cGMP standards or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of drug candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our drug candidates. In addition, such failure could be the basis for the NMPA to issue a warning or untitled letter, withdraw approvals for drug candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Any significant disruption in our potential supplier relationships could harm our business. We currently source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers, as well as through our licensors. We anticipate that, in the near term, all key materials will be sourced through third parties. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture some of our drugs. Such suppliers may not sell these key materials to us or our manufacturers at the times we need them or on commercially reasonable terms. We currently do not have any agreements for the commercial production of these key materials. Any significant delay in the supply of a product or drug candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product or drug testing and potential regulatory approval of our products or drug candidates. If we or our manufacturers are unable to purchase these key materials after regulatory approval has been obtained for our drug candidates, the commercialization of our products or the commercial launch of our drug candidates could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our products and drug candidates.

Furthermore, because of the complex nature of our compounds, we or our manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to make commercially successful products and drugs. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have limited experience manufacturing pharmaceutical products or drugs on a commercial scale and some of our current suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met.

We depend on our licensors or patent owners of our in-licensed patent rights to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors or such patent owners to effectively protect these patent rights could adversely impact our business and operations.

We have licensed and sublicensed patent rights from third parties for some of our development programs, including ZEJULA from GSK, Optune from Novocure, omadacycline (ZL-2401) from Paratek, bemarituzumab (FPA144) from Five Prime, durlobactam from Entasis, and margetuximab, MGD-013 and a pre-clinical multi-specific TRIDENT molecule from MacroGenics, ripretinib from Deciphera and INCMGA0012 (PD-1) from Incyte. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. We cannot be certain that the patents and patent applications for our products and drug candidates have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our drug candidates. If our licensors or such third parties fail to prepare, prosecute, or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drug candidates that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. For example, under our agreement with Novocure for Optune, Novocure owns and has the right to control all patent application and patent prosecution activities related to Optune in China, Hong Kong, Macau and Taiwan. Similarly, under our agreement with Five Prime for bemarituzumab (FPA144), Five Prime has the first right to enforce the licensed patents in China, Hong Kong, Macau and Taiwan, subject to certain exceptions. In addition, with respect to the patent portfolio for omadacycline (ZL-2401), which we sub-license from Paratek, Paratek has the first right to enforce such patent portfolio in territories outside of China, Hong Kong, Macau and Taiwan. Under our agreements with each of Entasis and Incyte, each of Entasis and Incyte has the first right to enforce the respective licensed patents in the licensed territory, including China, subject to certain exceptions. Under our agreement with Deciphera for ripretinib, Deciphera has the first right to enforce the licensed patents in China, Hong Kong, Macau and Taiwan, subject to certain exceptions. With respect to the patent portfolio for ZEJULA, which we sub-license from GSK, we have the first right to enforce such patent portfolio within China, Hong Kong and Macau. However, GSK maintains the right to enforce such patent portfolio in all other territories or, if we fail to bring an action within 90 days within China, Hong Kong or Macau, GSK can control such enforcement actions in those areas as well. In the case where GSK controls such enforcement actions, although we have rights to consult with GSK on such actions within China, Hong Kong and Macau, rights granted by GSK under ZEJULA to another licensee, such as Janssen Biotech, Inc. to whom GSK has granted an exclusive right to develop ZEJULA for the treatment of prostate cancer, could potentially influence GSK's interests in the exercise of its prosecution, maintenance and enforcement rights in a manner that may favor the interests of such other licensee as compared with us, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Even if we are permitted to pursue the enforcement or defense of our licensed and sub-licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our drug candidates that are subject of such licensed rights could be adversely affected.

Other Risks and Risks Related to Doing Business in China

If we fail to comply with environmental, health and safety laws and regulations of China, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce hazardous waste products. We are therefore subject to PRC laws and regulations concerning the discharge of waste water, gaseous waste and solid waste during our processes of research and development of drugs. We engage competent third party contractors for the transfer and disposal of these materials and wastes. We may not at all times comply fully with environmental regulations. Any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligation to take corrective measures. We cannot completely eliminate the risk of contamination or injury from these materials and wastes. In the event of contamination or injury resulting from the use or discharge of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil, administrative or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and third party liability insurance for injuries caused by unexpected seepage, pollution or contamination, such insurance may not provide adequate coverage against potential liabilities. Furthermore, China government may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our manufacturing facility and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations.

China's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

Substantially all of our operations are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China as well as China's economic, political, legal and social conditions in relation to the rest of the world. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. China's government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall economy in China, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, China's government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

Uncertainties with respect to Chinese legal system and changes in laws, regulations and policies in China could materially and adversely affect us.

We conduct our business primarily through our subsidiaries in China. PRC laws and regulations govern our operations in China. Our subsidiaries are generally subject to laws and regulations applicable to foreign investments in China, which may not sufficiently cover all of the aspects of our economic activities in China. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not always be aware of any potential violation of these

policies and rules. Such unpredictability regarding our contractual, property and procedural rights could adversely affect our business and impede our ability to continue our operations. Furthermore, since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties could materially and adversely affect our business and results of operations.

In January 2015, the Ministry of Commerce of China, or the MOFCOM, published a discussion draft of the proposed Foreign Investment Law. The Foreign Investment Law passed the legislative review in March 2019, and came into effect on January 1, 2020. Foreign-invested entities will enjoy national treatment in industry sectors that are not prohibited or restricted from foreign investment. The Foreign Investment Law imposes information reporting requirements on foreign investors and the applicable foreign invested entities. Non-compliance with the reporting requirements will result in corrective orders and fines between RMB 100,000 to 500,000. The Foreign Investment Law reinforces the duties of government authorities to protect intellectual property rights and trade secrets of foreign-investment entities. Government authorities cannot compel technology transfer by administrative means, reveal or provide trade secrets of foreign-invested entities to third parties. Last but not least, the Foreign Investment Law calls for the establishment of a foreign investment security review mechanism, details of which will be further developed by the Chinese government.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

We are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery laws of other jurisdictions, particularly China. As our business continues to expand, the applicability of the FCPA and other anti-bribery laws to our operations will continue to increase. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

Restrictions on currency exchange may limit our ability to receive and use financing in foreign currencies effectively.

Our PRC subsidiaries' ability to obtain foreign exchange is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and/or registration with PRC government authorities, including the state administration of foreign exchange, or SAFE. In particular, if we finance our PRC subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local counterpart of the SAFE. If we finance our PRC subsidiaries by means of additional capital contributions, the amount of these capital contributions must first be approved or filed by the relevant government approval authority.

In the light of the various requirements imposed by PRC regulations on loans to, and direct investment in, PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries. If we fail to complete such registrations or obtain such approval, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

PRC regulations relating to the establishment of offshore special purpose companies by PRC residents may subject our PRC resident beneficial owners or our wholly foreign-owned subsidiaries in China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.

In 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37. SAFE Circular 37 requires PRC residents to register with local branches of SAFE or competent banks designated by SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by the PRC residents in the offshore special purpose vehicles or PRC companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle. If the shareholders of the offshore holding company who are PRC residents do not complete their registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with SAFE registration and amendment requirements described above could result in liability under PRC law for evasion of applicable foreign exchange restrictions.

We will request PRC residents who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not be informed of the identities of all the PRC residents holding direct or indirect interest in our company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our PRC resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, restrict our cross-border investment activities, limit the ability of our wholly foreign-owned subsidiaries in China to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

PRC regulations establish complex procedures for some acquisitions of Chinese companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

PRC regulations and rules concerning mergers and acquisitions including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of PRC promulgated on August 30, 2007 and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the Prior Notification Rules issued by the State Council in August 2008 and amended in September 2018, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors, or the Security Review Rules issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise "national defense and security" concerns and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise "national security" concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such

transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises "national defense and security" or "national security" concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders.

China Enterprise Income Tax Law, or the EIT Law, which was promulgated in March 2007, became effective in January 2008 and was amended in February 2017 and December 2018, and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008 and amended in April 2019, define the term "de facto management bodies" as "bodies that substantially carry out comprehensive management and control on the business operation, employees, accounts and assets of enterprises." Under the EIT Law, an enterprise incorporated outside of PRC whose "de facto management bodies" are located in PRC is considered a "resident enterprise" and will be subject to a uniform 25% enterprise income tax, or EIT, rate on its global income. On April 22, 2009, PRC's State Administration of Taxation, or the SAT, in the Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or SAT Circular 82, further specified certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise may be regarded to have its "de facto management bodies" located in China and therefore be considered a PRC resident enterprise. These criteria include: (i) the enterprise's day-to-day operational management is primarily exercised in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in China; and (iv) 50% or more of voting board members or senior executives of the enterprise habitually reside in China. Although SAT Circular 82 only applies to foreign enterprises that are majority-owned and controlled by PRC enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in SAT Circular 82 may be adopted by the PRC tax authorities as the test for determining whether the enterprises are PRC tax residents, regardless of whether they are majority-owned and controlled by PRC enterprises.

We believe that neither Zai Lab Limited nor any of our subsidiaries outside of China is a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities, and uncertainties remain with respect to the interpretation of the term "de facto management body." If the PRC tax authorities determine that Zai Lab Limited or any of its subsidiaries outside of China is a PRC resident enterprise for EIT purposes that entity would be subject to a 25% EIT on its global income. If such entity derives income other than dividends from its wholly-owned subsidiaries in China, a 25% EIT on its global income may increase our tax burden. Dividends paid to a PRC resident enterprise from its wholly-owned subsidiaries in China may be regarded as tax-exempt income if such dividends are deemed to be "dividends between qualified PRC resident enterprises" under the EIT Law and its implementation rules. However, we cannot assure you that such dividends will not be subject to PRC withholding tax, as the PRC tax authorities, which enforce the withholding tax, have not yet issued relevant guidance.

In addition, if Zai Lab Limited is classified as a PRC resident enterprise for PRC tax purposes, we may be required to withhold tax at a rate of 10% from dividends we pay to our shareholders, including the holders of our ADSs, that are non-resident enterprises. In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% PRC withholding tax on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within China. Furthermore, gains derived by our non-PRC individual shareholders from the sale of our shares and ADSs may be subject to a 20% PRC withholding tax. It is unclear whether our non-PRC individual shareholders (including our ADS holders) would be subject to any PRC tax (including withholding tax) on dividends received by such non-PRC individual shareholders in the event we are determined to be a PRC resident enterprise. If any PRC tax were to apply to such dividends, it would generally apply at a rate of 20%. The PRC tax liability may be reduced under applicable tax treaties. However, it is unclear whether our non-PRC shareholders would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that Zai Lab Limited is treated as a PRC resident enterprise.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries, each of which is a wholly foreign-owned enterprise may pay dividends only out of its respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund.

Our PRC subsidiaries generate primarily all of their revenue in renminbi, which is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their renminbi revenues to pay dividends to us.

In response to the persistent capital outflow in China and renminbi's depreciation against U.S. dollar in the fourth quarter of 2016, the People's Bank of China, or PBOC, and the SAFE have promulgated a series of capital control measure in early 2017, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments.

The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

We and our shareholders face uncertainties in the PRC with respect to indirect transfers of equity interests in PRC resident enterprises.

The indirect transfer of equity interest in PRC resident enterprises by a non-PRC resident enterprise, or Indirect Transfer, is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. SAT Circular 7 sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding PRC assets directly or indirectly in the course of a group's overseas restructuring, and the factors to consider in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under PRC laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the PRC taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in China, or 90% or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the PRC taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-PRC tax payable on the gain derived from the indirect transfer of the PRC taxable assets is lower than the potential PRC income tax on the direct transfer of such assets. Nevertheless, a non-resident enterprise's buying and selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 and will not be subject to PRC tax pursuant to SAT Circular 7. Under SAT Circular 7, the entities or individuals obligated to pay the transfer price to the transferor shall be the withholding agent and shall withhold the PRC tax from the transfer price. If the withholding agent fails to do so, the transferor shall report to and pay the PRC tax to the PRC tax authorities. In case neither the withholding agent nor the transferor complies with the obligations under SAT Circular 7, other than imposing penalties such as late payment interest on the transferors, the tax authority may also hold the withholding agent liable and impose a penalty of 50% to 300% of the unpaid tax on the withholding agent. The penalty imposed on the withholding agent may be reduced or waived if the withholding agent has submitted the relevant materials in connection with the indirect transfer to the PRC tax authorities in accordance with SAT Circular 7.

However, as these rules and notices are relatively new and there is a lack of clear statutory interpretation, we face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchange or other transactions involving the transfer of shares in our company by investors that are non-PRC resident enterprises, or the sale or purchase of shares in other non-PRC resident companies or other taxable assets by us. Our company and other non-resident enterprises in our group may be subject to filing obligations or being taxed if our company and other non-resident enterprises in our group are transferors in such transactions, and may be subject to withholding obligations if our company and other non-resident enterprises in our group are transferees in such transactions. For the transfer of shares in our company by investors that are non-PRC resident enterprises, our PRC subsidiaries may be requested to assist in the filing under the rules and notices. As a result, we may be required to expend valuable resources to comply with these rules and notices or to request the relevant transferors from whom we purchase taxable assets to comply, or to establish that our company and other non-resident enterprises in our group should not be taxed under these rules and notices, which may have a material adverse effect on our financial condition and results of operations. There is no assurance that the tax authorities will not apply the rules and notices to our offshore restructuring transactions where non-PRC residents were involved if any of such transactions were determined by the tax authorities to lack reasonable commercial purpose. As a result, we and our non-PRC resident investors may be at risk of being taxed under these rules and notices and may be required to comply with or to establish that we should not be taxed under such rules and notices, which may have a material adverse effect on our financial condition and results of operations or such non-PRC resident investors' investments in us. We may conduct acquisition transactions in the future. We cannot assure you that the PRC tax authorities will not, at their discretion, adjust any capital gains and impose tax return filing obligations on us or require us to provide assistance for the investigation of PRC tax authorities with respect thereto. Heightened scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on potential acquisitions we may pursue in the future.

Any failure to comply with PRC regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. We plan to assist our employees to register their share options or shares. However, any failure of our PRC individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our PRC subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors and employees under PRC law.

Proceedings brought by the SEC against the Big Four PRC-based accounting firms, including our independent registered public accounting firm, could result in our inability to file future financial statements in compliance with the requirements of the Exchange Act.

In December 2012, the SEC instituted administrative proceedings under Rule 102(e)(1)(iii) of the SEC's Rules of Practice against the Big Four PRC-based accounting firms, including our independent registered public accounting firm, alleging that these firms had violated U.S. securities laws and the SEC's rules and regulations thereunder by failing to provide to the SEC the firms' audit work papers with respect to certain PRC-based companies under the SEC's investigation. On January 22, 2014, the administrative law judge, or the ALJ, presiding over the matter rendered an initial decision that each of the firms had violated the SEC's rules of practice by failing to produce audit workpapers to the SEC. The initial decision censured each of the firms and barred them from practicing before the SEC for a period of six months. On February 12, 2014, the Big Four PRC-based accounting firms appealed the ALJ's initial decision to the SEC. On February 6, 2015, the four China-based accounting firms each agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC and audit U.S.-listed companies. The settlement required the firms to follow detailed procedures and to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC, in response to future document requests by the SEC made through the CSRC. If the Big Four PRC-based accounting firms fail to comply with the documentation production procedures that are in the settlement agreement or if there is a failure of the process between the SEC and the CSRC, the SEC could restart the proceedings against the firms.

In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, United States-listed companies and the market price of our ADSs may be adversely affected.

If the accounting firms are subject to additional remedial measures, our ability to file our financial statements in compliance with SEC requirements could be impacted. A determination that we have not timely filed financial statements in compliance with SEC requirements would substantially reduce or effectively terminate the trading of our ADSs in the United States.

Certain of our investments may be subject to review from the Committee on Foreign Investment in the United States, or CFIUS, which may delay or block a transaction from closing.

The U.S. Congress has passed legislation that will expand the jurisdiction and powers of the CFIUS, the U.S. interagency committee that conducts national security reviews of foreign investment. President Trump signed the Foreign Investment Risk Review Modernization Act (FIRRMA) in August 2018. Pursuant to FIRRMA, investments in companies that deal in "critical technology" are subject to filing requirements and, in some instances, review and approval by CFIUS. The term "critical technology" includes, among others, technology subject to U.S. export controls and certain "emerging and foundational technology," a term that is still being defined but that is expected to include a range of U.S. biotechnology. If an investment by a foreign entity in a U.S. business dealing in "critical technology" meets certain thresholds, a filing with CFIUS is mandatory.

Accordingly, to the extent the U.S. portion of our business decides to take investments from foreign persons, such investments could be subject to CFIUS jurisdiction. To date, none of our investments have been subject to CFIUS review but, depending on the particulars of ongoing or future investments, we may be obligated to secure CFIUS approval before closing, which could delay the time period between signing and closing. If we determine that a CFIUS filing is not mandatory (or otherwise advisable), there is a risk that CFIUS could initiate its own review, if it determines that the transaction is subject to its jurisdiction. If an investment raises significant national security concerns, CFIUS has the authority to impose mitigation conditions or recommend that the President block a transaction.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our products and drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends, in part, on our ability to protect our products and drug candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the products and drug candidates and technology that we consider commercially important by filing PRC and international patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We also seek to protect our proprietary position by in-licensing intellectual property relating to our technology and drug candidates. We do not own or exclusively license any issued patents with respect to certain of our products and drug candidates in all territories in which we plan to commercialize our products and drug candidates. For example, we do not own or exclusively license any issued patents covering ZEJULA in Hong Kong or Macau. We do not own or exclusively license any issued patents covering margetuximab, MGD-013 and a pre-clinical multi-specific TRIDENT molecule in Macau or Taiwan, but we do non-exclusively in-license issued patents in China and Hong Kong and pending patent applications in China, Hong Kong or Taiwan covering them. We do not own or exclusively license any issued patents or pending patent applications covering Optune in Hong Kong, Macau, or Taiwan, but we do exclusively license issued patents and pending patent applications covering Optune in China. We do not own or exclusively license any issued patents covering INCMGA0012 (PD-1), but we do in-license two pending patent applications relating to INCMGA0012 (PD-1) in China, 2 in Taiwan and 1 in Hong Kong. We in-license 1 issued patent in China and 1 in Taiwan, but we also in-license 1 pending patent application relating to EXT2514 in China, 1 in Hong Kong, 1 in Taiwan. We cannot predict whether such patent applications or any of our other owned or in-licensed pending patent applications will result in the issuance of any patents that effectively protect our products and drug candidates. If we or our licensors are unable to obtain or maintain patent protection with respect to our products or drug candidates and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, our license and intellectual property-related agreements may not provide us with exclusive rights to use our in-licensed intellectual property rights relating to the applicable products and drug candidates in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. For example, under our agreements with GSK for ZEJULA, our licenses are limited to China, Hong Kong, and Macau. In the case of our agreements with Novocure for Optune, Paratek for omadacycline (ZL-2401), Five Prime for bemarituzumab (FPA144), and MacroGenics for margetuximab, MGD-013 and a pre-clinical multi-specific TRIDENT molecule, our licenses are limited to China, Hong Kong, Macau, and Taiwan. Also, in the case of our agreement with Entasis for durlobactam, our license is limited to China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. In the case of our agreement with Deciphera for ripretinib, our license is limited to China, Hong Kong, Macau and Taiwan. In the case of our agreement with Incyte for INCMGA0012 (PD-1) , our license s are limited to China, Hong Kong, Macau and Taiwan.

Patents may be invalidated and patent applications, including our in-licensed patent application relating to FP144, Optune, margetuximab, MGD-013, EXT2514, a pre-clinical multi-specific TRIDENT molecule or INCMGA0012 (PD-1) as well as Regeneron's patents relating to REGN1979, may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, the PRC and, recently, the United States have adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology, which we invented.

In addition, under PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the State Intellectual Property Office, or SIPO, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Moreover, even if patents do grant from any of the applications, the grant of a patent is not conclusive as to its scope, validity or enforceability.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, United States and abroad. We and our licensors and collaboration partners may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our technology, products or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products or drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we, or one of our licensors or collaboration partners, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our or our licensor's or collaboration partner's invention or other features of patentability of our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, limit the duration of the patent protection of our technology, or limit the price at which we can sell our products and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology, products or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, the terms of patents are finite. The patents we own or in-license and the patents that may issue from our currently pending owned and in-licensed patent applications generally have a 20-year protection period starting from such patents and patent applications' earliest filing date. Given the amount of time required for the development, testing and regulatory review of products and new drug candidates, patents protecting such products and drug candidates might expire before or shortly after such products or drug candidates are commercialized. As a result, our owned or in-licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our owned or in-licensed patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

We or our licensors or collaboration partners may become involved in patent litigation against third parties to enforce owned or in-licensed patent rights, to invalidate patents held by such third parties, or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that patents owned or in-licensed by us, our licensors or our collaboration partners do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe, misappropriate or otherwise violate their intellectual property or that a patent we or our licensors or collaboration partners have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In addition, third parties may initiate legal proceedings before administrative bodies in the United States or abroad, even outside the context of litigation, against us or our licensors with respect to our owned or in-licensed intellectual property to assert such challenges to such intellectual property rights. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our products and drug candidates.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid. Even if we are successful in defending against such challenges, the cost to us of any patent litigation or similar proceeding could be substantial, and it may consume significant management and other personnel time. We do not maintain insurance to cover intellectual property infringement, misappropriation or violation.

An adverse result in any litigation or other intellectual property proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one or more of our products or drug candidates, we would lose at least part, and perhaps all, of the patent protection covering such products or drug candidates. Competing products or drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our products or drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property in the PRC.

The validity, enforceability and scope of protection available under the relevant intellectual property laws in the PRC are uncertain and still evolving. Implementation and enforcement of PRC intellectual property-related laws have historically been deficient and ineffective. Accordingly, intellectual property and confidentiality legal regimes in China may not afford protection to the same extent as in the United States or other countries. Policing unauthorized use of proprietary technology is difficult and expensive, and we may need to resort to litigation to enforce or defend patents issued to us or our licensors to determine the enforceability, scope and validity of our proprietary rights or those of others. As noted above, we may need to rely on our licensors to enforce and defend our technologies. The experience and capabilities of PRC courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management's attention from our operations, which could harm our business, financial condition and results of operations. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, maintaining and defending patents on products and drug candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or PRC or from selling or importing products made using our inventions in and into the United States, the PRC or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions, including China. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Furthermore, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Developments in patent law could have a negative impact on our business.

Changes in either the patent laws or interpretation of the patent laws in the United States, PRC and other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, including changing the standards of patentability, and any such changes could have a negative impact on our business. For example, in the United States, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system as of March 2013, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post grant proceedings, including post grant review, *inter partes* review, and derivation proceedings. As a result of these changes, patent law in the United States may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions became effective in March 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications and our ability to obtain patents based on our discoveries and to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by registered patents and pending patent applications, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We also seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties that have access to them, such as our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally disclosed or misappropriated our trade secrets, including through intellectual property litigations or other proceedings, is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts in China and other jurisdictions inside and outside the United States are less prepared, less willing or unwilling to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. For example, competitors could purchase our products and drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our intellectual property protecting such technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be disclosed or independently developed by a competitor, we would have no right to prevent them, or others to whom they communicate it, from using that technology or information to compete against us, which may have a material adverse effect on our business, prospects, financial condition and results of operations.

If our products or drug candidates infringe, misappropriate or otherwise violate the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to sell or commercialize these products and drug candidates.

Our commercial success depends significantly on our ability to develop, manufacture, market and sell our products and drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. In the PRC and the United States, invention patent applications are generally maintained in confidence until their publication 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and invention patent applications are filed. Even after reasonable investigation, we may not know with certainty whether any third-party may have filed a patent application without our knowledge while we are still developing or producing that product. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any products or drug candidates we may develop, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any products or drug candidates we may develop and any other products, drug candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. There is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

- If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to:
- obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, if at all and even if we were able to obtain such licenses, they could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments;
- defend litigation or administrative proceedings;
- reformulate product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very expensive and time consuming;
- cease developing, manufacturing and commercializing the infringing technology, products or drug candidates; and
- pay such third party significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. Even if we are successful in such litigations or administrative proceedings, such litigations and proceedings may be costly and could result in a substantial diversion of management resources. Any of the foregoing may have a material adverse effect on our business, prospects, financial condition and results of operations.

Intellectual property litigation and proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to our, our licensor's or other third parties' intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that we or our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of competitors or their current or former employers or are in breach of non-competition or non-solicitation agreements with competitors or other third parties.

We could in the future be subject to claims that we or our employees, consultants or advisors have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of current or former employers, competitors or other third parties. Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not improperly use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer, competitor or other third parties.

Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and research personnel. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our products and drug candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our products and drug candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products and drug candidates, which would have a material adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary intellectual property rights to drug candidates for our development pipeline through acquisitions and in-licenses.

Although we also intend to develop drug candidates through our own internal research, our near-term business model is predicated, in large part, on our ability to successfully identify and acquire or in-license drug candidates to grow our drug candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such drug candidates from third parties on commercially reasonable terms or at all, including because we are focusing on specific areas of care such as oncology and inflammatory and infectious diseases. In that event, we may be unable to develop or commercialize such drug candidates. We may also be unable to identify drug candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such drug candidates. Any of the foregoing could have a materially adverse effect on our business, financial condition, results of operations and prospects.

The in-licensing and acquisition of third-party intellectual property rights for drug candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for drug candidates that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to suitable drug candidates, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for drug candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for drug candidates on terms that would allow us to make an appropriate return on our investment.

If we do not obtain patent term extension and data exclusivity for our products or any drug candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our products or any drug candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. The PRC has not established a patent term extension system, but the government proposed to grant patent term extension to new drugs that will be marketed in and outside China for up to 5 years.

In China, there is currently no effective law or regulation providing for patent term extension, patent linkage, or data exclusivity. Therefore, a lower-cost generic or biosimilar drug can emerge onto the market more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime and for establishing a pilot program for patent term extension. To be implemented, this framework will require promulgation of laws, regulations and detailed implementation measures. To date, no laws, regulations or implementation measures have been promulgated and become effective. Consequently, the absence of currently effective laws and regulations on patent linkage, patent term extension and data exclusivity or the cancellation of the currently effective five-year administrative exclusivity for domestically manufactured new drugs could result in much weaker protection for us against generic competition in China. For instance, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to any product or drug candidates we may develop or utilize similar gene therapy technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, our licensors, patent owners of patent rights that we have in-licensed, or current or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may discover certain technologies containing such trade secrets or know how through independent research and development and/or subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our ADSs

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If we fail to establish and maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The presence of material weaknesses in internal control over financial reporting could result in financial statement errors which, in turn, could lead to errors in our financial reports and/or delays in our financial reporting, which could require us to restate our operating results. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If we fail to maintain effective internal control over financial reporting in the future, our management and our independent registered public accounting firm may not be able to conclude that we have effective internal controls over financial reporting, investors may lose confidence in our operating results, the price of the ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, the ADSs may not be able to remain listed on the Nasdaq Global Market.

As a foreign private issuer, we are not subject to certain U.S. securities law disclosure requirements that apply to a domestic U.S. issuer, which may limit the information publicly available to our shareholders.

As a foreign private issuer we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act and therefore there may be less publicly available information about us than if we were a U.S. domestic issuer. For example, we are not subject to the proxy rules in the United States and disclosure with respect to our annual general meetings will be governed by the Cayman Islands requirements. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules thereunder. Therefore, our shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our ordinary shares or ADSs.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq Stock Market corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq Stock Market listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. We follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following: (i) the majority independent director requirement under Section 5605(b)(1) of the Nasdaq Stock Market listing rules, (ii) the requirement under Section 5605(d) of the Nasdaq Stock Market listing rules that a compensation committee comprised solely of independent directors governed by a compensation committee charter oversee executive compensation, (iii) the requirement under Section 5605(e) of the Nasdaq Stock Market listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors and (iv) the requirement under Section 5605(b)(2) of the Nasdaq Stock Market listing

rules that our independent directors hold regularly scheduled executive sessions. Cayman Islands law does not impose a requirement that our board of directors consist of a majority of independent directors. Nor does Cayman Islands law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We expect to lose our foreign private issuer status and be subject to U.S. domestic issuer disclosure requirements beginning in fiscal year 2021, which could result in significant additional costs and expenses.

As discussed above, we are currently a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2020. Currently, more than 50% of our ordinary shares are directly or indirectly held by residents of the U.S. and, therefore, we expect that we will lose our foreign private issuer status as of June 30, 2020. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on January 1, 2021, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq Stock Market listing rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange.

The audit report included in this Annual Report on Form 20-F was prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, you are deprived of the benefits of such inspection.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including the independent registered public accounting firm of our company, must be registered with the PCAOB, and are required by the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Because substantially all of our operations are within China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditor is not currently inspected by the PCAOB.

In May 2013, the PCAOB entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or CSRC, and the Ministry of Finance, to establish a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by the PCAOB in the United States or the CSRC or the Ministry of Finance in the PRC. The PCAOB has announced that, since May 2013, cooperation has not been sufficient to enable the PCAOB to obtain timely access to relevant documents and testimony necessary to carry out its mission. The PCAOB continues to address these issues with Chinese regulators, and whether the PCOAB will obtain equivalent access remains an open issue.

This lack of PCAOB inspections in China prevents the PCAOB from evaluating audits and quality control procedures of any auditors operating in China, including our auditor. As a result, investors may be deprived of the benefits of PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections. Additionally, the SEC, the U.S. Department of Justice and other authorities often have substantial difficulties in bringing and enforcing actions against non-U.S. persons and companies, including those based in China. Investors should understand the attendant risks. Further, as a result, investors may lose confidence in our reported financial information and procedures and the quality of our financial statements as a result thereof.

We do not currently intend to pay dividends on our securities, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ADSs.

We have never declared or paid any dividends on our ordinary shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on their ADSs at least in the near term, and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our investors purchased their ADSs.

The market price for our ADSs may be volatile which could result in substantial loss to you.

The market price for our ADSs has been volatile. From September 19, 2017 to April 24, 2020, the closing price of our ADSs ranged from a high of $65.80 to a low of $14.95 per ADS.

The market price of our ADSs is likely to be highly volatile and subject to wide fluctuations in response to factors, including the following:

- announcements of competitive developments;
- regulatory developments affecting us, our customers or our competitors;
- announcements regarding litigation or administrative proceedings involving us;
- actual or anticipated fluctuations in our period-to-period operating results;
- changes in financial estimates by securities research analysts;
- additions or departures of our executive officers;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiration of lock-up or other transfer restrictions on our outstanding ordinary shares of ADSs; and
- sales or perceived sales of additional ordinary shares or ADSs.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. For example, since August 2008, multiple exchanges in the United States and other countries and regions, including China, experienced sharp declines in response to the growing credit market crisis and the recession in the United States. As recently as March 2020, the exchanges in both the United States and China experienced a sharp decline. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs, which would also negatively affect the trading prices for our ADSs.

Fluctuations in the value of the renminbi may have a material adverse effect on our results of operations and the value of your investment.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. On July 21, 2005, China government changed its decade-old policy of pegging the value of the renminbi to the U.S. dollar, and the renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that China government would increase the flexibility of the exchange rate, and thereafter allowed the renminbi to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the renminbi by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day's value, respectively. On October 1, 2016, the renminbi joined the International Monetary Fund's basket of currencies that make up the Special Drawing Right, or SDR, along with the U.S. dollar, the Euro, the Japanese yen and the British pound. In the fourth quarter of 2016, the renminbi depreciated significantly while the U.S. dollar surged and China experienced persistent capital outflows. With the development of the foreign exchange

market and progress towards interest rate liberalization and renminbi internationalization, the Chinese government may in the future announce further changes to the exchange rate system. There is no guarantee that the renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the renminbi and the U.S. dollar in the future.

Significant revaluation of the renminbi may have a material adverse effect on your investment. For example, to the extent that we need to convert U.S. dollars into renminbi for our operations, appreciation of the renminbi against the U.S. dollar would have an adverse effect on the renminbi amount we would receive from the conversion. Conversely, if we decide to convert our renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the renminbi would have a negative effect on the U.S. dollar amount available to us. In addition, appreciation or depreciation in the value of the renminbi relative to U.S. dollars would affect our financial results reported in U.S. dollar terms regardless of any underlying change in our business or results of operations.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert renminbi into foreign currency.

Holders of ADSs have fewer rights than shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our fourth amended and restated memorandum and articles of association, an annual general meeting and any extraordinary general meeting may be called with not less than seven days' notice. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. If we ask for your instructions, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date and the depositary will send a notice to you about the upcoming vote and will arrange to deliver our voting materials to you. The depositary and its agents, however, may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the ordinary shares underlying your ADSs. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a holder or beneficial owner of ADSs, you may have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement or if you wish us or the depositary to participate in legal proceedings. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

You may not receive distributions on our ADSs or any value for them if such distribution is illegal or impractical or if any required government approval cannot be obtained in order to make such distribution available to you.

Although we do not have any present plan to pay any dividends, the depositary of our ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying our ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but are not so properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of our ADSs.

Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are incorporated under the laws of the Cayman Islands and currently have subsidiaries in China, Hong Kong, the Cayman Islands, the United States, Australia and the British Virgin Islands. If we succeed in growing our business we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us, our parent company and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

A tax authority could asset that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

If we are classified as a passive foreign investment company, U.S. investors could be subject to adverse U.S. federal income tax consequences.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are a PFIC, U.S. holders of our ADSs may suffer adverse tax consequences, including having gains realized on the sale of the ADSs treated as ordinary income rather than capital gain, the loss of the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of the ADSs.

As discussed in "Material United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations," we believe that our Hong Kong subsidiary, Zai Lab (Hong Kong) Limited, was a PFIC for its taxable year ended July 12, 2017 and that the Company and its other subsidiaries were not PFICs for the taxable years ended December 31, 2018 and 2019, and we do not expect that the Company and its subsidiaries will be treated as PFICs for the current taxable year, although no assurance can be provided in that regard. Notwithstanding the foregoing, the

determination of whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year and which depends on the composition of our income and the composition and value of our assets for the relevant taxable year. Because we hold a substantial amount of passive assets, including cash, and because the value of our assets for purposes of the PFIC rules (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early stage of our products and drug candidates, and by how, and how quickly, we spend any cash that is raised in any financing transaction, we cannot give any assurance that we will not be a PFIC for the current or any future taxable year.

Whether or not U.S. holders make a timely "qualified electing fund," or QEF election or mark-to-market election may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ADSs. Prospective investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to the ADSs. See "Material United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

If a United States person is treated as owning at least 10% of our common shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder (as defined below under "Material United States Federal Income Tax Considerations") is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ADSs, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes at least one U.S. subsidiary (Zai Lab (US), LLC), certain of our non-U.S. subsidiaries will be treated as controlled foreign corporations (regardless of whether Zai Lab Limited is treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries, if any, are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our ADSs.

Changes in tax law may adversely affect our business and financial results.

Under current law, we expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. Our actual tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) our ability to use net operating loss carryforwards to offset future taxable income and any adjustments to the amount of the net operating loss carryforwards we can utilize, and (5) changes in tax laws or the interpretation of such tax laws, and changes in U.S. GAAP.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted U.S. federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. The overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our

ADSs is also uncertain and could be adverse. We urge holders of our ADS to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our ADSs.

You may have difficulty enforcing judgments obtained against us.

We are a company incorporated under the laws of the Cayman Islands, and substantially all of our assets are located outside the United States. Substantially all of our current operations are conducted in the PRC. In addition, some of our directors and officers are nationals and residents of countries other than the United States. A substantial portion of the assets of these persons are located outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon these persons. It may also be difficult for investors to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors, some of whom currently reside in the United States and whose assets are located outside the United States. In addition, there is uncertainty as to whether the courts of the Cayman Islands or China would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under China Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of China Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of reciprocity with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to China Civil Procedures Law, China courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC laws or national sovereignty, security or public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States.

Investors may be subject to limitations on transfers of your ADSs.

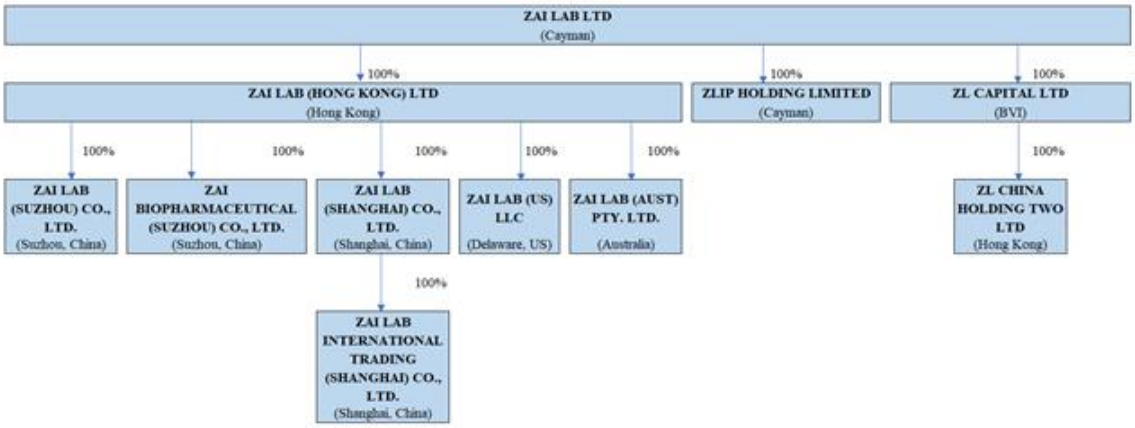
ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our company was founded in the Cayman Islands on March 28, 2013 as an exempted company with limited liability under the Companies Law, Cap 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands. Our principal executive offices are located at 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210. Our telephone number at that address is +86 21 6163 2588. The address of our registered office in the Cayman Islands is Harbour Place 2nd Floor, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands. Our agent for service of process in the United States is Cogency Global Inc., located at 10 E. 40th Street, 10th Floor, New York, NY 10016.

The chart below shows our principal subsidiaries as of March 31, 2020.



Since our founding, we have raised approximately $164.6 million in private equity financing. In September 2017, we completed our initial public offering in the United States, listing on the Nasdaq Global Market, raising approximately $157.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us. In September 2018, we completed a registered offering of ADSs, raising approximately $140.3 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us. In May 2019, we completed a registered offering of ADSs, raising approximately $215.4 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us. In January 2020, we completed a registered offering of ADSs, raising approximately $280.6 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us. In addition, we have received government grants totaling approximately $8.7 million since our inception.

As of December 31, 2019, we had ten active in-licensed clinical drug candidates for development in China, Hong Kong, Macau and, in certain instances, Taiwan, Australia, New Zealand and other countries throughout the Asia Pacific region, through partnerships with GSK, BMS, Paratek, Five Prime, Entasis, Novocure, MacroGenics, Deciphera and Incyte. In April 2020, our portfolio was expanded to eleven clinical-stage drug assets with the addition of REGN1979, through our partnership with Regeneron. To date, we have made upfront, milestone and clinical cost reimbursement payments totaling approximately $167.9 million since our inception in connection with these licensing arrangements. In early 2017, we built a small molecule drug product facility in Suzhou, China capable of supporting clinical and commercial production. In 2018, we built a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. The cost to complete the small molecule facility was approximately $6.7 million and was paid with cash on hand. The construction of the large molecule facility was completed in 2018, which cost approximately $12.9 million to complete.

Business

Overview of Our Business

We are an innovative, research-based, commercial-stage biopharmaceutical company focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China and global markets, including in the fields of oncology, infectious and autoimmune diseases. As part of that effort, we have assembled a leadership team with global experience and an extensive track record in navigating the regulatory process to develop and commercialize innovative drugs. Our mission is to leverage our expertise and insight to address the expanding needs of patients in China and to utilize our China-based competencies to improve the lives of patients worldwide.

Furthermore, Zai Lab was built on the vision that, despite having a significant addressable market and sizable growth potential, China has historically lacked access to many innovative therapies available in other parts of the world and its drug development infrastructure has been underutilized. There remains the need to bring new and transformative therapies to China. In recent years, the Chinese government has focused on promoting local innovation through

streamlining regulatory processes, improving drug quality standards and fostering a favorable environment, which we believe creates an attractive opportunity for the growth of innovation-focused companies such as Zai Lab.

As of April 2020, our portfolio consists of eleven assets, including two approved, commercial drug products and seven late-stage clinical assets targeting large, fast growing segments of China's pharmaceutical market. ZEJULA, our lead drug candidate is an oral, once-daily small molecule PARP 1/2 inhibitor being developed and commercialized outside of China, Hong Kong and Macau by our partner, GSK. ZEJULA has the potential to be a differentiated drug for treatment across multiple solid tumor types in China, including ovarian and certain other types of cancer. In March 2017, ZEJULA received FDA marketing approval and in November 2017, it received EMA marketing approval as a maintenance treatment for recurrent platinum-sensitive epithelial ovarian cancer. In April 2017, Tesaro, Inc., or Tesaro, which was later acquired by GSK, commercially launched the product in the United States under the commercial name ZEJULA. In October 2018, the Hong Kong Department of Health approved our application for ZEJULA in Hong Kong for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy and we began commercializing ZEJULA in Hong Kong in the fourth quarter of 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. In December 2019, ZEJULA was approved by the NMPA in China as a Category 1 maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy **.** ZEJULA was also designated as a "National Sciences and Technology Major Project" by the Chinese government as part of a key initiative to strengthen local innovation. In addition, the NMPA accepted and granted priority review to our supplemental New Drug Application, or sNDA, for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy in March 2020 and April 2020, respectively. We are also exploring the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

Across our broader portfolio, we currently have over 25 ongoing or planned clinical trials. We believe that our leadership team's extensive global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, with opportunities to bring innovative products to market in China efficiently.

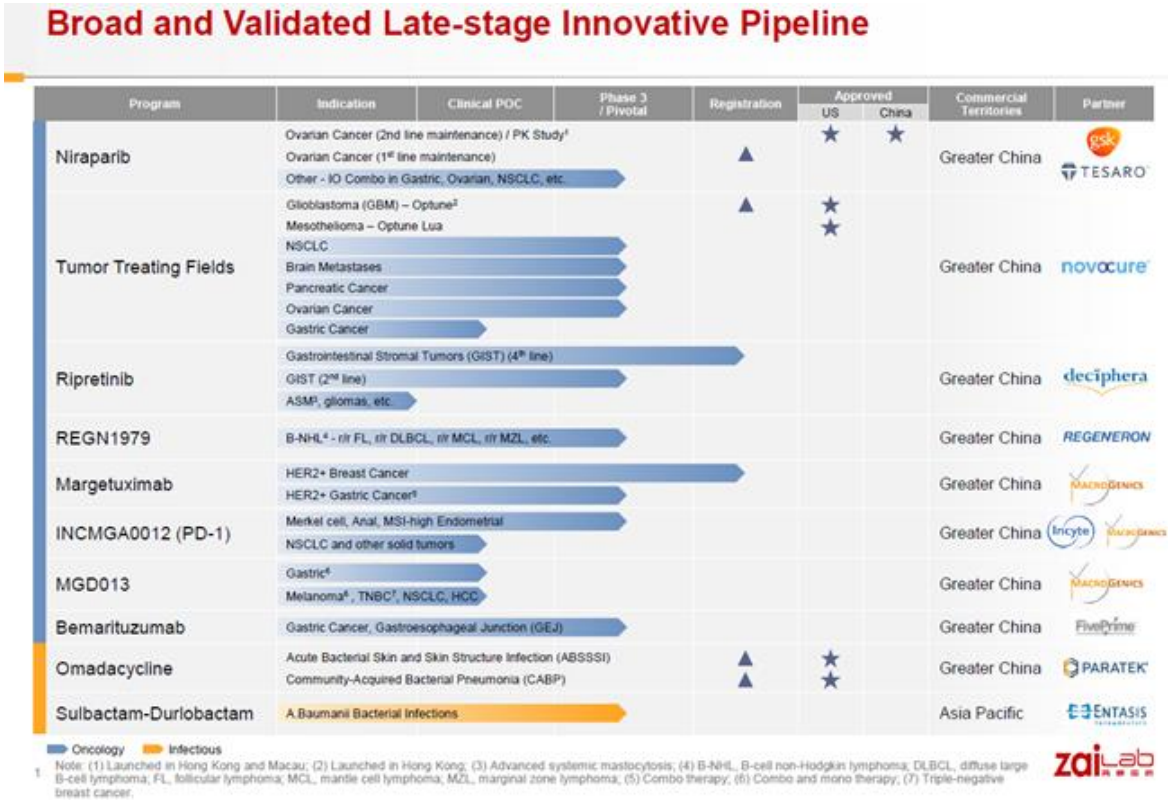
Our current eleven clinical-stage drug candidates were in-licensed for development in China, Hong Kong, Macau and, in certain instances, Taiwan, Australia, New Zealand and other countries throughout the Asia Pacific region.

We have built a premier, fully integrated drug discovery and development platform that aims to bring both in-licensed and internally-discovered medicines to patients in China and globally. Our in-house research and development team had previously been directly involved in the discovery and development of several innovative drug candidates at Hutchison Medi-Pharma, including fruquintinib and savolitinib. Our in-house research and development team focuses on the development of innovative therapeutics for the treatment of oncology and auto-immune diseases. We believe our discovery efforts will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new products and drug candidates for patients around the world. This effort has resulted in the identification of a number of proprietary candidates against targets in our focus areas that include immuno-oncology, DNA damage response/repair and oncogenic signaling that we are moving into pre-clinical development. Our company has a leadership team with extensive pharmaceutical research, development and commercialization track records in both global and Chinese biopharmaceutical companies. We believe this team and our in-house discovery and development capabilities will enable us to achieve our long-term goal of commercializing our internally discovered innovative medicine for patients worldwide.

We have built our own commercial team consisting of more than 298 employees as of December 31, 2019 to launch our portfolio of drug products. Part of our strategy to become a fully integrated biopharmaceutical company is the ability to produce both large and small molecule therapeutics under global standards, such as current good manufacturing practices, or cGMP. To this end, in the first half of 2017, we built a small molecule drug product facility capable of supporting clinical and commercial production, and in 2018, we built a large molecule facility capable of supporting clinical production of our drug candidates.

Our Innovative Pipeline

We have a broad pipeline of proprietary products and drug candidates that range from discovery stage to late-stage clinical to commercial-stage programs. The following table summarizes our commercial products, clinical-stage drug candidates and programs.



Our Products and Late-Stage Clinical Pipeline

As of December 31, 2019, our pipeline included two commercial products in China, Hong Kong and Macau and eight clinical-stage assets in oncology and infectious diseases, two therapeutic areas where there is a large unmet need and lack of innovative treatment options in China. In April 2020, our portfolio was further expanded with the addition of REGN1979. Within our broad and validated portfolio, the approved products and late-stage clinical drug candidates are:

Our Products

- **Niraparib (ZEJULA)** is a highly potent and selective oral, small molecule PARP 1/2 inhibitor with the potential to be a differentiated drug for treatment across multiple solid tumor types in China, including ovarian and certain types of lung cancers. We have licensed ZEJULA, or niraparib, from Tesaro (now GSK), which in March 2017 received FDA marketing approval and in November 2017, received EMA marketing approval for ZEJULA for maintenance treatment for women with recurrent platinum-sensitive epithelial ovarian cancer. We believe ZEJULA is uniquely suited for the China marketplace, where there is a large ovarian cancer population. Niraparib was commercially launched by Tesaro (now GSK) in the United States in April 2017. We commercialized ZEJULA in Hong Kong in the fourth quarter of 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. In China, ZEJULA has been approved as a Category 1 drug by the NMPA in December 2019 as maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. In

addition, the NMPA accepted and granted priority review to our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy in March 2020 and April 2020, respectively. We are also exploring the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications .

- **Optune (Tumor Treating Fields)** is a new treatment modality known as Tumor Treating Fields which has demonstrated overall survival benefit in patients with newly diagnosed GBM in a large randomized controlled clinical trial. Tumor Treating Fields is an innovative cancer therapy that uses electric fields tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die. Optune is currently marketed in the United States, the European Union and Japan for the first line and reoccurring treatment of GBM. Tumor Treating Fields delivery system was approved by the FDA in May 2019 under the brand name "Optune Lua™" to treat mesothelioma and has demonstrated clinical proof of concept in multiple other tumor types such as lung cancer and pancreatic cancer. Novocure currently has global Phase III studies in brain metastases, non-small cell lung cancer, or NSCLC, pancreatic cancer and ovarian cancer, which are large commercial opportunities in China. In September 2018, we announced a global strategic development collaboration with Novocure. We obtained an exclusive license to develop and commercialize Tumor Treating Fields in China, Hong Kong and Macau and will also support enrollment of Chinese patients to accelerate clinical trial enrollment for additional indications. In December 2018, within three months of signing the partnership deal with Novocure, we launched Optune in Hong Kong and treated its first patient with newly diagnosed GBM. In September 2019, the NMPA accepted the Marketing Authorization Application (MAA) of Optune, a Tumor Treating Fields delivery system for the treatment of GBM.

Late-Stage Clinical Pipeline

- **Ripretinib** is an investigational KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including GIST, systemic mastocytosis, or SM, and other cancers. Ripretinib was specifically designed to improve the treatment of GIST patients by inhibiting a broad spectrum of mutations in KIT and PDGFRα. Ripretinib is a KIT and PDGFRα inhibitor that blocks initiating and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST as well as the primary D816V exon 17 mutation involved in SM. Ripretinib also inhibits primary PDGFRα mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST. On June 11, 2019, Deciphera and we announced an exclusive license agreement to advance the development and commercialization of ripretinib in China, Hong Kong, Macau and Taiwan.

- **REGN1979** , developed by Regeneron, is a fully human bispecific antibody that binds to CD3, a T cell antigen associated with the T cell receptor (TCR) complex, and CD20. REGN1979 was granted orphan drug designation by the FDA for the treatment of diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL). REGN1979 has demonstrated clinical activity in heavily pre-treated patients with Relapsed/Refractory (R/R) B-non-Hodgkin lymphomas (B-NHL) in a Phase I trial and is currently being investigated in a potentially registrational Phase II program. We are exploring regulatory approval pathways for REGN1979 in R/R B-NHL in China by joining the global registrational Phase II program. On April 6, 2020, we entered into a collaboration agreement with Regeneron to develop and exclusively commercialize REGN1979 in oncology in China, Hong Kong, Taiwan and Macau.

- **Margetuximab** is an immune-optimized anti-HER2 monoclonal antibody developed by MacroGenics. In February 2019, MacroGenics announced positive top-line results from its SOPHIA Phase III clinical trial. Margetuximab demonstrated improved progression-free survival compared to HERCEPTIN (trastuzumab) when used in combination with chemotherapy in patients with HER2+ metastatic breast cancer. We plan to discuss with the NMPA a potential accelerated approval pathway for HER2+ breast cancer in China. In addition, jointly with MacroGenics, we plan to conduct the China portion of the global pivotal study in HER2+ gastric cancer, which is expected to start in the first half of 2020.We have exclusive rights to margetuximab in China, Hong Kong, Macau and Taiwan from MacroGenics.

- **INCMGA0012 (PD-1)** is an investigational monoclonal antibody that inhibits PD-1. INCMGA0012 (PD-1) is currently being evaluated as monotherapy in registration-directed trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer. In 2017, Incyte entered into an exclusive global collaboration and license agreement with MacroGenics for global rights to INCMGA0012 (PD-1). Incyte is currently developing INCMGA0012 (PD-1) in phase II/III clinical trials for the gastric cancer and oesophageal cancer; phase II clinical trials for anal cancer; endometrial cancer; merkel cell carcinoma; solid tumours; phase I/II clinical trials for colorectal cancer; and phase I clinical trials for acute myeloid leukaemia, among other indications. On July 2, 2019, Incyte and we announced that the companies have entered into a collaboration and license agreement for the development and commercialization of INCMGA0012 (PD-1), an investigational anti-PD-1 monoclonal antibody, in China , Hong Kong, Macau and Taiwan . We receive the rights to develop and exclusively commercialize INCMGA0012 (PD-1) in haematology and oncology in mainland China, Hong Kong, Macau and Taiwan. Incyte retains an option to assist in the promotion of INCMGA0012 (PD-1) in our licensed territories.

- **Bemarituzumab (FPA144)** is a humanized monoclonal antibody (IgG1 isotype) specific to the human fibroblast growth factor receptor 2b, or FGFR2b, in clinical development as a targeted therapy for tumors that overexpress FGFR2b, including gastric and gastroesophageal cancer. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually. We have licensed bemarituzumab from Five Prime as part of a global strategic collaboration. The randomized, controlled Phase III portion of the trial evaluating bemarituzumab in combination with a chemotherapy regimen, or the FIGHT trial, started in the fourth quarter of 2018. We enrolled the first patient from China in this international Phase III trial that will serve as a global registrational study for the treatment of front-line gastric and gastroesophageal cancers. In May 2018, we received CTA approval from the NMPA to enroll Chinese patients in the bemarituzumab global registrational study. We will manage the China portion of this global Phase III study and contribute patients from China to this Phase III study. In 2019, our partner Five Prime suspended trial enrollment in order to conduct a futility analysis prior to continuing patient enrollment. Patients enrolled into the trial are currently undergoing treatment and follow-up. Five Prime has paused enrollment in the FIGHT trial pending the occurrence of a sufficient number of events to trigger a futility analysis that is expected to occur in mid-2020. Approximately 150 patients with newly diagnosed advanced stage gastric cancer were enrolled into the FIGHT trial before Five Prime paused enrollment in the fourth quarter of 2019. Five Prime expects that it will only resume enrollment in the FIGHT trial if the trial passes the futility analysis.

- **Omadacycline (ZL-2401)** is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. We have licensed omadacycline from Paratek, which in October 2018 received FDA marketing approval. Omadacycline is primarily being developed for acute bacterial skin and skin structure infection (ABSSSI) and community-acquired bacterial pneumonia (CABP). Omadacycline is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. Drugs competing with omadacycline in the same class are only available in IV formulation, in contrast, omadacycline is available in both IV and oral once-daily formulations that makes treatment convenient for care givers and patients. We have completed the technology transfer and completed in 2019 the NMPA required microbiology, PK and clinical bridging programs. We engaged in discussions with the NMPA and key opinion leaders on our planned China development strategy for our NDA filing in China. In July 2018, we received CTA approval from the NMPA. In February 2020, the NMPA accepted our NDA with Category 1 new drug designation for NUZYRA for the treatment of CABP and ABSSSI.

- **Durlobactam (ZL-2402)** is a novel beta-lactamase inhibitor. We have licensed durlobactam from Entasis as part of a global strategic collaboration. Durlobactam restores activity of beta-lactams against Class A, C, and D beta-lactamases. Entasis is developing durlobactam as sulbactum-durlobactum (SUL-DUR), a fixed combination of durlobactam and sulbactam, for the treatment of Acinetobacter baumannii bacterial infections, including penem-resistant A. baumannii. Acinetobacter infections occur predominantly in the hospital setting; the pathogen is often multi-drug resistant (MDR), and has become extremely difficult to treat. The efficacy of the combined durlobactam and sulbactam was demonstrated in large microbiologic studies of well-characterized MDR Acinetobacter isolates from diverse regions, including Asia. The FDA has granted SUL-DUR Qualified Infectious Disease Product (QIDP) status as well as Fast Track and Priority Review status. Entasis has completed a Phase II cUTI trial in 2018, reviewed clinical Phase III

plans with FDA and initiated a pivotal Phase III study in MDR Acinetobacter pneumonia and bloodstream infections in 2019 , which will serve as a global registrational study. Zai Lab will manage the China portion of this global Phase III study and plans to contribute a significant number of patients from China. We plan to initiate patient dosing in the Asia-Pacific portion of the Phase III global registration trial of durlobactam for MDR Acinetobacter pneumonia and bloodstream infections in the first half of 2020.

For our late-stage oncology drug candidates with China, Hong Kong, Macau and Taiwan rights, our near-term development plan focuses on specific patient segments. These segments have an estimated annual incidence of over 1.6 million patients in China. We expect that the commercial success of our products will be driven by their differentiated clinical profiles, efficacy in Chinese patients and ability to provide clinical benefits over existing standards of care in a market where targeted therapies are either unavailable or less utilized relative to more developed markets.

Within our anti-infective portfolio, we believe that our two novel antibiotics, omadacycline and durlobactam, will address significant unmet patient and market needs.

With omadacycline, we have the chance to introduce into China a new broad-spectrum antibiotic with excellent activity not only against common Gram-positive and Gram-negative bacteria, but also against several MDR pathogens. The profile of omadacycline includes MRSA, penicillin- and macrolide-resistant streptococci, enterococci and ESBL-E. coli isolates. In addition, the availability of an IV and oral formulation allows step-down treatment of infections in the hospital and continued oral therapy in the ambulatory care setting. This favorable antimicrobial spectrum has been confirmed now for Chinese isolates as well.

With durlobactam, in collaboration with our partner, we are focusing on the combination with sulbactam, which we believe provides unique and specific bactericidal activity against Acinetobacter baumannii spp., an extremely difficult-to-treat pathogen associated with high mortality that is more prevalent in China than most other countries. In a study conducted by Zai Lab of Acinetobacter pathogens from Chinese patients, durlobactam demonstrated excellent activity against all isolates including MDR and carbapenem-resistant strains. The prevalent overuse of antibiotics, the evolution of resistant bacteria and state of current treatment practices are expected to lead to an increase in drug-resistant infection rates. In 2013, total antibiotic usage in China accounted for about half of the global antibiotic usage, with a per-capita use of antibiotics being more than five times that in Europe and the United States.

In 2015, the estimated incidence for ABSSSI and CABP was 2.8 million patients and 16.5 million patients, respectively, in China alone. In 2016, based on a national survey of over 1,300 hospitals in China, there were approximately 210,000 Acinetobacter baumannii infections. Due to the high rates of MDR, the Chinese government has identified the goal of developing one to two innovative anti-infective drugs by 2020.

In addition to mainland China, we intend to seek registration and commercialization of the above drug candidates in all areas where we have applicable rights. Notably in Hong Kong and Macau, products with existing approvals by the FDA, EMA or a comparable regulatory agency are eligible for an expedited registration process that does not require conducting local clinical trials.

While the overall patient population in Hong Kong and Macau is smaller compared to that of China, they are higher income markets with developed medical infrastructure, widely available private insurance and proven capacity to pay for advanced therapeutics. In addition to local patients, there is a significant opportunity to provide treatment for medical tourists from China, who visit these regions in order to access high-end cancer treatment, including prescription drugs that may not be available in mainland China.

Our Discovery Pipeline

Our in-house discovery team is dedicated to the research and discovery of novel therapeutics in the areas of oncology and autoimmune diseases, with a focus on large market opportunities with unmet clinical needs. Our aim is to produce up to two global INDs starting in 2020. We believe our discovery efforts will enable us to achieve our long-term goal of generating a sustainable, internally discovered product pipeline of new products and drug candidates for patients around the world. This effort has resulted in the identification of a number of proprietary candidates against targets in our focus areas that include immuno-oncology, DNA damage response/repair and oncogenic signaling that we are moving into pre-clinical development. Our discovery operations in Shanghai, China was established in 2016. Our discovery operations in San Francisco, California, was established in 2018. Our U.S. discovery team focuses on generating small and large molecule therapeutics and is currently creating a proprietary, best-in-class human Ig transgenic mouse platform.

Our Clinical Pipeline

ZEJULA

ZEJULA is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) polymerase 1/2, or PARP 1/2, inhibitor with the potential to be a first-in-class Category 1 drug for treatment across multiple solid tumor types in China. ZEJULA was approved in March 2017 by the FDA and in November 2017 by EMA, as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer. Maintenance therapy is for those women who have had prior treatment but are expected to see their cancer return, with the purpose of avoiding or slowing a recurrence if the cancer is in remission after the prior treatment. A platinum-sensitive cancer is one that responded to initial platinum-based chemotherapy and remained in remission post-chemotherapy for more than six months.

ZEJULA is the first PARP inhibitor to be approved by the FDA for ovarian cancer that does not require BRCA mutation or other biomarker testing. This makes ZEJULA suitable for a wide patient population and significantly more accessible to patients in China where BRCA biomarker diagnostic tests are not widely available.

We obtained an exclusive license for the development and commercialization of ZEJULA in China, Hong Kong and Macau in 2016. We commercialized ZEJULA in Hong Kong in the fourth quarter of 2018. In October 2018, the Hong Kong Department of Health approved our application for ZEJULA in Hong Kong for adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian cancer who are in a complete response or partial response to platinum-based chemotherapy and we began commercializing ZEJULA in Hong Kong in the fourth quarter of 2018. In June 2019, we received marketing authorization to commercialize ZEJULA in Macau for women with relapsed ovarian cancer. In December 2019, ZEJULA was approved by the NMPA in China as a Category 1 maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. ZEJULA was also designated as a “National Sciences and Technology Major Project” by the Chinese government as part of a key initiative to strengthen local innovation. In addition, the NMPA accepted and granted priority review to our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy in March 2020 and April 2020, respectively.

We initiated the Phase III study of ZEJULA in patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy in September 2017. In May 2018, we completed enrollment ahead of schedule for our pharmacokinetics, or PK, study for Chinese patients with platinum-sensitive ovarian cancer, and in June 2018, we initiated the second Phase III study in patients with platinum-responsive ovarian cancer as a first-line maintenance therapy and dosed our first patient. These studies are similar in design to Tesaro’s clinical studies of niraparib in ovarian cancer. In August 2018, we completed our PK study for Chinese patients with platinum-sensitive ovarian cancer, which demonstrated a comparable efficacy profile to studies in non-Chinese patients. We continue to explore ZEJULA in patients with breast cancer and non-small cell lung cancer in China. In February 2020, Zai Lab dosed the first patient in the Phase Ib study of niraparib with MGD-013, a first-in-class PD1/LAG-3 bispecific antibody, in advanced or metastatic gastric cancer. We are also exploring the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

Ovarian Cancer

Ovarian cancer had an estimated annual incidence of 52,000 patients in China in 2015, which is more than double that of the 21,300 patients in the United States and has seen increasing mortality rates. Since early symptoms of ovarian cancer are non-specific and difficult to detect, a majority of women with ovarian cancer are diagnosed when the disease is at an advanced stage, when prognosis is poor. Finding effective therapeutic approaches for advanced ovarian cancer patients represents a large unmet medical need. Given the broad applicability of ZEJULA across all patient populations, regardless of gBRCA mutation status, we are currently targeting the entire platinum sensitive ovarian cancer patient population. This represents a significant advantage for patient convenience and access, given that there is no need for patients to utilize diagnostic tests to determine their gBRCA mutation status, particularly in China where such tests are not widely available.

The current standard of care in China consists of radical surgery and platinum-based chemotherapy. Although platinum-based chemotherapy is effective at inducing an initial response, ovarian cancer will recur in approximately 85% of women. Many women continue to respond to second-line platinum based chemotherapy, and following a response, the guideline-recommended approach for many patients is surveillance, monitoring patients for disease progression and managing their symptoms. However, during the surveillance period, ovarian cancer survivors report anxiety about cancer antigen testing and fear of recurrence, many experiencing symptoms associated with post-traumatic stress disorder. After relapse, patients respond moderately or poorly to subsequent chemotherapy, with later lines of therapy leading to progressively shorter treatment-free intervals. Therefore, we believe effective maintenance therapies that address a broad patient population are needed to prolong the duration of response following platinum-based treatment.

Lung Cancer

Lung cancer has the highest total incidence as well as the highest mortality rate of any cancer in China. Annual incidence was estimated at 733,300 patients in China in 2015, which is more than triple the 221,200 patients in the United States for the same period. We intend to explore ZEJULA's efficacy in patients with lung cancer based on the large unmet need for effective treatment for such patients in China. According to the American Cancer Society, approximately 80% to 85% of lung cancers are non-small cell lung cancer and squamous cell carcinoma is about 25% to 30% of lung cancers.

Our Clinical Trial Designs and Strategy for ZEJULA in the China Market

Ovarian Cancer

In September 2018, we completed our open-label study evaluating the pharmacokinetic, or PK, profile of ZEJULA made in China in Chinese ovarian cancer patients. Results from the study show comparable PK profile of the Chinese patients administered ZEJULA to that of patients evaluated in Tesaro's global PK study. The study demonstrated that the drug exposure increased proportionally from 100mg to 300mg, with a Tmax of approximately three hours. Systemic exposure of ZEJULA, as measured by Cmax and AUC, increased approximately proportionally with increased dose. There were no unexpected safety issues noted during the trial. All key PK and safety parameters were comparable to those in global studies. The study results and population PK data did not identify ethnicity differences between Chinese and non-Chinese patients.

In January 2019, we completed patient enrollment of our Phase III trial evaluating ZEJULA as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. Recurrent ovarian cancer patients who have responded to a platinum-containing regimen were enrolled in the study and randomized 2:1 to receive either ZEJULA or placebo once daily. Patients were stratified by gBRCA status. Patients will be randomly assigned in a 2:1 ratio to receive ZEJULA or placebo once daily. Patients will be stratified by gBRCA status. The primary endpoint is progression-free survival. The primary analysis will be conducted in the entire study population, regardless of gBRCA mutation status. If the primary analysis meets the statistical significance, the study will be ended. If it does not, the study will continue for gBRCA mutation positive patients with the second-step primary analysis conducted in this population.

In November 2019, we completed patient enrollment of our Phase III trial evaluating ZEJULA as a first-line maintenance therapy in patients who are in a complete or partial response to first-line platinum-based chemotherapy. Advanced ovarian cancer patients were randomized 2:1 to receive niraparib or placebo as maintenance therapy. Randomization was stratified by use of neoadjuvant chemotherapy (yes or no), best response to platinum therapy (CR or PR), and homologous recombination deficiency (HRD) status (positive or negative/not determined). The primary end point was progression-free survival (PFS) in patients who had tumors with HRD+ve and in those in the overall population, as determined on hierarchical testing.

In China, ZEJULA has been approved as a Category 1 drug by the NMPA in December 2019 as maintenance therapy for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy. The NMPA accepted and granted priority review to our sNDA for ZEJULA as a maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy in March 2020 and April 2020, respectively.

Lung Cancer

We initiated a Phase III study in patients with platinum responsive small cell lung cancer as maintenance therapy in August 2018. Given the rapidly changing landscape in the management of small cell lung cancer, particularly with the introduction of PD1/PD-L1 antibodies in the first-line treatment of small cell lung cancer, we terminated this study to prioritize our resources to other opportunities including exploring potential combination regimen for ZEJULA and immuno-oncology agents in the maintenance setting for non-small cell lung cancer.

We continue to explore the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the other clinically relevant indications.

Background on PARP Inhibitors

One well-studied area of PARP activity relates to DNA repair. DNA contains genetic instructions used in the development and functioning of most known living organisms. DNA can be damaged by many types of mutagens, including oxidizing agents, alkylating agents, ultraviolet light and X-rays. An important property of DNA is that it can replicate, or make copies of itself. This is critical when cells divide because each new cell needs to have an exact copy of the DNA present in the old cell. It is also critical to the integrity and survival of cells that DNA damage can be repaired. Cells have evolved multiple mechanisms to enable such DNA repair, and these mechanisms are complementary to each other, each driving repair of specific types of DNA damage. If a cell's DNA damage repair system is overpowered, then the cell is programmed to die.

Radiation and certain chemotherapies such as alkylating agents and topoisomerase inhibitors induce significant damage to tumor cells, which results in programmed cell death. DNA repair mechanisms may reduce the activity of these anti-cancer therapies and, conversely, inhibition of DNA repair processes may enhance the effects of DNA-damaging anti-cancer therapy. For example, cancer cells can maintain viability despite disruption of the key DNA repair pathway known as the homologous recombination pathway, but they become particularly vulnerable to chemotherapy if an alternative DNA repair pathway is disrupted. This is known as "synthetic lethality"—a situation where the individual loss of either repair pathway is compatible with cell viability, but the simultaneous loss of both pathways results in cancer cell deaths. Since PARP inhibitors block DNA repair, PARP inhibition is thought to be an important part of cancer therapy.

Clinical studies have shown that PARP inhibitors are effective as a monotherapy in patients with certain types of cancer, including those with gene mutations as discussed below. PARP inhibitors have also been explored in numerous clinical trials to enhance chemotherapy treatments, including in combination with temozolomide (TMZ), cisplatin, carboplatin, gemcitabine and topotecan.

ZEJULA Mechanism of Action

Many DNA repair processes involve PARP-1 and PARP-2, which are zinc-finger DNA-binding enzymes that sense DNA damage and convert it into intracellular signals to promote DNA repair. PARP inhibitors block DNA repair by the base excision repair pathway. PARP inhibitors appear most effective when used to treat tumors with underlying defects in DNA repair or when combined with another DNA-damaging agent. This is because, in normal cells, the homologous recombination pathway compensates for PARP-mediated inhibition of the base excision repair pathway and maintains the fidelity of DNA repair. In cells with a deficiency in the homologous recombination pathway, such as those with BRCA-1 and BRCA-2 mutations, PARP inhibition leads to irreparable double-strand breaks, collapsed replication forks, and an increased use of the less effective nonhomologous end joining pathway. These disruptions ultimately result in synthetic lethality, and, in this manner, treatment with PARP inhibitors represents an opportunity to selectively kill cancer cells with deficiencies in homologous recombination and other DNA repair mechanisms. PARP inhibitors also have an additional mechanism of action known as "PARP trapping." The effect of PARP trapping is to poison DNA by stabilizing PARP-1 and PARP-2 at sites of DNA damage, generating complexes that may be even more toxic than the unrepaired single-strand breaks which result from PARP inhibition.

ZEJULA is designed to be a highly potent, selective inhibitor of PARP-1 and PARP-2. In an ovarian cancer patient-derived xenograft model, where tumor models are established from transplantation of a human tumor specimen from a cancer patient directly into a mouse, ZEJULA has been shown to have greater tumor concentration, allowing it to deliver sustained anti-tumor activity as compared to olaparib, an FDA-approved PARP inhibitor marketed by AstraZenaca for gBRCA+ ovarian cancer patients who have received at least three prior lines of chemotherapy.

ZEJULA Clinical Results

NOVA, a Phase III maintenance study of ZEJULA versus placebo in patients with recurrent platinum-sensitive ovarian cancer.

In March 2017, the FDA approved ZEJULA as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer, regardless of BRCA mutation or biomarker status, three months ahead of the FDA's scheduled decision date (PDUFA date). ZEJULA's FDA approval followed the release of successful results from Tesaro's NOVA trial in which ZEJULA demonstrated a clinically meaningful increase in progression-free survival in women with recurrent ovarian cancer, regardless of gBRCA mutation or biomarker status. Treatment with ZEJULA reduced the risk of disease progression or death by 73% in gBRCA mutation positive patients (hazard ratio = 0.27) and by 55% in patients without gBRCA mutations (hazard ratio = 0.45). Hazard ratio is the probability of an event (such as disease progression or death) occurring in the treatment arm divided by the probability of the event occurring in the control arm of a study, with a ratio of less than one indicating a lower probability of an event occurring for patients in the treatment arm. P-value is a measure of the probability of obtaining the observed sample results, with a lower value indicating a higher degree of statistical confidence in these studies. The magnitude of benefit was similar for patients entering the trial with a partial response or a complete response to platinum treatment.

The NOVA trial was a Phase III randomized double-blind trial that assessed the effectiveness of ZEJULA compared with placebo to delay tumor progression following a platinum containing chemotherapy regimen. Patients enrolled into one of two independent cohorts based on gBRCA mutation status. A total of 553 patients were enrolled in the NOVA study at 107 centers worldwide. The study population has 203 patients assigned to the gBRCA mutation positive cohort and 350 patients assigned to the gBRCA mutation negative cohort. Among the patients in the gBRCA mutation negative cohort, 162 had tumors that were tumors deficient in homologous recombination, or HRDpos, and 134 had tumors did not have a homologous recombination deficiency, or HRDneg. The homologous recombination deficiency status was not determined for 54 patients. The gBRCA mutation negative cohort analyses included all patients randomized, regardless of homologous recombination deficiency status.

Within each cohort, patients were randomized 2:1 to receive ZEJULA or placebo, and were continuously treated with placebo or ZEJULA until progression. The primary endpoint of this study was progression free survival. Secondary endpoints included patient-reported outcomes, chemotherapy free interval length, and OS. This trial successfully achieved its primary endpoint in both cohorts, showing that ZEJULA treatment significantly prolonged progression free survival, compared to control in patients who were gBRCA mutation positive and in patients who were gBRCA mutation negative. In addition, within the gBRCA mutation negative cohort, ZEJULA treatment significantly prolonged progression free survival compared to placebo for the prospectively defined patient population with HRDpos tumors. A high proportion of patients in both treatment groups in both cohorts had received three or four prior lines of chemotherapy. The most common treatment-emergent grade 3/4 adverse events in the ZEJULA arm of the NOVA study, based on the National Cancer Institute's Common Terminology Criteria for Adverse Event, or CTC, which is a set of criteria for the standardized classification of adverse effects of drugs used in cancer therapy (with one and two being relatively mild and higher numbers up to five being more severe), were thrombocytopenia, anemia, and neutropenia.

The figures below present the results for the primary endpoint of progression free survival for the three primary efficacy populations.

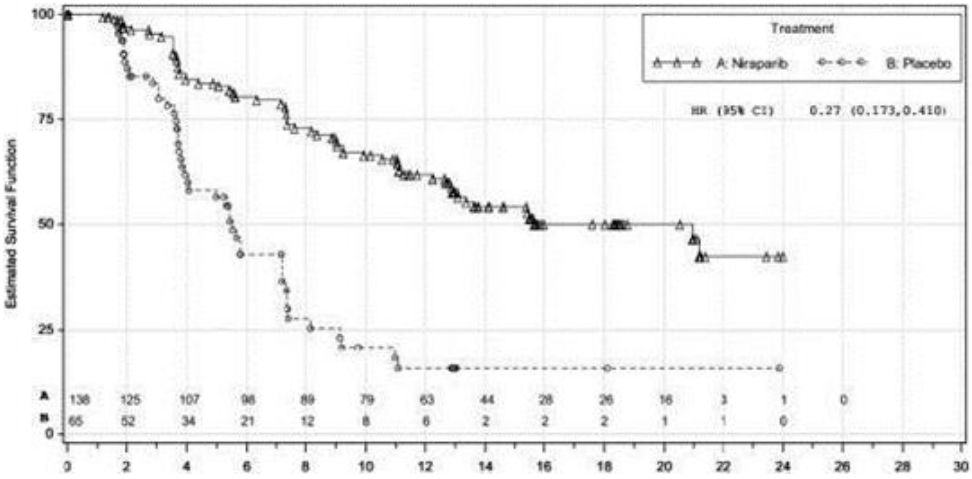
Figure 1: Progression free survival was significantly longer for patients who received ZEJULA compared to those who received placebo for all primary efficacy populations.

Treatment	Median PFS (95%CI) (Months)	Hazard Ratio (95%CI) p Value	Disease Progression Free (%) 6 Months	12 Months	18 Months
gBRCAmut Cohort					
Niraparib (N = 138)	21.0 (12.9, NE)	0.27 (0.173, 0.410)	80%	62%	50%
Placebo (N = 65)	5.5 (3.8,7.2)	p	43%	16%	16%
HRDpos Subgroup					
Niraparib (N = 106)	12.9 (8.1, 15.9)	0.38 (0.243, 0.586)	69%	51%	37%
Placebo (N = 56)	3.8 (3.5, 5.7)	p	35%	13%	9%
Non-gBRCAmut Cohort					
Niraparib (N = 234)	9.3 (7.2, 11.2)	0.45 (0.338, 0.607)	61%	41%	30%
Placebo (N = 116)	3.9 (3.7, 5.5)	p	36%	14%	12%

Source: Tesaro.

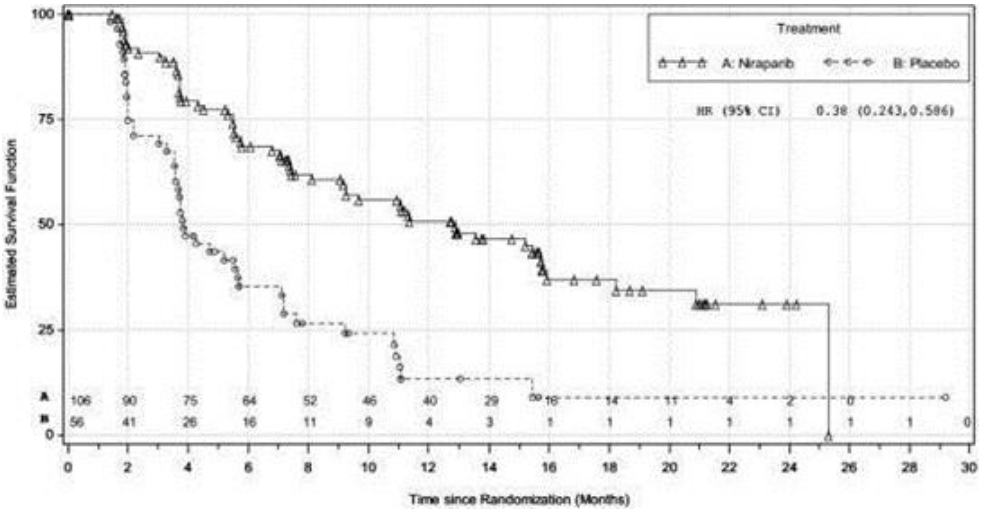
Notes: gBRCAmut = gBRCA mutation positive; non-gBRCA mut = gBRCA mutation negative

Figure 2: Progression free survival in the gBRCA mutation positive cohort of patients treated with ZEJULA versus placebo



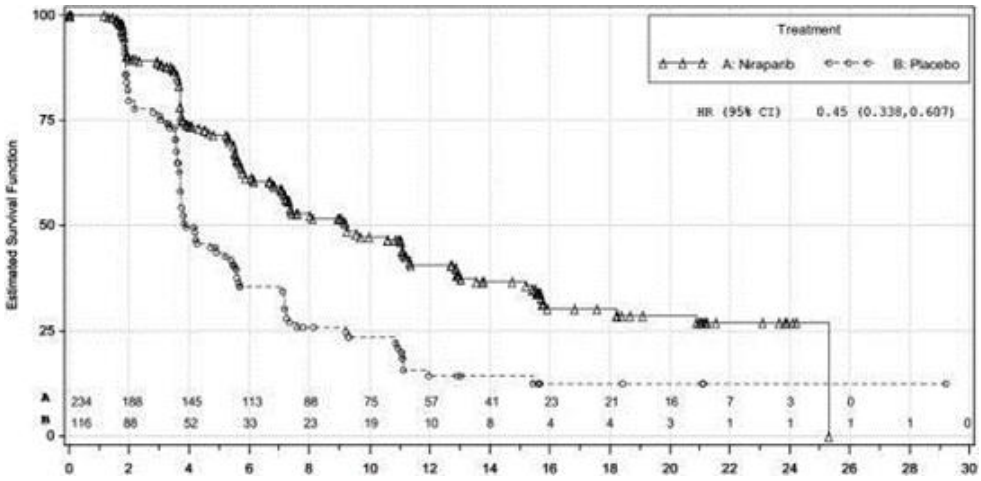
Source: Tesaro.

Figure 3: Progression free survival in the HRDpos group of the gBRCA mutation negative cohort of patients treated with ZEJULA versus placebo



Source: Tesaro.

Figure 4: Progression free survival in the overall gBRCA mutation negative cohort of patients treated with ZEJULA versus placebo



Source: Tesaro.

Within the gBRCA mutation positive cohort, the median progression free survival was 21.0 months on ZEJULA versus 5.5 months on placebo (hazard ratio=0.27; p

As it is maintenance therapy, quality of life is important to patients receiving treatment. Patient-reported outcome data from validated survey tools indicated that ZEJULA-treated patients reported no significant difference from placebo in measures associated with symptom specific and general quality of life.

Furthermore, ZEJULA treatment did not reduce the effectiveness of subsequent therapies, and continued to show carry-over of the beneficial treatment effect in the secondary efficacy measure of second objective disease progression, which is time from randomization to objective tumor progression on next-line treatment or death from any cause. OS data, while immature, showed no negative impact of ZEJULA treatment.

The incidences of CTC grade 3/4 treatment-emergent adverse events (74% vs 23%), serious adverse events (30% vs 15%), treatment-emergent adverse events leading to treatment interruption (69% vs 5%), treatment-emergent adverse events leading to dose reduction (67% vs 15%), and treatment-emergent adverse events leading to treatment discontinuation (15% vs 2%) were higher for ZEJULA versus placebo. There were no on-treatment deaths reported.

The most commonly observed hematologic treatment-emergent adverse events (all CTC grades) related to ZEJULA were thrombocytopenia (61%), anemia (50%) and neutropenia (30%). Although CTC grade 3/4 hematologic laboratory events were common at the initiation of treatment, no severe clinical sequelae were observed and relatively few patients discontinued due to these adverse events. Dose adjustment based on individual tolerability during the first cycles substantially reduced the incidence of these events beyond the third 28-day treatment cycle, indicating the overall effectiveness of the approach to dose modification. Overall the treatment-emergent adverse events were manageable, with no negative impact on quality of life.

PRIMA, a Phase III maintenance study of ZEJULA versus placebo in patients with advanced ovarian cancer following response on front-line platinum-based chemotherapy.

PRIMA is a randomized, double-blind, phase III trial evaluating niraparib versus placebo as maintenance therapy in *patients* with advanced ovarian cancer following response on front-line platinum-based chemotherapy. The study was designed to enrol subjects with Stage III or IV ovarian cancer (including fallopian and peritoneal cancers) who had previously completed front-line platinum-based therapy with a physician-assessed response of CR or PR. Randomization was stratified by use of neoadjuvant chemotherapy (yes or no), best response to platinum therapy (CR or PR), and homologous recombination deficiency (HRD) status (positive or negative/not determined). The primary end point was progression-free survival (PFS) in patients who had tumors with HRD+ve and in those in the overall population, as determined on hierarchical testing.

From July 2016 through June 2018 and across 220 sites worldwide, a total of 733 patients were randomized at 2:1 to receive niraparib or placebo as maintenance therapy, of whom 373 (50.9%) had tumors with HRD. Among the patients in this category, the median PFS was significantly longer in the niraparib group than in the placebo group (21.9 months vs. 10.4 months; hazard ratio for disease progression or death, 0.43; 95% confidence interval [CI], 0.31 to 0.59; P

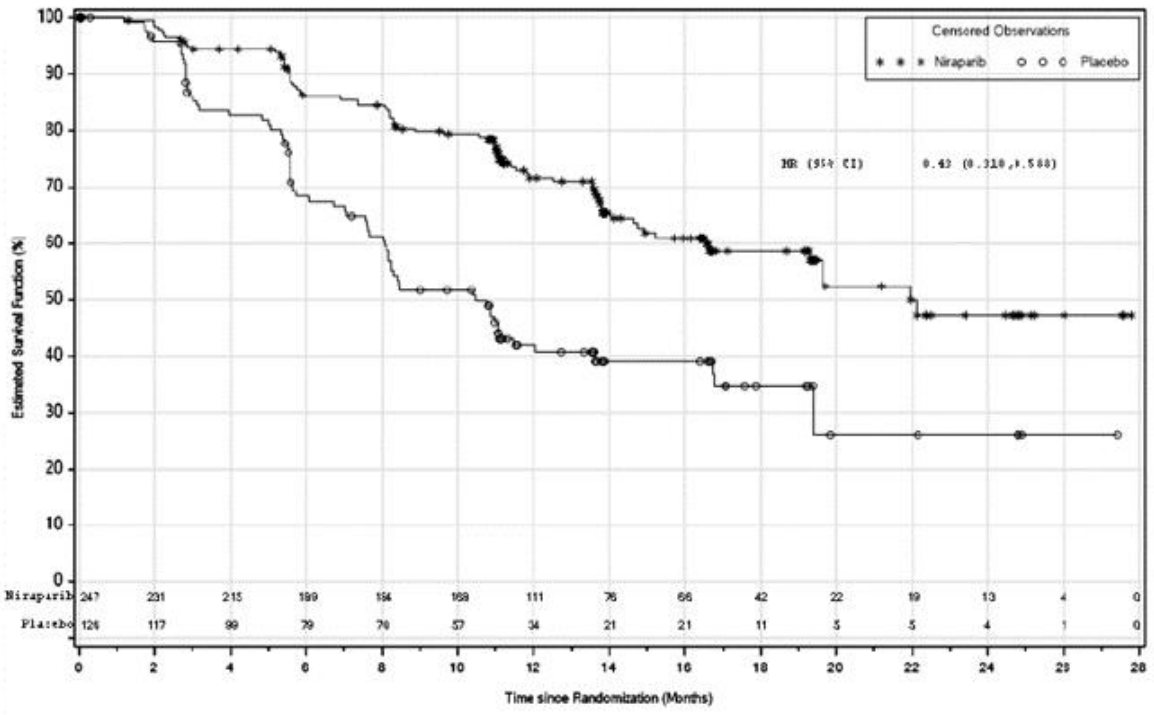
The safety profile observed in the PRIMA study was consistent with the known safety profile of niraparib seen in previous clinical studies and other PARP inhibitors, including gastrointestinal and hematological events. In the safety population, for the niraparib versus placebo treatment arms, the incidences of CTCAE Grade ≥3 TEAEs (70.5% versus 18.9%), SAEs (32.2% versus 13.1%), TEAEs leading to treatment interruption (79.5% versus 18.0%), TEAEs leading to dose reduction (70.9% versus 8.2%), and of TEAEs leading to treatment discontinuation (12.0% versus 2.5%) were higher for those receiving niraparib vs placebo. There were no on-treatment deaths reported during the study. The incidence of the most commonly reported events (overall and Grade ≥3) was higher for subjects who received a fixed starting dose of niraparib (300mg) compared with those who received an individualized starting dose based on baseline body weight and platelet count (300mg or 200mg).

Table 1: Primary efficacy endpoint of PFS based on blinded independent central review (BICR) (ITT Population)

Parameters	HRDpos		Overall	
	Niraparib (N = 247)	placebo (N = 126)	Niraparib (N = 487)	Placebo (N = 246)
PFS (months)				
median (95% CI)	21.9 (19.3, NE)	10.4 (8.1,12.1)	13.8 (11.5,14.9)	8.2 (7.3,8.5)
Survival distribution function (95% CI)				
6-month	0.86 (0.81,0.90)	0.68 (0.59,0.76)	0.73 (0.69,0.77)	0.60 (0.53,0.66)
12-month	0.72 (0.65,0.77)	0.42 (0.33,0.51)	0.53 (0.48,0.58)	0.35 (0.29,0.42)
18-month	0.59 (0.50,0.66)	0.35 (0.25,0.45)	0.42 (0.36,0.47)	0.28 (0.21,0.35)
24-month	0.47 (0.36,0.58)	0.26 (0.14,0.39)	0.32 (0.25,0.39)	0.23 (0.14,0.32)
30-month	0.47 (0.36,0.58)	0.26 (0.14,0.39)	0.32 (0.25,0.39)	0.23 (0.14,0.32)
P value	0.0001		0.0001	
HR (95% CI)	0.43 (0.310,0.588)		0.62 (0.502,0.755)	

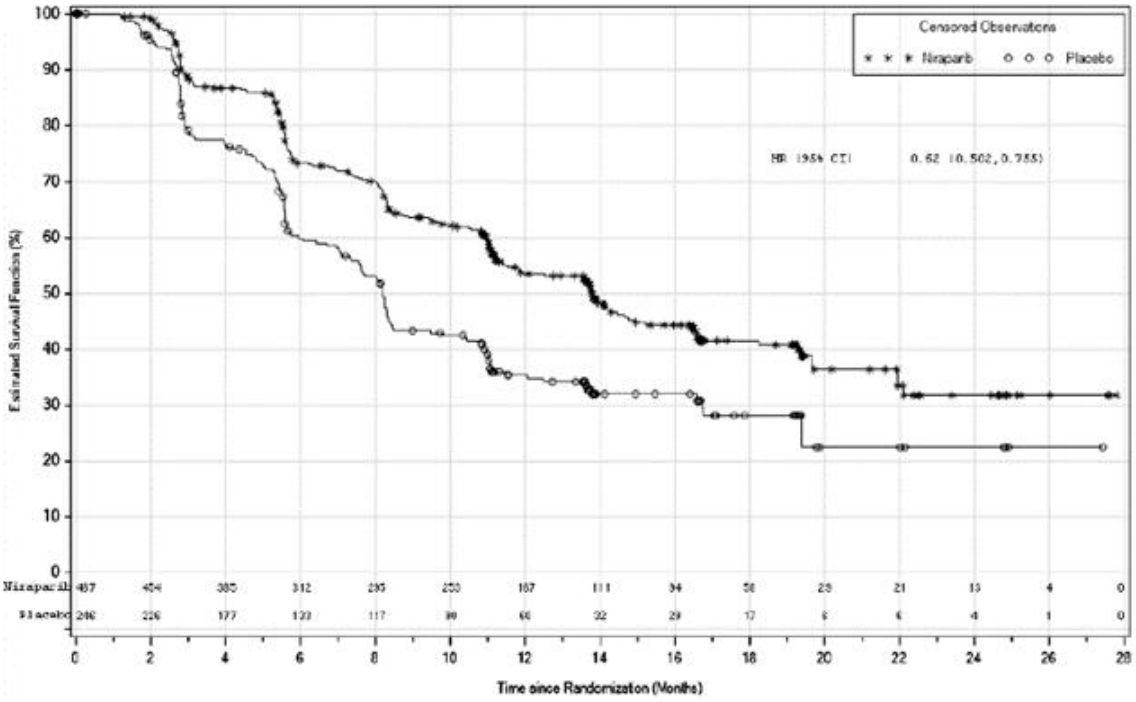
Source: GSK.

Figure 5: Kaplan-Meier plot of PFS by BICR assessment in subjects with HRD tumors (ITT Population)



Source: GSK.

Figure 6: *Kaplan-Meier plot of PFS by BICR assessment in overall population (ITT Population)*



Source: GSK.

Based on PRIMA results, sNDA application for niraparib for first-line maintenance treatment for women with platinum-responsive advanced ovarian cancer has been submitted to FDA.

ZEJULA Pre-clinical Development

As discussed below, Merck, Sharp & Dohme Corp. (a subsidiary of Merck & Co. Inc.), or Merck Corp., and our partner Tesaro (now GSK) have completed various pre-clinical trials to evaluate the pharmacodynamics, pharmacokinetics and toxicology profile of ZEJULA.

Pharmacodynamics . In pre-clinical trials studying ZEJULA's pharmacodynamics, ZEJULA was found to be a potent and selective PARP-1 and PARP-2 inhibitor that displayed at least a 100-fold selectivity over other PARP-family members PARP-3, v-PARP, and Tankyrase-1. A commonly used quantitative measure of potency is IC_{90} , which represents the concentration of a drug that is required to suppress 90% of the target enzyme. The IC_{90} of ZEJULA for PARylation in BRCA-deficient tumor cells correlates with functional suppression of single strand breakage repair and anti-tumor effects on BRCA mutation positive tumor cells.

Normal primary cells were resistant to ZEJULA with the most sensitive cells (megakaryocytes) exhibiting a 13-fold selectivity margin as compared to BRCA mutation positive tumor cells *in vitro* . Maximal *in-vivo* efficacy was achieved in BRCA 1 mutation positive ovarian tumor models with once-daily oral administration of ZEJULA at a dose sufficient to suppress 90% of the PARP enzymatic activity in the tumor at eight hours after the dose, which translated to greater than 50% inhibition of PARP activity in peripheral blood mononuclear cells at eight hours post dose.

The therapeutic potential of ZEJULA was evaluated in a study designed to examine the benefit of ZEJULA in maintenance setting, *i.e.,* daily ZEJULA treatment following a regression induced with a platinum-based regimen. In this study, tumors in mice receiving maintenance ZEJULA therapy became undetectable whereas regrowth was observed in those receiving only the chemotherapy regimen. These data support the concept that maintenance ZEJULA therapy after tumor response to chemotherapeutic agents may prolong recurrence-free survival.

ZEJULA showed no significant observable effects in nonclinical safety pharmacology studies at clinically relevant doses across the species evaluated.

Pharmacokinetics. ZEJULA elicited desirable and consistent pharmacokinetic profiles in nonclinical species *in vivo.* The oral absorption in rats and dogs was rapid, with moderate to high bioavailability. The compound is readily distributed to the brains of rats and monkeys to a modest extent, suggesting additional therapeutic potential.

Elimination of ZEJULA and its metabolites was fecal and renal in rats, while mainly renal in dogs. The potential risk for drug—drug interactions was determined to be minimal for ZEJULA, due to the lack of the interactions between ZEJULA and the hepatic drug-metabolizing CYP enzymes, the major hepatic and renal uptake transporters (OATP1B1, OATP1B3, OAT1, OAT3, and OCT2), and BSEP, an efflux transporter known to be associated with hepatotoxicity. The *in vitro* metabolic results, combined with the *in vivo* pharmacokinetic findings, demonstrated that ZEJULA had a desirable disposition profile with a minimal potential for drug—drug interactions, consistent with the development of ZEJULA as an anticancer agent.

Toxicology . A comprehensive pre-clinical toxicology program was conducted to support the administration of ZEJULA in patients with cancer. This program included oral repeat-dose toxicity studies (up to three-months duration) in dogs and rats, genotoxicity and phototoxicity studies. The results obtained from the general toxicity studies in rats and dogs indicated that ZEJULA causes bone marrow suppression which leads to decreases in circulating white and red blood cells. Infections and septicemia were a consequence of bone marrow suppression and lymphoid depletion. These findings are linked to pharmacology of ZEJULA and showed reversibility.

ZEJULA—Pharmacokinetics

The pharmacokinetic profile of ZEJULA has been evaluated in multiple clinical studies, with an overall ZEJULA-dosed population of 526 patients.

Absorption . ZEJULA exhibited linear pharmacokinetic, dose proportional exposure, and dose-independent absorption and clearance. Following repeat administrations of the daily recommended dose of 300 mg, ZEJULA accumulation on day 21 was consistent for both the area under the plasma concentration-time curve and maximum concentration (approximately two- to three-fold). ZEJULA was shown to be highly orally bioavailable (F ~73%). Bioavailability is a measure of the absorption of drug and is expressed as a percentage of the administrated case of the drug which reaches the patient's system. ZEJULA can be administered with or without food.

Distribution . ZEJULA was moderately protein bound to human plasma (83.0%). The apparent volume of distribution was 1220 L, indicating an extensive tissue distribution of ZEJULA.

Metabolism . The carboxylesterases-catalyzed amide hydrolysis was delineated to be the major primary pathway, followed by the uridine-5'-diphospho-glucuronosyltransferases (UGT)-mediated glucuronidation and the other minor secondary pathway (*i.e* ., methylation). The major circulating metabolites in humans are the carboxylic acid and the glucuronides of carboxylic acid. The metabolic profile seen in humans is consistent with what was detected in the experimental species (rats and dogs).

Elimination . In an absorption, metabolism and elimination study in cancer patients using 14C-radioactive ZEJULA, a mean measured total of 86.2% of the radioactive dose was recovered in urine and fecal samples collected daily from 0 to 504 hours (21 days) post dose after single oral administration of 14C-ZEJULA. It suggests minimal long-term retention of ZEJULA or its metabolites in body. Moreover, hepatobiliary clearance and renal excretion are the major routes of elimination in humans.

Intrinsic Effects . Population pharmacokinetic analysis identified no intrinsic factors such as age, race, hepatic impairment, renal impairment would have significant impact on the pharmacokinetic of ZEJULA.

Optune and Tumor Treating Fields

Overview of Tumor Treating Fields

Tumor Treating Fields were invented in 2000 by Professor Emeritus Yoram Palti of the Technion Institute of Technology in Israel, who founded Novocure (Israel) in 2000, conducted pre-clinical studies of Tumor Treating Fields, developed a medical device capable of delivering Tumor Treating Fields to patients, and finally brought Tumor Treating

Fields into clinical use through clinical testing in patients with recurrent glioblastoma. Today, after more than 15 years of pre-clinical research, it is known that Tumor Treating Fields are an electric field based loco-regional, antimitotic treatment modality, which inhibits the growth of cancerous tumors *in vitro* and *in vivo* . As intermediate frequency (200 kHz) and low intensity (1-3 V/cm) alternating electric fields, Tumor Treating Fields act predominantly during two phases of mitosis: 1) during metaphase, by disrupting the formation of the mitotic spindle, and 2) during cytokinesis, by dielectrophoretic dislocation of intracellular constituents resulting in apoptosis. Tumor Treating Fields cannot stimulate nerves or muscles, nor do they lead to heating of the tumor or surrounding tissues. Since Tumor Treating Fields are generated using electrically insulated electrodes (transducer arrays), there is no direct current flow into the tissue so that electrolysis and tissue damage do not occur over time. Since most normal adult brain cells proliferate very slowly, if at all, they are not affected by the Tumor Treating Fields.

The efficacy of Tumor Treating Fields is frequency dependent on specific cell types. The anti-mitotic effect of Tumor Treating Fields has been shown in multiple cell lines when the appropriate frequency was utilized. This includes but not limited to the following tumor models: glioblastoma at 200 kHz, NSCLC at 150kHz; breast carcinoma at 120kHz; melanoma at 100kHz.

Four Phase III trials of Tumor Treating Fields in a variety of solid tumors are ongoing. PANOVA-3 is Tumor Treating Fields combined with chemotherapy for newly-diagnosed pancreatic cancer. LUNAR is targeting advanced NSCLC with disease progression on or after prior platinum-based treatment, to evaluate Tumor Treating Fields combined with chemotherapy versus chemotherapy alone, METIS trial is intended for patients who have recently been diagnosed with brain metastases from NSCLC, and ENGOT-ov50/INNOVATE-3 trial is intended for patients who have recently been diagnosed with ovarian cancer that progressed and became resistant to chemotherapy containing platinum (platinum resistant ovarian cancer).

A Phase II, single arm, multi-center, open-label trial (EF-31, ZL-8301-001) to evaluate the safety and efficacy of treatment with Tumor Treating Fields and chemotherapy as first-line treatment for subjects with unresectable gastroesophageal junction (GEJ) adenocarcinoma or gastric (GC) adenocarcinoma is ongoing. This study is conducted in Hong Kong and mainland China and the first patient was dosed in January 2020. The First-Patient-In (FPI) occurred in January 2020 in Hong Kong. The initiation of enrollment in China is expected in the second half of 2020.

Optune Device Description

Optune is a portable battery or power supply operated device which act by delivering low intensity (1-3 V/cm), intermediate frequency (100-300 kHz), alternating Tumor Treating Fields to the patient's shaved head by means of electrically insulated surface transducer arrays. It has been FDA approved for the treatment of recurrent GBM and has received CE mark for the treatment of both recurrent and newly diagnosed GBM. The device has been available commercially in the European Union and in the United States since October 2011. Optune was approved in Japan for the treatment of recurrent GBM in March 2015. The indication of Optune in the United States was expanded to include treatment of adult patients with newly diagnosed GBM in combination with TMZ in October 2015. Additionally, we commercially launched Optune in Hong Kong for the treatment of GBM in December 2018.

Indications for Optune Use

GBM, a malignant form of astrocytoma, is the most common primary intracranial neoplasm. The incidence of GBM increases steadily above 45 years of age with a prevalence of approximately 7,500 cases in the United States Despite numerous attempts to improve the outcome of patients with GBM, the 3-year survival of these patients is only 6% with median survival of 14.6 months.

- Optune is indicated for the treatment of adult patients (22 years of age or older) with histologically-confirmed recurrence in the supra-tentorial region of GBM. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.
- Optune with TMZ is indicated for the treatment of adult patients with newly diagnosed, supratentorial GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

Pivotal Study of Tumor Treating Fields for Recurrent GBM Subjects

In a prospective, randomized, open label, active parallel control trial (EF-11) was conducted to compare the effectiveness and safety. A total of 237 patients (120 Optune; 117 best supportive care, BSC) with progressive or recurrent GBM were enrolled in the study. Baseline characteristics were similar between treatment groups. In the ITT population which included all randomized subjects, overall survival in subjects treated with Optune was comparable to that observed in subjects treated with BSC (median OS=6.3 vs. 6.4 months; p =0.98). The pivotal study data establish that Optune therapy is comparable to BSC therapy in extending OS.

The one-year survival is similar in the Optune and BSC groups in the ITT population (21.9% vs. 22.1%). Progression free survival at 6 months (PFS6) is the same in the ITT population (21.4% vs. 15.2%). Radiological response rates from the subset of patients evaluated were reported as 14% for the Optune group compared to 9.6% for the BSC group in the ITT population. Median time to progression, or TTP, was 9.3 weeks for Optune vs. 9.6 weeks for BSC.

Optune subjects experienced fewer adverse events in general, significantly fewer treatment related adverse events, and significantly lower gastrointestinal, hematological and infectious adverse events compared to BSC controls. The only device-related adverse event seen was a mild to moderate skin irritation beneath the device transducer arrays, which was easily treated with topical ointments. Finally, certain quality of life measures were better in Optune subjects as a group when compared to subjects receiving effective BSC chemotherapy.

Pivotal Study of Optune for Newly Diagnosed GBM

An international Phase III trial (EF-14) in newly diagnosed GBM, evaluating the role of Optune in combination with TMZ maintenance after surgery and chemoradiation versus TMZ alone was conducted between July 2009 and September 2014 to evaluate efficacy and safety.

A total of 695 patients were randomized, the median number of maintenance TMZ cycles was 6 and 5 cycles, for Optune /TMZ and TMZ alone, respectively. The median progression-free survival was 6.7 months for the patients treated with Optune /TMZ versus 4.0 months for TMZ alone (HR 0.63;95% CI 0.52-0.76; p

Based on the data, FDA expanded approval of Optune in combination with TMZ for the treatment of adult patients with newly diagnosed GBM.

Our Strategy for Tumor Treating Fields in the China Market

Given the strong clinical data from randomized control trials of Optune and its approval status in the European Union and United States in recurrent and newly diagnosed GBM, Zai Lab plans to leverage the global study data to seek potential regulatory approval in China. Zai Lab intends to participate in the ongoing global studies of Tumor Treating Fields, and will also conduct trials of Tumor Treating Fields in Chinese patients with gastric cancer.

Ripretinib

Ripretinib is an investigational KIT and PDGFRα kinase switch control inhibitor in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including GIST, systemic mastocytosis, or SM, and other cancers. Ripretinib was specifically designed to improve the treatment of GIST patients by inhibiting a broad spectrum of mutations in KIT and PDGFRα. Ripretinib is a KIT and PDGFRα inhibitor that blocks initiating and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST as well as the primary D816V exon 17 mutation involved in SM. Ripretinib also inhibits primary PDGFRα mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

We obtained an exclusive license to develop and commercialize ripretinib in China, Hong Kong, Macau and Taiwan in 2019.

In December 2019, an NDA was submitted to the FDA for ripretinib in the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib. The NDA submission is based on positive results from our first Phase III study, INVICTUS, in fourth-line and fourth-line plus GIST patients, for whom there are currently no approved therapies other than avapritinib in the U.S. which is approved for GIST patients with PDGFRα exon 18 mutations only (estimated approximately 6% of all patients with newly-diagnosed GIST). In August 2019, the top-line results from INVICTUS was published, including that the study achieved its primary endpoint of improved PFS compared to placebo as determined by blinded independent central radiologic review using modified RECIST. In February 2020, the FDA accepted the NDA for ripretinib for the treatment of patients with fourth-line and fourth-line plus GIST, granted priority review and set an action date of August 13, 2020 under the PDUFA.

Our Clinical Trial Designs and Strategy for ripretinib in the China Market

Zai Lab will seek regulatory approval for ripretinib in China using data from global studies and China bridging studies. In February 2020, Zai Lab received the NMPA approval to conduct the bridging study in ≥4L GIST. In additional, Zai Lab also plans to conduct a 2L bridging study in the GIST patients in China.

Ripretinib Mechanism of Action

KIT and PDGFRα are dual switch kinases, each containing i) an auxiliary inhibitory switch encoded by KIT exon 11 or PDGFRα exon 12 and ii) a main activation loop switch within the kinase domain encoded by KIT exons 17 and 18 or PDGFRα exons 18 and 19. This dual switch mechanism carefully regulates cellular kinase activity by controlling kinase conformation in either an "on" or "off" position. Oncogenic kinase mutations predominantly function by disrupting one or more regulatory switch mechanisms, leading to dysregulated switch function and loss of normal, physiologic conformational control. Ripretinib is a novel switch-control tyrosine kinase inhibitor (TKI) specifically designed to broadly inhibit KIT and PDGFRα kinase signaling through a dual mechanism of action that locks the kinase into an inactive conformation, resulting in inhibition of downstream signaling and cell proliferation.

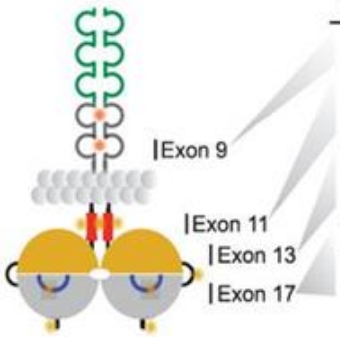
Ripretinib precisely and durably binds to both the switch pocket region and the activation loop to lock the kinase in the inactive "off" state. Portions of ripretinib mimic the inhibitory loop and occupy the switch pocket, thereby preventing the activation loop's entry. Other residues on ripretinib bind to the activation loop, stabilizing it out of the switch pocket and covering the adenosine triphosphate (ATP) binding site, so kinase activation cannot occur.

This dual mechanism of action secures KIT and PDGFRα kinases in their inactive conformations providing broad in vitro inhibition of KIT and PDGFRα kinase activity, including wild type and multiple primary and secondary mutations. Ripretinib also inhibits other kinases in vitro, such as PDGFRβ, TIE2, VEGFR2, and BRAF.

Gastrointestinal Stromal Tumors *(GIST)*

GISTs are the most common sarcoma of the gastrointestinal tract and present most often in the stomach or small intestine. The typical patient is over 50 years old. According to the American Cancer Society, in 2019 approximately 4,000 to 6,000 patients were newly diagnosed with GIST in the U.S. Estimates for 5-year survival range from 48% to 90% depending upon the stage of the disease at diagnosis.

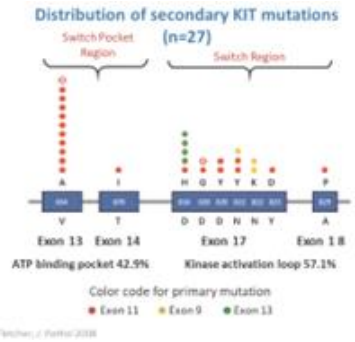
GIST is a disease driven initially by primary mutations in KIT kinase in approximately 75% to 80% of cases or in PDGFRα kinase in approximately 5% to 10% of cases. In approximately 13% of all GIST patients, the disease is not driven by KIT or PDGFRα but by other genetic mutations or alterations. Primary mutations in the KIT gene are found in exon 11 in approximately 67% of GIST patients, in exon 9 in approximately 10% of GIST patients, and less frequently in exon 13 or 17. Primary mutations in the PDGFRα gene are found in exon 18 (a mutation referred to as D842V being the most frequent) in approximately 6% of GIST patients and more rarely in exon 12. Activation of these kinases caused by primary mutations leads to uncontrolled cancer cell growth and spread. The diagram below illustrates the mutations that drive GIST:

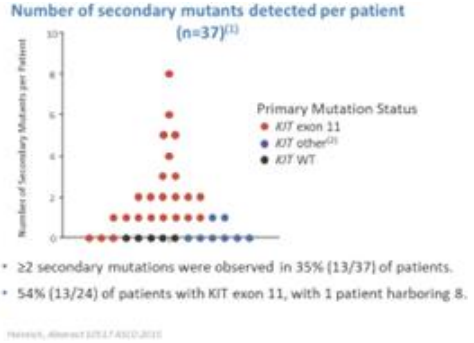


Domain	Gene	1° Mutation Frequency	2° Mutation Frequency
D5	*KIT*	10%	
JM	*KIT*	67	
	PDGFRA	1	
TK1	*KIT*	1	56
	PDGFRA	1	
A-Loop	*KIT*	1	41
	PDGFRA D842V	5	
	PDGFRA	1	3

Source: Hemming M et al. Translational insights into gastrointestinal stromal tumors and current clinical advances. Annals of Oncology; 29: 2037-2045, 2018.

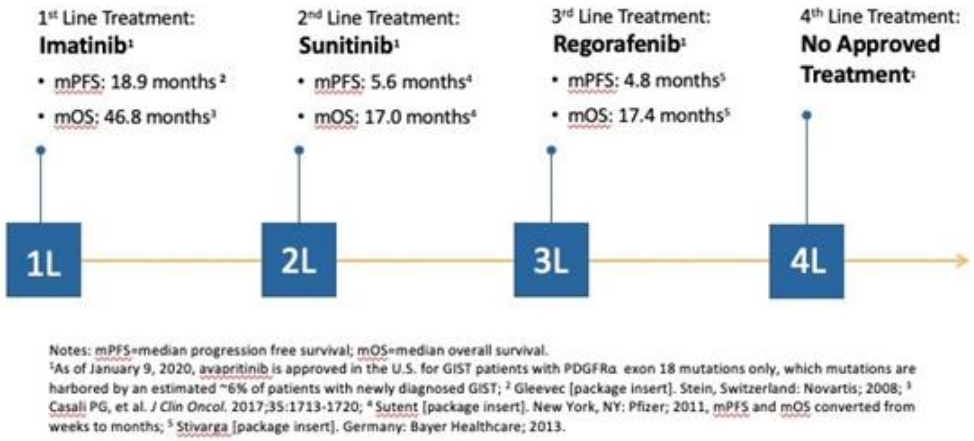
Metastatic KIT-driven GIST is a disease characterized by many mutations in KIT, with over 90% of individual KIT-driven GIST patients harboring multiple mutations that drive progression of their disease. Multiple secondary mutations can arise within an individual patient and/or tumor in different areas or sites of tumor growth. Drug resistant secondary mutations in patients with KIT-driven GIST span exon regions 13 to 18, and in a recent study, 35% of GIST patients had at least two secondary mutations, each as illustrated below.





The complex heterogeneity of KIT mutations within individual tumors and individual patients is a major cause of resistance to existing therapies, which individually only address a subset of the mutations driving disease progression. A kinase inhibitor that could inhibit a broad spectrum of clinically relevant KIT mutations could be of high therapeutic value in the treatment of KIT-driven GIST in patients who are unresponsive to treatment or have grown resistant to treatment. In PDGFRα-driven GIST, there are no approved therapies other than avapritinib. The primary PDGFRα mutations are mostly insensitive to imatinib and other drugs approved for GIST. The design of ripretinib as a PDGFRα switch control inhibitor may make the appearance of secondary mutations less likely after treatment than with a traditional kinase inhibitor.

The following table shows reported PFS or TTP (as applicable), ORR, overall survival, all as per RECIST, for imatinib, sunitinib, and regorafenib in first-line, second-line, and third-line GIST, respectively, based upon the published results of registrational trials that were presented to the FDA for approval of these drugs.



Notes: mPFS=median progression free survival; mOS=median overall survival.
[1]As of January 9, 2020, avapritinib is approved in the U.S. for GIST patients with PDGFRα exon 18 mutations only, which mutations are harbored by an estimated ~6% of patients with newly diagnosed GIST; [2] Gleevec [package insert]. Stein, Switzerland: Novartis; 2008; [3] Casali PG, et al. *J Clin Oncol*. 2017;35:1713-1720; [4] Sutent [package insert]. New York, NY: Pfizer; 2011, mPFS and mOS converted from weeks to months; [5] Stivarga [package insert]. Germany: Bayer Healthcare; 2013.

While imatinib, sunitinib, and regorafenib inhibit certain clinically relevant initiating and drug resistance-causing mutations in KIT, these approved drugs, in addition to avapritinib, each inhibit only a limited subset of KIT and PDGFRα mutations known to occur in GIST patients. Although GIST patients may experience periods of disease control with these treatments, due to the heterogeneous nature of the mutations that drive the disease, many patients continue to progress and ultimately fail all lines of treatment.

Clinical development of Ripretinib in GIST

INVICTUS: Completed Phase III Study in Fourth-Line and Fourth-Line Plus GIST

The INVICTUS Phase III study was a randomized, double-blind, placebo-controlled, global, multicenter trial to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. The trial enrolled 129 patients who had a confirmed diagnosis of GIST and had previously received at least three different kinase inhibitors including imatinib, sunitinib, and regorafenib. Patients were treated with ripretinib or placebo, in accordance with their randomization, until they developed disease progression, experienced unacceptable toxicity, or withdrew consent. Placebo patients had the opportunity to cross over to ripretinib treatment upon disease progression with placebo. Patients on ripretinib had the opportunity to remain on their current dose or escalate to 150 mg twice daily (BID) upon disease progression.

Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily (QD) in repeated 28-day cycles with best supportive care. Patients were evaluated for PFS based upon independent radiologic review of CT scans, as assessed by modified RECIST. Tumor response assessments per modified RECIST were conducted every cycle for the first three cycles and then every two cycles thereafter beginning with the fourth cycle. The primary efficacy endpoint was PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST included ORR, overall survival (OS), and TTP.

In 2019, the top-line results from INVICTUS is published, including that the study achieved its primary endpoint of improved PFS compared to placebo.

In the INVICTUS study, ripretinib demonstrated a median PFS of 6.3 months (27.6 weeks) compared to 1.0 month (4.1 weeks) in the placebo arm and significantly reduced the risk of disease progression or death by 85% (Hazard Ratio (HR) of 0.15, 95% Confidence Interval (0.09,0.25), p-value The following graph shows the estimated PFS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated PFS Probability for Ripretinib and Placebo Arms

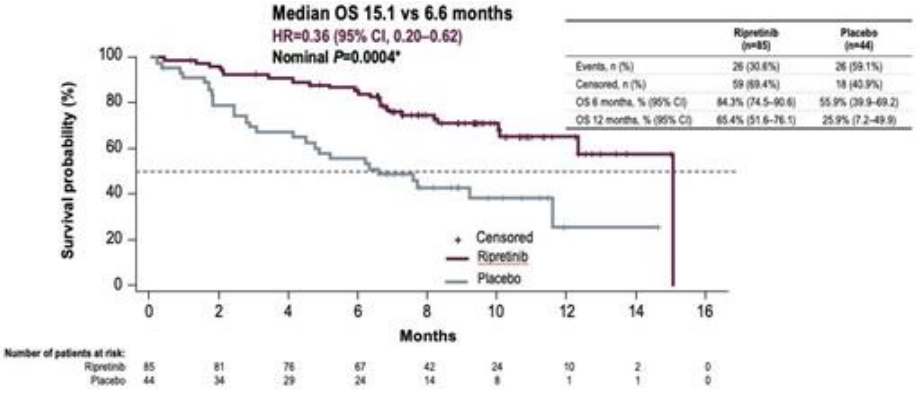
	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	51 (60.0%)	37 (84.1%)
Censored, n (%)	34 (40.0%)	7 (15.9%)
PFS 6 months, % (95% CI)	51.0% (39.4–61.4)	3.2% (0.2–13.8)

*Double-blind period

For the key secondary endpoint of ORR as determined by blinded independent radiologic review using modified RECIST, ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p-value=0.0504), which was not statistically significant. As of the cutoff date of May 31, 2019, the median duration of response had not been reached with seven of the eight patients still responding to treatment. All responders had partial responses.

Ripretinib also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint of OS (median OS 15.1 months with ripretinib compared to 6.6 months with placebo, HR = 0.36, 95% Confidence Interval (0.20,0.62), nominal p-value=0.0004). The OS data for the placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment. The following graph shows the estimated OS probability at each time point for the ripretinib and placebo arms in INVICTUS:

INVICTUS: Estimated OS Probability for Ripretinib and Placebo Arms



	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	26 (30.6%)	26 (59.1%)
Censored, n (%)	59 (69.4%)	18 (40.9%)
OS 6 months, % (95% CI)	84.3% (74.5–90.6)	55.9% (39.9–69.2)
OS 12 months, % (95% CI)	65.4% (51.6–76.1)	25.9% (7.2–49.9)

*Due to hierarchal testing procedures of the endpoints, the OS endpoint could not be formally tested because the ORR was not statistically significant.

Data includes all time periods, including dose escalations. Placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment.

Ripretinib was generally well tolerated and the adverse events reported in the INVICTUS study were consistent with data from previously presented Phase I study results. Grade 3 or 4 treatment-emergent adverse events (TEAEs) occurred in 42 patients (49%) on the ripretinib arm compared to 19 patients (44%) on the placebo arm. Grade 3 or 4 TEAEs in greater than 5% of patients in the ripretinib arm were anemia (9%; n=8), abdominal pain (7%; n=6), and hypertension (7%; n=6). Grade 3 or 4 TEAEs in greater than 5% of patients in the placebo arm were anemia (14%; n=6).

The below table lists all TEAEs (and corresponding grade 3 and 4 TEAEs) in greater than 10% of patients in the ripretinib arm compared to the placebo arm in INVICTUS.

INVICTUS: TEAEs in >10% of Patients

(and Corresponding Grade 3 and 4 TEAEs)

Treatment Emergent Adverse Event	Ripretinib any grade (n=85)	Ripretinib grade 3 and 4 (n=85)) [1]	Placebo any grade (n=43)) [2]	Placebo grade 3 and 4 (n=43)) [1,2]
Any TEAE or grade 3/4 TEAE [3]	**84 (98.8%)**	**42 (49.4%)**	**42 (97.7%)**	**19 (44.2%)**
Alopecia	44 (51.8%)	0	2 (4.7%)	0
Fatigue	36 (42.4%)	3 (3.5%)	10 (23.3%)	1 (2.3%)
Nausea	33 (38.8%)	3 (3.5%)	5 (11.6%)	0
Abdominal pain	31 (36.5%)	6 (7.1%)	13 (30.2%)	2 (4.7%)
Constipation	29 (34.1%)	1 (1.2%)	8 (18.6%)	0
Myalgia	27 (31.8%)	1 (1.2%)	5 (11.6%)	0
Diarrhea	24 (28.2%)	1 (1.2%)	6 (14%)	1 (2.3%)
Decreased appetite	23 (27.1%)	1 (1.2%)	9 (20.9%)	1 (2.3%)
Palmar-plantar erythrodysesthesia syndrome	18 (21.2%)	0	0	0
Vomiting	18 (21.2%)	3 (3.5%)	3 (7%)	0
Headache	16 (18.8%)	0	2 (4.7%)	0
Weight decreased	16 (18.8%)	0	5 (11.6%)	0
Arthralgia	15 (17.6%)	0	2 (4.7%)	0
Blood bilirubin increased	14 (16.5%)	1 (1.2%)	0	0
Edema peripheral	14 (16.5%)	1 (1.2%)	3 (7%)	0
Muscle spasms	13 (15.3%)	0	2 (4.7%)	0
Anemia	12 (14.1%)	8 (9.4%)	8 (18.6%)	6 (14%)
Hypertension	12 (14.1%)	6 (7.1%)	2 (4.7%)	0
Asthenia	11 (12.9%)	1 (1.2%)	6 (14%)	2 (4.7%)
Dry skin	11 (12.9%)	0	3 (7%)	0
Dyspnea	11 (12.9%)	0	0	0
Hypophosphatemia	9 (10.6%)	4 (4.7%)	0	0
Lipase increased	9 (10.6%)	4 (4.7%)	0	0
Pruritus	9 (10.6%)	0	2 (4.7%)	0
Stomatitis	9 (10.6%)	0	0	0

[1] Corresponding grade 3 and 4 TEAEs to TEAEs in >10% of patients receiving ripretinib
[2] 44 patients were randomized to placebo, but 1 did not receive treatment
[3] Regardless of causality

TEAEs leading to dose reduction occurred in 7% of patients on the ripretinib arm compared to 2% on the placebo arm. TEAEs leading to dose interruption occurred in 24% of patients on the ripretinib arm compared to 21% on the placebo arm. TEAEs leading to study treatment discontinuation occurred in 8% of patients on the ripretinib arm compared to 12% of patients on the placebo arm. TEAEs leading to death occurred in 6% of patients on the ripretinib arm compared to 23% on the placebo arm.

INTRIGUE: Ongoing Phase III Study in Second-Line GIST

The INTRIGUE Phase III study is an interventional, randomized, global, multicenter, open-label study to evaluate the safety, tolerability, and efficacy of ripretinib compared to sunitinib in approximately 358 patients with GIST previously treated with imatinib. Patients are randomized 1:1 to either 150 mg of ripretinib once daily or 50 mg of sunitinib once daily for four weeks followed by two weeks without sunitinib. The primary efficacy endpoint is PFS as determined by independent radiologic review using modified RECIST. Secondary endpoints as determined by independent radiologic review using modified RECIST include ORR and OS.

REGN1979

Overview

Non-Hodgkin lymphomas (NHL) is the most common hematologic malignancy in the world. It comprises a heterogeneous group of malignancies with lymphoid characteristics that arise from hematopoietic progenitor cells. NHL ranks the seventh most common malignancy and accounts for approximately 4.5% of all cancers occurring in the US. There were approximately 74,200 new cases and 19,970 deaths due to NHL in 2019 in the US. In China, an estimated 88,090 new cases and 48,129 deaths were due to NHL in 2018.

Among the heterogeneous group of NHLs, 85-90% are of B-cell origin (B-NHL) and include follicular lymphoma (FL), diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), and several other B-NHLs. DLBCL and FL are the two most common subtypes of B-NHL, accounting for approximately 45.8% and 8.1%-23.5% of NHL in China. Anti-CD20 antibodies in combination with chemotherapy are the standard of care for the treatment of B-NHLs; however, despite initial responses, many patients relapse, often with progressively shorter response durations in subsequent lines of therapy and have a poor outcome.

REGN1979 is a fully human bispecific antibody that binds to CD3, a T cell antigen associated with the T-cell receptor (TCR) complex, and CD20. REGN1979 is designed to bridge CD20-expressing cells with cytotoxic T cells by binding to the CD3 subunit of the TCR, resulting in CD20-directed polyclonal T cell killing. REGN1979 was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of FL and DLBCL and was invented by Regeneron using the company's proprietary *VelocImmune* ® technology and proprietary *Veloci-Bi* ® bispecific platform. *Veloci-Bi* ® allows for the generation of full-length bispecific antibodies similar to native antibodies that are amenable to production by standard antibody manufacturing techniques, and likely to have favorable antibody-like pharmaco-kinetic properties.

REGN1979 has demonstrated clinical activity in heavily pre-treated patients with Relapsed/Refractory (R/R) B-NHL in a Phase I trial and is currently being investigated in a potentially registrational Phase II program.

Our Clinical Trial Designs and Strategy for REGN1979 in the China Market

Zai Lab is exploring regulatory approval pathways for REGN1979 in R/R B-NHL in China by joining the global Phase II program with multiple, potentially registrational cohorts of different subtypes of R/R B-NHL.

Mechanism of Action

Bispecific antibodies are an emerging class of therapeutic molecules which have been engineered to engage more than one target. When targeted to CD3, a component of the T cell receptor (TCR), and a tumor target antigen, these molecules can direct cytotoxic effector T cells to kill tumor cells in an antigen-specific manner that is independent of the specificity of the TCR. In the case of REGN1979, that binds to CD3 and CD20 (a B cell surface antigen present on normal B cells and several B cell lineage malignancies), this binding directs T-cells to specifically kill CD20 expressing target cells.

Pre-clinical and Clinical Background

Pre-clinical Pharmacology

In vitro assays were performed to examine the ability of REGN1979 to bind to target cells and to activate T-cells to specifically kill CD20-expressing target cells. REGN1979 was shown to bind to both Raji cells, a CD20+ B-cell lymphoma line, and Jurkat cells, an immortalized CD3+ T-cell line, as well as to primary human B and T-cells. In cellular cytotoxicity assays, REGN1979 was able to engage T cells to kill CD20-expressing cells in a target dependent manner. In these cytotoxicity assays, REGN1979 also induced the expression of T-cell activation markers, T-cell proliferation, and cytokine release.

In vivo experiments utilizing murine tumor models were performed to evaluate the anti-tumor efficacy of REGN1979. In a model where Raji (B) lymphoma cells were grown in mice and human PBMC were added as effector cells, REGN1979 treatment resulted in significant tumor growth suppression.

Nonclinical pharmacokinetics

The PK profile of REGN1979 was evaluated in cynomolgus monkeys during a single-dose PK study. In general, the PK of total REGN1979 in the monkey is described by non-linear, target-mediated elimination. Following a single IV infusion, mean total REGN1979 serum maximum concentration (Cmax) values in monkeys increased in an approximately dose-proportional manner. The concentration-time profile of total REGN1979 was characterized by a short distribution phase, followed by a saturating beta elimination phase at higher doses and an accelerated target mediated elimination phase at low doses (and corresponding low serum concentrations). Target mediated elimination (presumably due to binding of REGN1979 to the CD20 target on B cells) was observed in the distribution phase and correlated with the nearly complete depletion of B cells observed 24 hours post infusion. The duration of peripheral B cell depletion increased with the REGN1979 dose and in general, the rate of B cell repletion was positively correlated with the rate of clearance of total REGN1979.

Nonclinical Toxicology

The toxicity profile of REGN1979 was evaluated in an exploratory, non-GLP, single-dose intravenous (IV) infusion toxicology study (dose level 1mg/kg) and a 4-week repeat dose GLP-toxicology study (dose levels 0.01, 0.1, and 1 mg/kg). The no-observed-adverse-effect-level (NOAEL) for each of the toxicology studies conducted is considered to be 1.0 mg/kg, the highest dosage administered. REGN1979 resulted in B cell depletion at all doses tested, with earlier recovery at the lower doses. This depletion extended into deep tissues including lymph nodes and spleen. A transient release of cytokines was observed whose magnitude correlated with the strength of the dose, and at the highest dose several animals also displayed some vomiting with the first dose. Neither cytokine release nor symptoms occurred upon second or subsequent dosing. An ex vivo tissue cross-reactivity study also was conducted to assess the binding specificity of REGN1979 in a panel of human and cynomolgus monkey tissues. All staining in this study was consistent with expected reactivity with the target antigens, and no unanticipated cross-reactivity of REGN1979 was observed.

Clinical Background

In an ongoing Phase I study (NCT02290951) of REGN1979 in patients with B-cell malignancies, a total of 110 patients (61 with DLBCL; 31 with grade 1 to 3a FL; 9 with MCL; 6 with MZL; and 3 with other B-cell malignancies) were treated with REGN1979 ranging from 0.03-320 mg as of 3rd September 2019. Patients had a median of 3 prior lines of therapy (range 1-11).

Among the 22 patients with R/R FL who were treated with ≥5 mg of REGN1979, the overall response rate (ORR) was 95.5% and the complete response (CR) rate was 77.3%. Patients with R/R FL who were treated with ≥80 mg of REGN1979 had an ORR of 100%. The median progression-free survival for R/R FL patients treated with ≥5mg of REGN1979 was 11.4 months (95% CI, 6.7-not evaluable). In the DLBCL cohort, the objective response rate (ORR) was 57.9% (11/19), and the CR rate was 42.1% (8/19) with treatment at ≥80 mg of REGN1979. At this dosage, the ORR was 71.4% in those patients not treated with prior chimeric antigen receptor (CAR) T-cell therapy (n = 7), which included all CRs. In those who received prior CAR T-cell therapy, the ORR and CR rate were 50% and 25%, respectively. The response rate was higher in patients who had not previously received CAR T-cell therapy (Figure 14). Survival rates and ongoing response rates are shown in Figure 15 by diagnosis, dose of REGN1979, and prior CAR T therapy.

Figure 14. Efficacy results by diagnosis and dose of REGN1979

Diagnosis	FL, n (%)	DLBCL, n (%)	DLBCL with prior CAR T therapy, n (%)	DLBCL without prior CAR T therapy, n (%)
Dose of REGN1979	≥5mg	≥80mg	≥80mg	≥80mg
N	22	19	12	7
ORR	21 (95.5)	11 (57.9)	6 (50.0)	5 (71.4)
CR	17 (77.3)	8 (42.1)	3 (25.0)	5 (71.4)
PR	4 (18.2)	3 (15.8)	3 (25.0)	0
SD	1 (4.5)	2 (10.5)	1 (8.3)	1 (14.3)
PD	0	3 (15.8)	2 (16.7)	1 (14.3)
Not available	0	3 (15.8)	3 (25.0)	0

CAR, chimeric antigen receptor; CR, complete response; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease

Figure 15. Median survival and responses by diagnosis, prior CAR T therapy and REGN1979 dosing

	Patients with FL	DLBCL with prior CAR T therapy	DLBCL without prior CAR T therapy
Dose of REGN1979	**≥5mg**	**≥80mg**	**≥80mg**
N	22	12	7
Median PFS, months (95% CI)	11.4 (6.7–not evaluable)	NR	NR
Median duration of follow-up, months (range)	6.8 (1.0–22.1)	2.6 (0.4–9.9)	5.3 (1.2–11.8)
Number of patients with ongoing response at last assessment	14/21	4/6	5/5
Number of patients with ongoing CRs at last tumor assessment	12/17	3/3	5/5

CAR, chimeric antigen receptor; CR, complete response; DLBCL, diffuse large B-cell lymphoma; FL, follicular lymphoma; NR, not reported; PFS, progression-free survival

No dose limiting toxicities (DLTs) were observed during dose escalation. The most common treatment-emergent adverse events (TEAEs) of any grade were pyrexia (80%) and cytokine release syndrome (CRS, 59.1%). Grade 3–4 TEAEs that occurred in 10% or more of patients are anemia (21.8%), hypophosphatemia (19.1%), neutropenia (19.1%), lymphopenia (19.1%), thrombocytopenia (13.6%), and leukopenia (10.0%). CRS grade ≥3 occurred in 6.4% of patients and no seizures or grade 4–5 neurologic events were observed.

Preliminary data from the Phase I study showed broad antitumor activity with REGN1979 in heavily pretreated R/R B-NHL patients, including some with progression after prior chimeric antigen receptor T (CAR T)-cell therapy. REGN1979 has been tolerated at doses up to 320 mg weekly, with no observed dose limiting toxicities.

REGN1979 is currently evaluated in a potentially pivotal Phase II program. This open-label, multi-center, Phase II program (NCT03888105) is evaluating the efficacy and safety of REGN1979 in different disease-specific cohorts, including patients with R/R FL, DLBCL, MCL, MZL and other B-NHL subtypes. Recruitment of this study is ongoing.

Margetuximab

Overview

Approximately 25% of breast tumors overexpress the HER2 protein which is a member of the ErbB receptor tyrosine kinase family and plays an important role in the growth and proliferation of HER2-expressing cancer cells. HER2 expression has been associated with aggressive metastatic cancers with a poor prognosis. The overall incidence of breast cancer is similar between the U.S. (~268,600 new cases in 2019) and China (~278,800), so is the proportion of patients with HER2+ breast cancer. Many HER2-targeting agents have been developed and marketed with trastuzumab (Herceptin) as one of the most important treatments for HER2+ breast cancer.

Margetuximab is a human/mouse chimeric IgG1 anti-HER2 antibody with an optimized Fc domain designed to outperform trastuzumab whose mechanism of action involves not only the inhibition of the signal transduction pathway from HER2, but also the antibody-dependent cytotoxicity (ADCC) mediated by the binding of the Fc domain of the antibody with CD16A (Fc g receptor IIIA or Fc g R I I I A) expressed on the surface of the natural killer (NK) cells and macrophages. Both 158V and 131H variants bind the Fc of IgG1 with higher affinity than their respective allelic counterparts. With optimized Fc domain, margetuximab binds different CD16 variants with similar affinity, leading to stronger ADCC than trastuzumab. A Phase III trial known as SOPHIA compared margetuximab in combination with chemotherapy with trastuzumab in combination with chemotherapy in HER2+ breast cancer after 2 or more lines of treatment with other HER2-targeting agents including trastuzumab and pertuzumab. The study reported positive outcome indicating that margetuximab is superior to trastuzumab in a heavily pretreated HER2+ metastatic breast cancer. Additional clinical trials are being planned to evaluate margetuximab in HER2+ breast and gastric cancer.

Our Clinical Trial Designs and Strategy for Margetuximab in the China Market

Zai Lab is exploring regulatory approval pathways for margetuximab in HER2+ breast cancer in China using a bridging approach which may require a PK study and a bridging trial. In February 2020, the first patient was dosed in the registrational bridging study of margetuximab in combination with chemotherapy for the treatment of patients with metastatic HER2-positive breast cancer. Data from the positive SOPHIA study and the bridging study data will be used to support potential regulatory filing and approval in China. In additional, Zai Lab plans to participate in the upcoming global studies of margetuximab (MAHOGANY) in combination with a PD-1 antibody or a PD-1 x LAG-3 bispecific DART molecule in gastric cancer sponsored by MacroGenics in HER2+ first line treatment of gastric cancer. *Margetuximab Mechanism of Action*

HER2 oncoprotein drive the aggressive behavior of HER2+ breast and other cancer and it proves to be a good target for cancer therapeutics exemplified by the clinical success of the monoclonal antibody trastuzumab. Margetuximab is believed to mediate its therapeutic activity against HER2+ tumours by a combination of mechanisms that are initiated by binding of margetuximab to HER2 expressed on the cell surface, including the following:

- Direct impact on HER2 receptor leading to reduced HER receptor dimerization and subsequent activation, induction of endocytosis of the HER2 receptor, and prevention of shedding of the extracellular domain of the HER2 receptor (thereby preventing formation of a constitutively active truncated intracellular receptor)
- Induction of apoptosis
- Antibody-mediated cellular cytotoxicity, or ADCC, and presentation of the antigenic determinants of opsonized cells to antigen-presenting cells.

Fcγ-receptor (FcγR)-mediated mechanisms, such as ADCC, play a critical part in the action of many antibodies including trastuzumab. Optimization of the Fc component of margetuximab enhances binding to the V/F heterozygous subtype and the F/F homozygous subtype of FcγR compared to trastuzumab, potentially leading to enhanced ADCC activity in a broader patient population. Margetuximab significantly increased the level of ADCC activity mediated by Fc domain optimization, and the enhanced ADCC was observed in a range of breast, gastric, bladder and colorectal cancer cell lines. Margetuximab maintains the same direct anti-proliferative activity as trastuzumab, but, in contrast to trastuzumab, margetuximab interacts efficiently with both 158F and 158V allotypes of CD16A due to specific mutations introduced into its Fc region. Consistent with its enhanced binding to CD16A, margetuximab exhibits enhanced *in vitro* antitumor activity against HER2-expressing tumor cell lines, including against lines expressing low HER2 levels, and in xenograft models in human CD16A+ transgenic mice. The data from the nonclinical pharmacology studies support the hypothesis that margetuximab can be active against HER2-expressing tumors.

Margetuximab Pre-clinical and Clinical Background

Nonclinical Pharmacology

In ligand binding studies, compared to the wild-type Fc domain, margetuximab imparts enhanced binding to both the CD16A-158F and CD16A-158V alleles. Binding to human CD32A is unchanged (131H allele) or decreased (131R allele), and there is a substantial decrease in binding to the human inhibitory receptor, CD32B. In the monkey, the optimized Fc domain of margetuximab imparts increased binding to all three cynomolgus FcγRs (CD16A, CD32A and CD32B) compared to the wild type Fc domain.

Consistent with its enhanced binding to CD16A, margetuximab exhibits enhanced antitumour activity against HER2-expressing tumour cell lines *in vitro* and in xenograft models in human CD16A-transgenic mice. Margetuximab, as a single agent, is active against HER2-expressing breast, ovarian or pancreatic tumours in a manner consistent with that of trastuzumab. In general, HER2 3+ tumours (breast BT474 and ovarian SKOV3 cell lines) were highly sensitive to treatment with either margetuximab or a trastuzumab analogue, RES120, with maximal effects observed at the lowest dose tested. Margetuximab showed enhanced activity against JIMT-1 xenografts compared to RES120 in mCD16-/- hCD16A+ transgenic mouse lines. JIMT-1 is a HER2+ (2+ by HercepTest) line derived from a metastatic breast cancer patient that progressed on trastuzumab therapy and is insensitive to trastuzumab anti-proliferative activity. Margetuximab was also active as a single agent against HER2-expressing gastric cancer xenografts and when combined with a chemotherapy agent (taxane or irinotecan). The anti-tumour effects of the combinations were enhanced compared to that of the individual agents.

Based on *in vitro* secondary pharmacology studies conducted with human PBMC and anti-HER2 monoclonal antibodies in the absence or presence of immobilized HER2 antigen, the optimized Fc domain of margetuximab does not contribute to enhanced cytokine release *in vitro* . These data suggest that margetuximab is not likely to induce cytokine release in human patients to levels any higher than those induced by trastuzumab.

Margetuximab exhibited anti-tumour activity equal to or better than that of RES120, its WT Fc domain counterpart, in all models tested and increased potency compared with RES120 in a selected system where the contribution of the optimized Fc domain can be ascertained. These data support the hypothesis that margetuximab is more potent than trastuzumab. In addition, margetuximab exhibited enhanced tumour activity when combined with chemotherapy agents. For patients with HER2-expressing tumours, margetuximab has the potential to expand the benefit to the whole patient population, irrespective of the CD16A genotype. Thus, these data support the use of margetuximab, in combination with chemotherapy, to treat HER2+ breast cancer.

Nonclinical pharmacokinetics

In the single dose toxicology study, intravenous infusion of margetuximab at 50 mg/kg led to a mean Cmax of 1.62 mg/mL for males and 1.70 mg/mL for females. The terminal phase half-life was estimated to be 223.9 hours in males and 233.9 hours in females, while serum clearance was 0.434 mL/hr and 0.400 mL/hr in males and females, respectively. The volume of distribution at steady state (Vss) was estimated to be 132.4 mL in males and 127.2 mL in females, which is similar to the plasma volume. No gender related differences were apparent in the pharmacokinetic profile. The pharmacokinetic properties for RES120, an antibody identical to margetuximab except for the presence of a wild type human IgG1 Fc domain, were similar to those for margetuximab. In the multi-dose toxicology study, margetuximab was administered weekly for 6 weeks at doses of 15, 50 or 150 mg/kg. Toxicokinetic measurements showed an increase in exposure to margetuximab with increasing dose. Cmax appeared to increase linearly with dose following the first dose on Day 1; however, increases in Cmax were not dose proportional following the sixth dose on Day 36. Similar trends were observed with respect to AUC0-∞. Terminal serum half-life ranged from 133 to 189 hours on Day 1 and 176 to 222 hours on Day 36. Serum clearance ranged from 0.55 to 1.09 mL/hr on Day 1 and 0.20 to 0.36 mL/hr on Day 36. The volume of distribution approximated to the blood volume. No substantial gender differences were observed. The more rapid clearance following the first dose on Day 1 as compared to Day 36 was probably due to binding to the target receptor and saturation of this binding following multiple doses. Taken together, these data indicate that the pharmacokinetic profile of margetuximab in monkeys is comparable to that of other anti-HER2 IgG1 monoclonal antibodies

Nonclinical Toxicology

Margetuximab has been investigated in single and repeat dose toxicity studies in the cynomolgus monkey and in a battery of *in vitro* tissue cross-reactivity studies in human and cynomolgus monkey tissues. Cynomolgus monkeys (Macaca fascicularis) express both the target antigen and FcγRs that are relevant for modeling margetuximab. A direct comparison of margetuximab and trastuzumab revealed similar staining patterns in human and cynomolgus monkey tissues. A second (rodent) species was not used in repeat dose toxicity studies because margetuximab, which retains the HER2-binding properties of 4D5, the original precursor to the trastuzumab antibody, does not cross react with rodent HER2/neu.

In a pilot toxicology study in cynomolgus monkeys margetuximab or RES120 was well tolerated when administered by IV infusion at a single dose of 50 mg/kg. There were no test article-related mortalities and no test article-related changes with regard to clinical signs, food consumption, body weights, haematology, coagulation, or urinalysis parameters. There were also no macroscopic, organ weight or microscopic findings related to the administration of RES120 or margetuximab. Mild increases in alanine aminotransferase (ALT), aspartate aminotransferase (AST), and lactate dehydrogenase (LD), with both margetuximab and RES120, were consistent with a nonhepatic source and can be observed following 1-hour infusions and frequent blood sampling for toxicokinetic analysis. In the repeat dose study, margetuximab, administered weekly via 1-hour intravenous infusion for six weeks at 15, 50 and 150 mg/kg, was well tolerated in male and female cynomolgus monkeys. There were no margetuximab-related mortalities or clinical signs and no test article-related changes in food consumption, body weights, ECG, troponin I or ophthalmic examinations, physical examinations, blood pressure or heart rate, haematology, coagulation, or urinalysis parameters. No margetuximab-related changes were observed in natural killer (NK) cell cytolytic activity during the dosing or recovery intervals. There were no gross findings observed at necropsy, no organ weight or organ weight ratio alterations, and no microscopic findings attributed to the administration of margetuximab (including no findings in heart tissue).

Clinical Background

HER2-expressing tumors represent ~25% of breast cancer and ~ 20% of gastric cancer. The HER2 positive rate may be lower for gastric cancer in China. HER2-targeting agents have had significant impact on the behavior of HER2+ breast and gastric cancers. In the metastatic setting, trastuzumab in combination with pertuzumab and chemotherapy has become the standard of care (SOC) in the first line treatment of HER2-postive breast cancer, while trastuzumab in combination with chemotherapy is the SOC in the first line treatment of HER2+ gastric cancer. Trastuzumab has been demonstrated to improve PFS of patients with gastric and GEJ tumors that overexpress HER-2 from 5.5 months to 6.7 months and OS from 11.1 months to 13.8 months when added to chemotherapy compared to chemotherapy alone. The addition of a targeted mAb to chemotherapy has also demonstrated improved PFS and OS in the second line setting. Ramucirumab (a mAb targeting the vascular endothelial growth factor pathway) improved median OS to 9.6 months when added to paclitaxel chemotherapy compared to 7.4 months with paclitaxel chemotherapy alone.

HER2 is a protein found on the surface of some cancer cells that promotes growth and is associated with aggressive disease and poor prognosis. Approximately 15-20% of breast cancer cases are HER2-positive, representing approximately 45,000 new cases annually in the U.S. according to the American Cancer Society Breast Cancer Facts & Figures 2019-2020. Monoclonal antibody-based therapies targeting HER2 have greatly improved outcomes of patients with HER2-positive breast cancer and are now standard of care in both early- and late-stage disease. Ongoing HER2 blockade is recommended for patients who have relapsed or refractory HER2-positive disease; after progression occurs during treatment with other HER2-directed therapies, the need for additional agents in later lines remains.

In December 2019, MacroGenics submitted a Biologics License Application (BLA) to the FDA for margetuximab for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy. The BLA submission was based primarily on data from SOPHIA, the Phase III clinical trial comparing margetuximab plus chemotherapy versus trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer who have previously been treated with anti-HER2-targeted therapies. In February 2020, the BLA was accepted for review by the FDA.

The SOPHIA study enrolled 536 patients at approximately 200 trial sites across North America, Europe and Asia. Patients were treated with either margetuximab or trastuzumab in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine). All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine. Primary endpoints are sequentially-assessed progression-free survival (PFS), determined by centrally-blinded radiological review, and overall survival (OS). A pre-specified exploratory objective of the study was to evaluate the effect of CD16A (Fcγ receptor) allelic variation on margetuximab activity; approximately 85% of the overall human population, as well as patients enrolled in the SOPHIA study, carry the CD16A 158F allele, which has been previously associated with diminished clinical response to trastuzumab and other antibodies.

In June 2019, at a medical conference, the data from SOPHIA as of the aforementioned October 2018 data cut-off that showed a statistically significant improvement in PFS in patients treated with margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in the intention-to-treat (ITT) population after 265 PFS events (median PFS=5.8 months versus 4.9 months; hazard ratio [HR]=0.76; 95% confidence interval [CI]: 0.59-0.98; P=0.033). In the pre-specified, exploratory subpopulation of patients carrying the CD16A 158F allele, PFS was prolonged by 1.8 months in the margetuximab arm compared to the trastuzumab arm (median PFS=6.9 months versus 5.1 months; HR=0.68; 95% CI: 0.52-0.90; P=0.005). The data from the planned first interim analysis of OS based on 158 OS events. This interim analysis was not expected to and did not reach statistical significance. In the ITT population, median OS was 18.9 months in the margetuximab arm versus 17.2 months in the trastuzumab arm (HR=0.95; 95% CI: 0.69-1.31). In the pre-specified, exploratory subpopulation of patients carrying the CD16A 158F allele, median OS was 23.6 months in the margetuximab arm versus 16.9 months in the trastuzumab arm (HR=0.82; 95% CI: 0.58-1.17). As a secondary outcome measure in the SOPHIA study, the objective response rate (ORR) in the ITT population was 22% in the margetuximab arm (95% CI: 17.3-27.7%) compared to 16% in the trastuzumab arm (95% CI: 11.8-21.0%).

At a medical conference in December 2019, the data from the planned second interim analysis of OS as of a September 2019 cut-off after 270 OS events showed that, OS favored margetuximab plus chemotherapy compared with trastuzumab plus chemotherapy in the ITT population; however, these data were not expected to and did not reach statistical significance (median OS=21.6 months versus 19.8 months; HR=0.89; 95% CI: 0.69-1.13; nominal P=0.326). The final pre-specified OS analysis is planned after 385 OS events have accrued, which is projected to occur in the second half of 2020, at which point the results may or may not reach statistical significance. Among the genetically

defined exploratory subpopulation of patients carrying a CD16A 158F allele, the median OS at the second interim analysis was prolonged by 4.3 months in the margetuximab arm compared to the trastuzumab arm (23.7 months versus 19.4 months; HR=0.79; 95% CI: 0.61-1.04; nominal P=0.087). Among the approximately 15% of patients who were homozygous for the CD16A 158V allele, the trastuzumab arm performed better than the margetuximab arm.

As of the April 2019 data cut-off for safety, Grade 3 or greater adverse events occurred in 142 (54%) patients on the margetuximab arm compared to 140 (53%) patients on the trastuzumab arm. Serious adverse events occurred in 43 (16%) patients on the margetuximab arm compared to 49 (18%) patients on the trastuzumab arm. Infusion-related reactions (IRR) were more common with margetuximab treatment than with trastuzumab (13% versus 3%) and were mostly Grade 1 or 2 and associated with the first dose. A substudy evaluating shorter, 30-minute infusions of margetuximab in Cycle 2 and beyond showed no effect on safety outcomes, including risk or severity of IRR.

Gastric Cancer

Cancer of the stomach, also called gastric cancer (GC), and cancer of the gastroesophageal junction (GEJ), which is where the esophagus joins the stomach, are collectively referred to as gastroesophageal adenocarcinoma, which is the third leading cause of cancer death worldwide according to the World Health Organization in 2018. Both GC and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a 5-year survival of 5-20%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for the approximately 20% of patients whose tumors are HER2-positive.

In September 2019, two ongoing Phase II, open-label, dose escalation and expansion study of margetuximab plus pembrolizumab, an anti-PD-1 monoclonal antibody, in patients with advanced HER2-positive GC or GEJ cancer who have previously been treated with chemotherapy and trastuzumab in the metastatic setting were presented. In this study, 92 patients, including 61 patients with GC and 31 patients with GEJ, who had HER2-positive disease, were treated at the recommended Phase II dose of 15 mg/kg margetuximab and 200 mg pembrolizumab, both administered every three weeks, and were included in the analysis. HER2 positivity was characterized by a score of 3+ by immunohistochemistry (IHC), or IHC3-positve, or a score of 2+ by IHC and detection by fluorescence in situ hybridization (FISH), or IHC2-positive/FISH-positive. Patients in the study were enrolled irrespective of programmed death-ligand 1 (PD-L1) expression status. We reported data as of July 10, 2019. As of this data cut-off date, the study was ongoing with eight patients remaining on therapy. Acceptable tolerability was observed in this study in patients treated with margetuximab and pembrolizumab. Grade 3 or higher treatment-related adverse events (TRAE) occurred in 19.6% of patients. Response rates, median PFS and OS observed in the ongoing study are summarized in the following table:

	Gastroesophageal Adenocarcinoma (GEA = GC + GEJ)				**Gastric Cancer (GC)**			
	ORR	DCR	Median PFS (months)	Median OS (months)	ORR	DCR	Median PFS (months)	Median OS (months)
All Patients	20*/92 (21.7%)	50/92 (54.4%)	2.7	12.5	18*/61 (29.5%)	40/61 (65.6%)	4.1	13.9
HER2 IHC3+	20*/71 (28.2%)	45/71 (63.4%)	4.3	13.9	18*/55 (32.7%)	38/55 (69.1%)	4.7	14.6
HER2 IHC3+/PD-L1+	12/25 (48.0%)	19/25 (76.0%)	4.8	20.5	12/23 (52.2%)	19/23 (82.6%)	5.5	20.5

* Three unconfirmed responses; ORR includes complete responses (CR) and partial responses (PR); DCR=disease control rate and includes CR, PR and stable disease (SD).

Based on these results, in September 2019, MacroGenics initiated the MAHOGANY study, a Phase II/III registration-directed clinical trial to evaluate, in Module A, margetuximab in combination with MGA012, an anti-PD-1 monoclonal antibody, in patients with tumors that are both HER2-positive and PD-L1 positive. This approach is designed as a chemotherapy-free regimen that engages both innate and adaptive immunity for the treatment of patients with GC or GEJ cancer in the first-line setting. The primary outcome measure for efficacy in Module A is ORR per Response Evaluation Criteria in Solid Tumors (RECIST) v 1.1. In Module B, is to evaluate margetuximab with chemotherapy and MGA012 or MGD-013, a PD-1 x LAG-3 bispecific DART molecule, compared to standard of care therapy of trastuzumab with chemotherapy in MAHOGANY study. In this portion of the randomized, controlled study, patients are planned to be enrolled irrespective of PD-L1 expression. The primary outcome measure for efficacy in Module B is planned to be OS.]

INCMGA0012 (PD-1)

INCMGA0012 (PD-1) is an investigational monoclonal antibody that inhibits PD-1. INCMGA0012 (PD-1) is currently being evaluated as monotherapy in registration-directed trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma and anal cancer.

We obtained an exclusive license to develop and commercialize INCMGA0012 (PD-1) in China, Hong Kong, Macau and Taiwan in 2019.

Clinical Background

PD-1 is expressed on T cells (CD4+ and CD8+), B cells, NK cells, and myeloid-derived cells. The interaction of PD-1 with its ligands, PD-L1 and PD-L2, forms a negative signaling axis in T cells to suppress T cell function which is the mechanism utilized by the immune system to help maintain self-tolerance and modulate the duration and amplitude of physiological immune responses.

PD-L1 and PD-L2 have also been found to be abnormally expressed by tumor cells in the tumor microenvironment. Extensive research has shown that cancer cells co-opt certain immune checkpoint pathways, including the PD-1 pathway, as a major mechanism of immune evasion/ resistance, particularly against T cells that are specific for tumor antigens. Disruptors of this pathway using antibodies that inhibit PD-1 receptor-ligand interactions have been shown to inhibit tumor growth in murine models through enhancing T cell proliferation and restore immune responses. Moreover, blocking the PD-1–PD-L1/L2 pathway has been clinically validated as an effective cancer treatment in multiple clinical settings.

INCMGA00012 is an antibody that binds PD-1 and is currently under development as a therapeutic candidate for the treatment of multiple solid tumors, both as a monotherapy and in combination with other agents.

Clinical Pharmacology

Preliminary PK data from the 167 participants in the dose expansion cohorts receiving weight-based or flat doses of INCMGA00012 suggested that first dose INCMGA00012 exposure increased in a dose-proportional manner, consistent with the observations in participants receiving weight-based doses. A population PK analysis demonstrated that the concentrations of INCMGA00012 can be adequately described by a 2-compartment model, and body weight dependence of clearance was characterized by a power relationship with an exponent of 0.911.

Simulations demonstrated that the median steady-state concentration of INCMGA00012 500 mg Q4W was approximately 21.1 μg/mL, which is the median trough concentration for pembrolizumab 200 mg Q3W.

Clinical Safety

Adverse events in participants treated with INCMGA00012 monotherapy included fatigue, diarrhea, nausea, and pyrexia (very common), ALT increased, colitis, dysgeusia, hyperthyroidism, hypothyroidism, influenza-like illness, infusion-related reaction, lipase increased, myalgia, pruritus, and rash (includes terms of rash, maculopapular rash, and macular rash) (common), and pneumonitis (uncommon). These AEs are similar to those observed with other anti–PD-1 antibodies.

The 375 mg Q3W and 500 mg Q4W doses were selected for further development based on favorable safety and PK profiles.

Clinical Efficacy

Preliminary efficacy data demonstrate clinical activity of INCMGA00012 based on durable RECIST responses in multiple tumor types. Preliminary efficacy in terms of RECIST response has been shown in previously treated NSCLC, cervical, and endometrial cancers. Based on the available data, the preliminary efficacy profile of INCMGA00012 is consistent with that of other anti-PD-1 antibodies.

INCMGA00012 is currently in development as a single agent or in combinations in multiple tumor types including endometrial cancer, anal cancer, NSCLC, and others.

MGD-013

Overview

MGD-013 is designed to block the interaction of PD-1 or LAG-3 with their respective ligands, thereby contributing to sustain or restore the function of exhausted T cells. MGD-013 is an Fc-bearing bispecific tetravalent (bivalent for each antigen) DART protein engineered as a hinge stabilized IgG4 molecule designed to concomitantly bind PD-1 and LAG-3, 2 checkpoint molecules expressed by T lymphocytes following antigen-induced activation. MGD-013 is under development as a therapeutic candidate for the treatment of cancer.

In November 2018, under the terms of the collaboration agreement, MacroGenics exclusively licensed to Zai Lab regional development and commercialization rights to MGD-013 in China, Hong Kong, Macau and Taiwan. In February 2020, the first patient was dosed in a Phase Ib dose escalation and expansion clinical study of MGD-013 in combination with niraparib, a PARP (poly [ADP-ribose] polymerase) inhibitor, for the treatment of patients with advanced or metastatic GC or GEJ cancer who failed prior treatment.

Our Clinical Trial Designs and Strategy for MGD-013 in the China Market

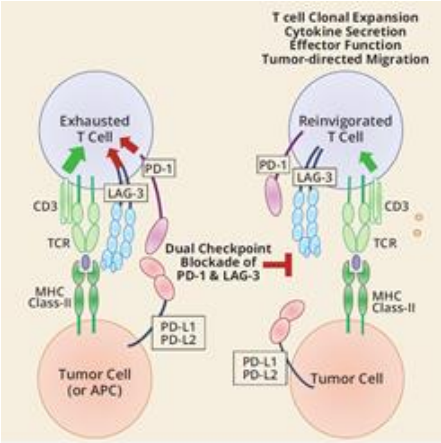
Our global partner, Macrogenics, is conducting a Phase I, open-label, dose escalation and cohort expansion study designed to characterize the safety, tolerability, PK, pharmacodynamics, immunogenicity, and preliminary antitumor activity of MGD-013 administered by IV infusion on a Q2W or Q3W schedule. The study consists of a Dose Escalation Phase to determine the MTD or MAD (if no MTD is defined) of MGD-013, followed by a Cohort Expansion Phase to further define the safety and initial antitumor activity of MGD-013 with the dose established in the Dose Escalation Phase. To date, the RP2D of MGD-013 on a Q2W or Q3W had been selected and the Cohort Expansion is ongoing in multiple tumor types.

In addition, Zai Lab plans to participate in the upcoming global MAHOGANY study of margetuximab in combination with INCMGA013 or MGD-013 in gastric cancer sponsored by MacroGenics in HER2+ first line treatment of gastric cancer and to initiate MAHOGANY Cohort B in China, Hong Kong, Macau and Taiwan in the second half of 2020.

MGD-013 Mechanism of Action

PD-1 and LAG-3 protein play an important role in immune response regulation. PD-1 is expressed on T (CD4+ and CD8+) cells, B cells, natural killer cells, and myeloid-derived cells. LAG-3 is a membrane protein that belongs to the Ig superfamily and binds to MHC-II. It enhances T regulatory cell activity and negatively regulates T cell proliferation and differentiation. LAG-3 has been shown to be expressed on dysfunctional T cells and is a marker for T regulatory cells. Upon interaction with their respective ligands, PD-1 and LAG-3 act as negative regulators of T cell function. The combined PD-1 and LAG-3 expression on tumor-infiltrating lymphocytes (TILs) or chronically viral-infected T cells have been correlated with immune dysfunction, also known as “T cell exhaustion”. LAG-3 appears to negatively regulate CD4+ and CD8+ T cell proliferation, function, and homeostasis in a manner that is distinct from that of PD-1.

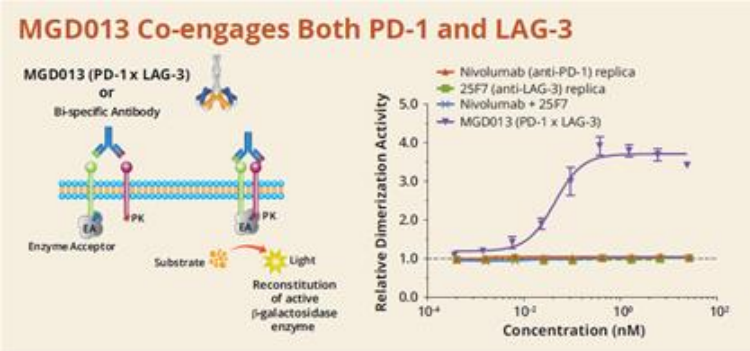
Cancer cells can co-opt certain immune-checkpoint pathways, including the PD-1 pathway, as a major mechanism of immune evasion/resistance, particularly against T cells that are specific for tumor antigens (seen in the Figure below). Blockade of PD-1 provides clinical benefit in patients with certain advanced tumors. Furthermore, combined blockade of 2 inhibitory receptors on T cells may exert greater efficacy than monotherapy. Studies in mouse tumor models have indicated that PD-1 and LAG-3 blockade can synergize to generate potent tumor eradicating immunity. Furthermore, translational studies using TILs from patients with ovarian cancer showed that NY-ESO-1 antigen-specific LAG-3+/PD-1+ CD8+ T cells were impaired in their ability to respond to antigen stimulation, but following combined LAG-3 and PD-1 blockade, T cell responsiveness could be restored to a greater extent than a single-agent blockade. Together, these data suggest that, in tumors in which PD-1 and/or LAG-3 are expressed on TILs, dual therapy may increase response rates and/or effectiveness of immunotherapy. Currently, several anti–LAG-3 mAbs are under investigation in clinical trials, either as a monotherapy or in combination with anti–PD-1.



Sadhna Shankar, et al. Abstract No. P244, SITC 2017

MGD-013 Pre-clinical Background

In vitro studies were performed to evaluate the ability of MGD-013 to co-engage PD-1 and LAG-3 receptors within an enzyme dimerization assay. Briefly, serial equal molar dilutions of MGD-013, nivolumab replica, and/or relatlimab replica (negative control antibodies) were incubated with the DiscoverX PathHunter® U2OS PD1/LAG-3 dimerization cell line. PathHunter cells are genetically engineered to over-express the two proteins, whereby one protein is fused to Prolink and the second protein is fused to the enzyme acceptor (EA) of the β-galactosidase enzyme. As shown in the figure below, co-engagement of two proteins by MGD-013, but not anti-PD-1 and/or anti-LAG-3 mAbs, drives complementation between PK and EA, resulting in the reconstitution of an active β-galactosidase enzyme that cleaves a substrate to generate chemiluminescent signal.



Sadhna Shankar, et al. Abstract No. P244, SITC 2017

Clinical background

MGD-013 is currently in Phase I development in a basket trial of multiple tumour types. The specific indication for MGD-013 has not been defined and data from the basket trial may inform on the selection of specific indications for further development.

Bemarituzumab (FPA144)

Overview

Gastric cancer, including gastroesophageal junction (GEJ) cancer, carries a poor prognosis, with five year OS rates below 30% for advanced stage disease (Stage III and IV) in the United States and China. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually.

Bemarituzumab, which we licensed from Five Prime, is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastroesophageal cancer. In December 2017, Five Prime initiated dosing in a Phase I safety lead-in portion of its Phase I/III clinical trial of bemarituzumab in combination with the mFOLFOX6 chemotherapy regimen in patients with previously untreated, advanced gastric or gastroesophageal cancer. The randomized, controlled Phase III portion of the trial evaluating bemarituzumab plus chemotherapy, the FIGHT trial, was initiated in the second half of 2018 and Zai Lab enrolled the 1 st patient in October 2018 in this global registrational study for the treatment of front-line gastric and gastroesophageal cancers. We and Five Prime intend to use the proposed global pivotal Phase III study and additional supportive data from clinical and nonclinical development to form the basis of an eventual marketing application for bemarituzumab both within and outside of China.

Five Prime has paused enrollment in the FIGHT trial pending the occurrence of a sufficient number of events to trigger a futility analysis that is expected to occur in mid-2020. Approximately 150 patients with newly diagnosed advanced stage gastric cancer were enrolled into the FIGHT trial before Five Prime paused enrollment in the fourth quarter of 2019. Five Prime expects that it will only resume enrollment in the FIGHT trial if the trial passes the futility analysis and Five Prime will look to enter into a collaboration or license agreement that will pay for all or substantially all of any future development and commercialization costs for bemarituzumab.

In March 2020, Five Prime announced the publication of results from the Phase I escalation and expansion study of bemarituzumab in patients with advanced solid tumors and FGFR2b-selected gastroesophageal adenocarcinoma in the digital edition of the Journal of Clinical Oncology. The purpose of the Phase I trial was to evaluate the safety, pharmacokinetics, and preliminary activity of single-agent bemarituzumab in patients with FGFR2b-overexpressing GEA. Seventy-nine patients were enrolled in the trial and no dose-limiting toxicities were reported. Bemarituzumab was well tolerated and the most frequent treatment-related adverse events (TRAEs) were fatigue, nausea, and dry eye. The overall response rate observed in this study of advanced-stage patients with high FGFR2b-overexpressing GEA was 17.9% (95% CI 6.1% to 36.9%) with five of 28 patients achieving a confirmed partial response.

Our Clinical Trial Designs and Strategy for Bemarituzumab (FPA144) in the China Market

As bemarituzumab is a targeted biologic, the clinical development of bemarituzumab will ultimately be in selected patients with alterations in the fibroblast growth factor receptor 2, or FGFR2, pathway that are most likely to respond to this novel agent. The tumor types most relevant to date include gastric, bladder, and possibly cholangiocarcinoma. Each of these cancers needs new therapeutic options. The FIGHT (bemarituzumab-004) study is designed to evaluate the efficacy, safety, and PK of bemarituzumab in combination with modified FOLFOX (infusional 5-FU, leucovorin, and oxaliplatin) (mFOLFOX6) chemotherapy treatment. Patients with gastrointestinal (GI) tumors will be enrolled in a Phase I safety run in, while the Phase III will enroll gastric cancer patients specifically selected for FGFR2 expression and/or FGFR2 gene amplification (FGFR2 selected) who are eligible for first-line mFOLFOX6 chemotherapy. The primary endpoint for Phase I part is the incidence of Grade 2 or higher AEs assessed as related to bemarituzumab by the Investigator and the incidence of clinical laboratory abnormalities defined as DLTs. The primary endpoint for the Phase III part is the OS, defined as time from enrollment until death from any cause.

China is participating in the Phase III part of above global trial and contributing largely on patient enrollment. In 2019, Five Prime suspended trial enrollment in order to conduct a futility analysis prior to continuing patient enrollment. Patients enrolled into the trial are currently undergoing treatment and follow-up.

Bemarituzumab Mechanism of Action

Bemarituzumab is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor (National Center for Biotechnology Information; NCBI; reference sequence ID NP_001138385.1) that blocks FGF ligand binding to the receptor. Bemarituzumab is directed against the third Ig region of the FGFR2b receptor isoform, the region that is alternatively spliced and regulates ligand specificity. This antibody is glycosylated, but is produced in a Chinese hamster ovary (CHO) cell line that lacks the *FUT8* gene (α1,6-Fucosyltransferase) and therefore lacks a core fucose in the polysaccharide portion of the antibody. The absence of the core fucose results in higher affinity for the Fc receptor FcγRIIIa compared to the fucosylated molecule and potentially enhances immune cell-mediated tumor cell killing. The antibody has thus been glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). Bemarituzumab inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation in cell culture in FGFR2b overexpressing gastric and breast cancer cell lines. Bemarituzumab also inhibits tumor growth in FGFR2b overexpressing gastric and breast xenograft models. The 3 potential mechanisms of action of bemarituzumab thus include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and enhancing ADCC.

Bemarituzumab can produce complete and durable tumor growth inhibition in FGFR2b-overexpressing and FGFR2 gene-amplified gastric cancer xenografts in immune-compromised mice where FGFR2b is considered a driver of tumor growth. In addition, bemarituzumab demonstrates recruitment of natural killer (NK) cells and concomitant tumor growth inhibition in the 4T1 syngeneic tumor model with modest expression of FGFR2b. These data suggest that ADCC may be efficacious in patients without FGFR2 gene amplification with moderate FGFR2b overexpression, and that ADCC activity may be a major contributor to the mechanism of action in these patients.

Additionally, since bemarituzumab is specific for the FGFR2b receptor, it does not interfere with signaling of the other FGFs/ FGFRs, including FGFR2c. In contrast to the FGFR tyrosine kinase inhibitors (TKIs), bemarituzumab does not inhibit FGF23 signaling. FGF23 is a ligand involved in calcium/phosphate metabolism. Thus, treatment with bemarituzumab is not expected to cause the dose-limiting hyperphosphatemia associated with the FGFR TKIs.

Bemarituzumab Pre-clinical and Clinical Background

Nonclinical Pharmacology

The nonclinical pharmacology program for bemarituzumab has been designed to assess the *in vitro* and *in vivo* pharmacologic action of bemarituzumab with particular focus on efficacy and safety. *In vitro* pharmacodynamic (PD) studies have been performed to characterize the binding affinity of bemarituzumab to FGFR2b *in vitro* , as well as to assess the ability of bemarituzumab to inhibit FGFR2b ligand binding, downstream signaling, and cell proliferation. In addition, the ability of bemarituzumab to induce ADCC has been determined *in vitro* . The *in vivo* pharmacology of bemarituzumab has been studied in animal models of tumor growth. Safety pharmacology studies including CNS, cardiovascular, and respiratory rate assessments have been incorporated into the toxicology studies. Bemarituzumab inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation of FGFR2b-overexpressing gastric and breast cancer cell lines. Bemarituzumab also inhibits tumor growth in FGFR2b-overexpressing gastric and breast xenograft models, including regression in some models. In addition, Five Prime has demonstrated *in vitro* that bemarituzumab mediates ADCC in cells expressing FGFR2b.

Nonclinical Pharmacokinetics

The PK characteristics of bemarituzumab were investigated as a part of both nonclinical TK and PK studies in rat and cynomolgus monkey. Single-dose and repeat-dose studies evaluated bemarituzumab doses of 1–150 mg/kg. In those studies, bemarituzumab was administered intravenously, either as a bolus injection or a 30-minute infusion, and given weekly in the repeat-dose studies. Determination of serum concentrations of bemarituzumab and anti-bemarituzumab antibodies were performed using immunoassay methods developed by Five Prime and validated for use in GLP toxicology studies in rat and monkey.

Between rat and cynomolgus monkey, bemarituzumab demonstrated consistent PK behavior following IV administration, and the PK characteristics observed were consistent across all studies. Half-life was dose-dependent ranging from approximately 20-40 hours at low doses (1-1.5mg/kg) to 100-200+ hours at the highest doses (100-150 mg/kg) tested in cynomolgus monkey. Estimates of the initial volume of distribution approximated the plasma volume, suggesting that bemarituzumab did not distribute beyond the plasma compartment immediately after dosing, which is typical of large proteins including antibodies.

The majority of antibodies demonstrate dose-dependent elimination consistent with target-mediated elimination, where clearance decreases as a function of dose (eg, trastuzumab, rituximab, gemtuzumab, and panitumumab). Bemarituzumab demonstrated dose-dependent, nonlinear PK, similar to what has been observed for other mAbs. This was marked by a faster clearance at the terminal phase of the plasma concentration-time profile, a greater than dose-proportional increase in exposure with increasing dose, and a longer half-life with increasing dose. Target-mediated clearance was saturable at doses ≥ 10 mg/kg for single doses and doses ≥ 5 mg/kg following repeat doses, marked by dose-proportional increases in exposure at doses exceeding this level when dosed at weekly intervals. Since bemarituzumab binds equivalently to rat, monkey, and human FGFR2b, the nonclinical data provide a solid foundation to understanding the profile in clinical studies with bemarituzumab.

The PK studies supporting the TK studies showed dose-dependent increases in exposure supporting the reliability of these studies to assess toxicity. Anti-drug antibodies (ADAs) were confirmed in 6.0% of rats and 10.4% of monkeys after 13 weeks of dosing in the two 13-week GLP toxicology studies. Thus, the low incidence of ADAs did not impede the validity of the toxicological evaluation and is not predictive of what will occur in humans.

Nonclinical Toxicology

Six nonclinical *in vivo* toxicology studies were performed using bemarituzumab: two studies in rat and four studies in monkey. In rat, a dose-range finding, repeat-dose toxicology study (four weekly doses of 1.5, 30, or 150 mg/kg and a repeat-dose GLP toxicity study of 13 weekly doses of 1, 5, or 100 mg/kg with a nine-week recovery phase) were performed. In monkey, a single-dose PK/tolerability study (single dose of 10 mg/kg), a dose-range finding, repeat-dose toxicology study (four weekly doses of 1.5, 30, or 150 mg/kg), an ophthalmic–focused, repeat-dose tolerability study (four weekly doses of 1.5, 5, 15, 30, or 150 mg/kg), and a repeat-dose GLP toxicology study (13 weekly doses of 1, 5, or 100 mg/kg with a 15-week recovery phase) were performed.

Bemarituzumab was well-tolerated when administered intravenously once per week for 4 weeks at doses up to 150 mg/kg in rats. Corneal epithelium thinning was seen in animals receiving bemarituzumab at 1.5 mg/kg and higher, and these findings were considered treatment-related. The additional corneal changes were also considered treatment-related, but it is unclear whether they are a direct effect or secondary to the corneal thinning. For the hypertrophic changes in the RPE, it is unclear if the changes are a direct treatment-related effect since changes to the RPE can be caused by a multitude of factors. No pathological findings were detected in the RPE in the 13-week GLP rat toxicity study.

Bemarituzumab was well tolerated when administered by IV once per week for 4 doses up to 150 mg/kg in cynomolgus monkeys. Findings potentially related to bemarituzumab were corneal epithelium thinning and a unilateral cataract in one high-dose animal.

Bemarituzumab administered to rats once per week for 13 weeks at 1, 5, or 100 mg/kg resulted in treatment-related findings at all dose levels, although most of the effects occurred or were more pronounced in animals given 5 and 100 mg/kg. The most prominent findings were tooth abnormalities (clinical, macroscopic, and microscopic findings) and body weight loss/lack of weight most likely secondary to the tooth findings that necessitated early euthanasia of three animals at 100 mg/kg, ocular findings (ophthalmic and microscopic findings), macroscopic and/or microscopic findings in the Harderian gland and oral mucosa at 5 mg/kg and 100 mg/kg, and macroscopic and/or microscopic findings in the tongue at all dose levels. Bemarituzumab-related but non-adverse microscopic findings were also noted in the mammary gland of animals in all dose groups. With the exception of bemarituzumab-related effects on incisors, some degree of recovery was evident for all findings at the end of the recovery phase. Since all findings in the 1 mg/kg dose group were minimal, without clinical consequences, and recoverable, the HNSTD was determined to be 1 mg/kg when given weekly for 13 weeks.

Bemarituzumab given to male and female cynomolgus monkeys by IV infusion once per week for 13 weeks at 1, 5, or 100 mg/kg was well tolerated. Bemarituzumab-related effects were limited to microscopic findings of corneal atrophy in animals given 5 and 100 mg/kg and mammary gland atrophy in females from all dose groups. These findings were not associated with clinical sequelae and were not observed at the end of the recovery phase, indicating complete recovery. Therefore, based on the lack of other correlating findings or changes (eg, ophthalmic findings or clinical observations) and the demonstrated reversal, neither bemarituzumab-related microscopic finding was considered adverse. The HNSTD is considered to be above the 100 mg/kg level when given weekly for 13 weeks.

The data from the tissue cross-reactivity study demonstrated that the expression of the target of bemarituzumab is similar between the species used for toxicology studies and humans, and suggest that the safety findings from the nonclinical toxicology studies are likely to apply to the clinic.

Examinations of the reproductive organs in the toxicological studies demonstrated no evidence of reproductive target toxicity. No specific reproductive toxicity tests have been conducted for bemarituzumab to date.

Bemarituzumab is an IgG1 monoclonal antibody directed against FGFR2b and is being developed for the treatment of malignancies that overexpress FGFR2b. The toxicology and TK studies with bemarituzumab were completed in rat and cynomolgus monkey to support the design of the clinical trial.

Clinical Background

Gastric cancer, including gastroesophageal junction (GEJ) cancer, carries a poor prognosis, with five year OS rates below 30% for advanced stage disease (Stage III and IV) in the United States and China. Intensive multimodal therapy fails to cure the majority of patients with locoregional disease and for advanced stage disease, standard chemotherapy provides only short-term benefits. First-line chemotherapy used in metastatic or recurrent disease consists of a fluoropyrimidine (5FU, capecitabine, or S-1) with a platinum agent (usually oxaliplatin or cisplatin). This combination chemotherapy treatment prolongs survival by 6 months compared to best supportive care but still only provides short-term benefit, with a progression free survival (PFS) of five to six months and a median OS of nine to 10 months.

Attempts to improve upon standard platinum and fluoropyrimidine combinations include the addition of the targeted monoclonal antibody (mAb) trastuzumab in patients whose tumors overexpress human epidermal growth factor receptor 2 (HER-2). Trastuzumab has been demonstrated to improve PFS of the approximately 20% of patients with gastric and GEJ tumors that overexpress HER-2 from 5.5 months to 6.7 months and OS from 11.1 months to 13.8 months when added to chemotherapy compared to chemotherapy alone. The addition of a targeted mAb to chemotherapy has also demonstrated improved PFS and OS in the second line setting. Ramucirumab (a mAb targeting the vascular endothelial growth factor pathway) improved median OS to 9.6 months when added to paclitaxel chemotherapy compared to 7.4 months with paclitaxel chemotherapy alone.

FGFR2 amplification in gastric cancer results in high levels of FGFR2b expression, which is correlated with poor prognosis for OS with a hazard ratio (HR) reported as high as 4.59 when compared to patients without FGFR2b overexpression. FGFR2 is amplified in approximately 3% to 9% of tumors from patients with gastric cancer, with similar rates being observed across Japan, Korea, China, and the United Kingdom, and across platforms used to assess gene amplification (including reverse transcription polymerase chain reaction; RT-PCR; fluorescence in situ hybridization; FISH; and single nucleotide polymorphism; SNP; arrays). Using a validated immunohistochemistry (IHC) assay to specifically detect FGFR2b expression in solid tumors, approximately 12% of gastric cancers from China express a range of FGFR2b protein. To date, no drug has been approved for the FGFR2b-overexpressing molecular subset of patients with gastric cancer including cancer of the GEJ.

Bemarituzumab is a recombinant, afucosylated, humanized immunoglobulin G1 (IgG1) kappa monoclonal antibody directed against FGFR2b. bemarituzumab is glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). Pre-clinically, bemarituzumab blocks ligand binding and acts as a targeted immunotherapy that drives NK cells and recruits T cells into targeted tumors. As well as driving NK cells into tumors, *in vivo* pre-clinical studies have shown that bemarituzumab creates an “inflamed” tumor microenvironment consisting of recruited T cells and elevated levels of programmed death-ligand 1 (PD-L1). The three potential mechanisms of action of bemarituzumab include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and ADCC.

Bemarituzumab is being developed in combination with chemotherapy for the treatment of patients with unresectable, locally advanced, or metastatic gastric cancer including cancer of the GEJ whose tumors overexpress FGFR2b, as determined by an investigational device(s) being developed as a companion diagnostic test(s). Evaluation of this agent in patients with gastric cancer whose tumors have alterations of FGFR2 is an important strategy to improve the outcome for these patients.

A Phase I study, bemarituzumab-001, entitled “A Phase I Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of bemarituzumab in Patients with Advanced Solid Tumors” is ongoing in the United States, South Korea, and Taiwan. Safety and efficacy data in 74 patients, including preliminary data from an expansion cohort of 24 gastric cancer patients with high FGFR2b overexpression (IHC 3+ intensity in ≥ 10% of tumor cells as determined in a laboratory developed test), support further clinical investigation of bemarituzumab in patients with FGFR2b-selected tumors. Based on an August 7, 2017 data cut, treatment with bemarituzumab resulted in no dose-limiting toxicities

(DLTs) reported at doses up to 15 mg/kg administered every two weeks. Of the 74 patients who have received at least one dose of bemarituzumab, 50 patients had gastric cancer, of whom 24 had gastric cancer with high FGFR2b overexpression and were evaluable for response. Of these 24 patients, four, or 16.7% (95% CI 4.7-37.4%), reported a radiographically confirmed partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) criteria (version 1.1). The median duration of response (DoR) in these four patients was 15.4 weeks (95% CI 9.1 to 19.1 weeks). Conversely, no responses were reported in the 25 patients with gastric cancer who either had low or moderate FGFR2b overexpression, were IHC negative, or who had unknown FGFR2b status. One patient with gastric cancer did not have measurable disease and was inevaluable for response.

To address the unmet medical need of patients with unresectable, locally advanced, or metastatic gastric cancers and based on the preliminary Phase I data, Five Prime is proposing bemarituzumab-004 (FIGHT), a double-blind, randomized, controlled, global Phase III study of bemarituzumab in combination with modified FOLFOX6 (mFOLFOX6) chemotherapy, preceded by a Phase I safety run-in. The Phase I safety run-in will be conducted in the United States and will assess safety and tolerability and identify the recommended dose (RD) of bemarituzumab as an add-on therapy to fluorouracil, leucovorin, and oxaliplatin (mFOLFOX6, a combination that is used globally) for patients with gastrointestinal (GI) tumors. The global Phase III portion of the study will evaluate the efficacy and safety of bemarituzumab in combination with mFOLFOX6 versus placebo in combination with mFOLFOX6 in patients with unresectable, locally advanced, or metastatic gastric cancers whose tumors have FGFR2b overexpression, as determined by an IHC assay, and/or *FGFR2* amplification, as determined by a circulating tumor DNA (ctDNA) assay. The proposed Phase III study will enroll a majority of Asian patients, from countries including Japan, South Korea, Taiwan, Thailand, and China. The proposed Phase III study will employ 2 diagnostic assays, the Ventana Medical Systems, Inc. FGFR2b IHC assay and the Personal Genome Diagnostics (PGDx) next-generation sequencing (NGS) assay for *FGFR2* testing. The goal is to establish the clinical utility of the IHC and NGS assays for use as companion diagnostic tests. The primary endpoint for the proposed Phase III study will be OS, supported by a principle secondary endpoint of investigator-assessed PFS. Other secondary and exploratory endpoints include overall response rate (ORR), DoR, and physical function, as measured by EQ-5D-5L and EORTC QLQ-C30. Additional development of bemarituzumab for the treatment of gastric cancer includes bemarituzumab-002, a Phase I pharmacokinetic (PK) safety study in Japan. This dose escalation study is designed to assess the PK and safety of single agent bemarituzumab and will identify the RD for single agent bemarituzumab in Japanese patients. The first cohort of three patients treated on bemarituzumab-002 had no DLTs reported at doses of 10 mg/kg administered every two weeks.

Omadacycline (ZL-2401)

Omadacycline is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. Omadacycline is primarily being developed for ABSSSI, CABP and UTI in both the hospital and community settings and is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. Omadacycline has been granted QIDP and Fast Track status by the FDA. The drug has been administered to over 1,500 patients and has an established safety and tolerability profile. In October 2018, following priority review, Omadacycline was approved by FDA for both indications and for both the IV and oral once-daily formulations.

In June 2016, Paratek announced positive top-line efficacy data in a Phase III registration study in ABSSSI which demonstrated the efficacy and safety of IV to oral once-daily omadacycline compared to linezolid. In April 2017, Paratek announced positive top-line results from a global, pivotal Phase III clinical study in CABP which demonstrated the efficacy, general safety and tolerability of IV to oral omadacycline compared to moxifloxacin. In July 2017, Paratek also announced positive top-line results from a Phase III study comparing oral-only administration of omadacycline in ABSSSI compared to oral-only linezolid, which met all of its primary endpoints.

Omadacycline was approved by the FDA in October 2018 for both indications. It was launched as NUZYRA in the United States in February 2019. It is labeled for once-daily oral or intravenous administration for the treatment of adults with CABP and ABSSSI. The European Marketing Authorization Application for oral and IV omadacycline was submitted in October 2018.

In October 2019, Paratek announced that it is withdrawing its application in Europe for Nuzyra for business reasons. While approvable by EMA for skin infections, EMA requested a second study in CABP to meet current European regulatory standards of two Phase III studies in the indication. Paratek plans to re-submit application to EMA following completion of the planned Post-Marketing Approval CABP study already agreed with the FDA.Paratek conducted two exploratory studies in UTI for dose-finding purposes, one in women with acute cystitis (cUTI) and another in patients with pyelonephritis (cUTI). As per a press release in October 2019, Paratek plans to conduct additional analyses and investigations for these UTI indications.

We obtained the exclusive license to develop, manufacture and commercialize omadacycline in the field of all human therapeutic and preventative uses (other than biodefense) in China, Hong Kong, Macau and Taiwan in April 2017. In March 2020, Zai Lab entered into a contract sales agreement with Hanhui, a local pharmaceutical company with a strong commercial presence in antibiotics. The agreement allows us to leverage Hanhui's existing infrastructure to optimize a potential future commercial launch of omadacycline in China given that omadacycline is a broad spectrum antibiotic in both the hospital and community setting .

Our Clinical Trial Designs and Strategy for Omadacycline in the China Market

We have completed the technology transfer stage and discussed with key opinion leaders our planned China development activities in preparation for NMPA interactions. We have submitted documents and filed for an investigational new drug application, or IND, with Chinese health authorities in January 2018 and submitted our NDA in December 2019.

Zai has actively engaged key opinion leaders in discussions on our planned China development strategy, on study design in China, and the interpretation or data from the program.

We have also completed a bioequivalence study for the oral tablet which showed almost identical PK exposures of the new China-produced formulation comparison to the formulation used by Paratek in the clinical trial program.

We have completed a microbiology study investigating the activity of omadacycline against pathogens obtained from Chinese and other Asian patients. In this pilot trial of 3,832 isolates, omadacycline activity was essentially identical to the susceptibility results obtained in a larger 2016 surveillance study of 21,000 isolates conducted outside China (mainly in the United States and the European Union). These data have been published in an article titled "Antimicrobial Activity of Omadacycline Tested against Clinical Bacterial Isolates from Hospitals in mainland China, Hong Kong and Taiwan: Results from the SENTRY Antimicrobial Surveillance Program (2013 to 2016)" in Antimicrobial Agents and Chemotherapy 2019 63 (3): e02262-18. doi: 10.1128/AAC.02262-18]. We have also completed a microbiology study against 1,041 more recent patient isolates from China. This study further confirmed the undiminished activity of omadacycline against ABSSSI and CABP pathogens; publication of this data is pending.

We have also conducted a PK study in Chinese patients with both the IV and oral formulation. This study showed similar exposure to Caucasians with the selected dosing regimens for the IV formulation and somewhat higher but well tolerated exposures with the PO formulation. PK/PD analysis suggest that omadacycline IV and PO at standard doses will provide excellent coverage against pathogens from Chinese sources.

We have enrolled 125 patients in a ABSSSI in our clinical efficacy study with linezolid as comparator. Results showed equal clinical efficacy in both treatment arms. Likewise, the safety/tolerability of omadacycline in Chinese patients was excellent. These studies were part of our bridging plan for regulatory approval in China as discussed with regulators. They also were designed, conducted and analyzed in collaboration with Chinese KOLs in PK, microbiology and infectious disease.

Background on Tetracycline Antibiotics

The tetracycline class of antibiotics was introduced into the clinic in the 1960s and found considerable use in the treatment of respiratory and gastrointestinal infections. They are mostly bacteriostatic drugs interfering with protein synthesis by binding selectively to the bacterial 30S ribosomal subunit.

Tetracyclines provide excellent broad-spectrum coverage of Gram-positive, Gram-negative, anaerobes and special pathogens (e.g., malaria, anthrax, Lyme borrelia, nocardia). Resistance is due to efflux mechanisms and ribosomal mutations, but despite the gradual and inevitable increase in resistance over many decades of continued use, doxycycline is still an effective and commonly used drug today.

Omadacycline – Pharmacokinetics

Studies showed that oral doses of 300 mg provide bioequivalent exposure with the therapeutic IV dose of 100 mg. Like with other tetracyclines, absorption is affected by food and divalent cations. The drug has a long half-life (approximately 17 hours) and excellent penetration into tissues, including alveolar and epithelial lining fluid. In contrast to other tetracyclines, plasma protein binding is low (20%) and not dose-related. The drug is not metabolized and excretion is predominantly via the biliary route. There is no need for dose adjustment in hepatic or renal impairment.

Omadacycline Clinical Results

Phase III Pivotal Trial—ABSSSI / OASIS—ABSI 1108

Omadacycline was statistically non-inferior to linezolid IV/PO in a direct comparison study following a protocol established under an SPA agreed to with the FDA as well as the criteria outlined by the EMA. In this trial, patients with wound infections, major abscesses, and erysipelas/cellulitis were enrolled in equal numbers. On average, patients received IV omadacycline for 4.4 days, and oral omadacycline for 5.5 days.

S. aureus (both MSSA and MRSA) was the predominant pathogen isolated from patients followed by streptococci. Clinical response and bacterial eradication rates showed the high efficacy of omadacycline against skin pathogens including MRSA.

Figure 7: Omadacycline vs Linezolid—ABSSSI Trial—Primary Efficacy Outcomes

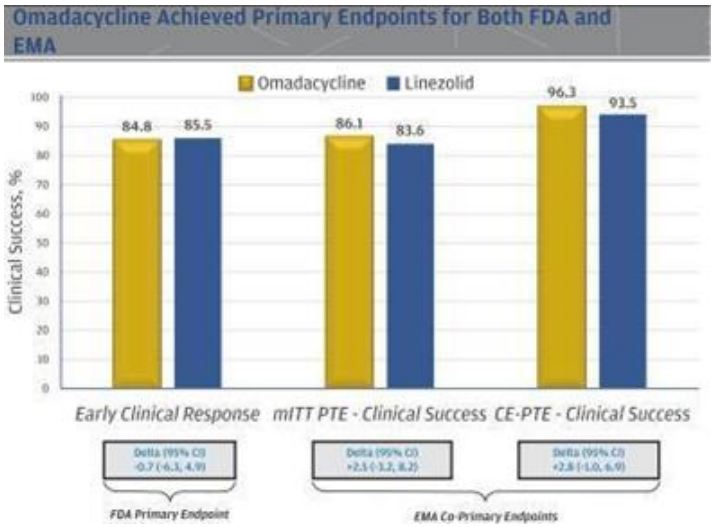
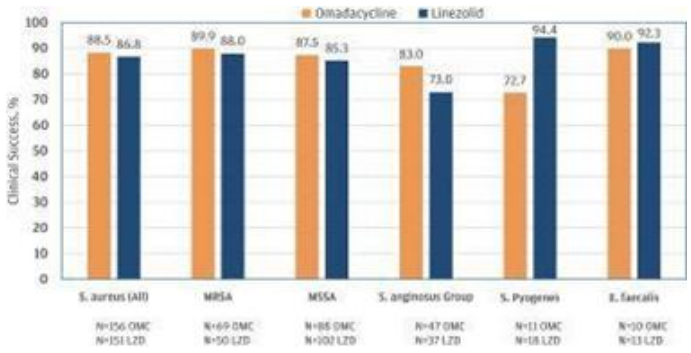


Figure 8: Early Clinical Success by Pathogen—micro-mITT Population



The safety / tolerability profile was very similar between the treatment arms with only a slightly higher rate of gastrointestinal side effects and infusion site reactions in omadacycline recipients. There was no significant imbalance in treatment emergent adverse events, or TEAEs, serious TEAEs, premature discontinuations or deaths.

This study was recently published in the New England Journal of Medicine (W O'Riordan et al. Omadacycline for Acute Bacterial Skin and Skin-Structure Infections, N Engl J Med 2019; 380:528-538).

Figure 9: Study ABSI-1108: Most Frequent TEAEs (> 3%)—Safety Population

	Omadacycline N = 323 %	Linezolid N = 322 %
Subjects with Any TEAE	**48.3**	**45.7**
Nausea	12.4	9.9
Infusion Site Extravasation	8.7	5.9
Subcutaneous Abscess	5.3	5.9
Vomiting	5.3	5.0
Cellulitis	4.6	4.7
Headache	3.1	4.0
ALT Increased	2.8	4.3
AST Increased	2.5	3.7
Diarrhea	2.2	3.1

Phase III Pivotal Trial—CABP / OPTIC—CABP1200

Omadacycline was non-inferior to moxifloxacin IV/oral in this direct comparison study following a protocol established under an SPA agreed with the FDA as well as the criteria outlined by the EMA. In this trial, patients with PORT Class II—IV were recruited; less than 25% of patients had received non-study antibiotics before enrollment.

Streptococcus pneumoniae and Mycoplasma pneumoniae were the predominant pathogens isolated, followed by H. influenzae, H. parainfluenzae, Legionella and Chlamydophila. The clinical response rates were high for all respiratory pathogens isolated at entry and very similar between omadacycline and moxifloxacin, a powerful respiratory fluoroquinolone.

Figure 10: CABP Study—OPTIC: Primary Efficacy Results—FDA Analysis

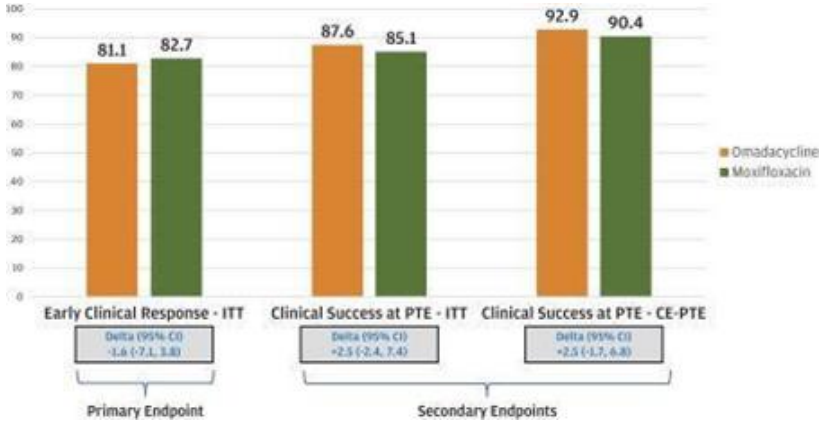


Figure 11: CABP Study—OPTIC: Primary Efficacy Results—EMA Analysis

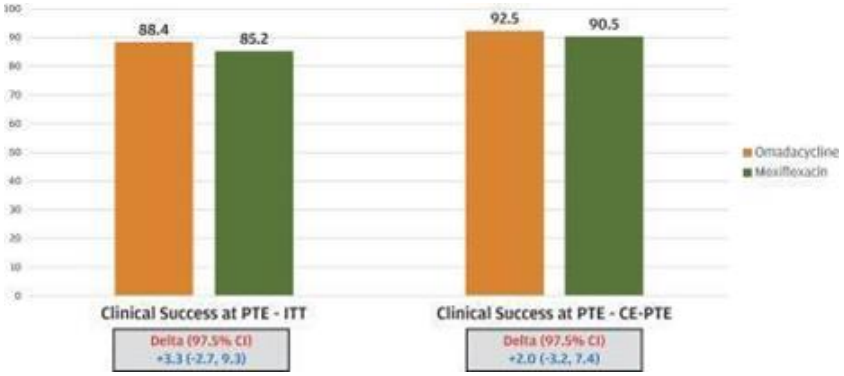


Figure 12: CABP Study—OPTIC: Clinical Success at PTE by Baseline Pathogen

	Omadacycline (N = 204)		Moxifloxacin (N = 182)	
Baseline Pathogen	**N**	**Clinical Success n(%)**	**N1**	**Clinical Success n(%)**
Atypical Pathogens	118	109 (92.4)	106	97 (91.5)
Mycoplasma Pneumoniae	70	66 (94.3)	57	50 (87.7)
Chlamydophila Pneumoniae	28	25 (89.3)	28	25 (89.3)
Legionella Pneumophila	37	35 (94.6)	37	36 (97.3)
Gram-Negative Bacteria (aerobes)	79	67 (84.8)	68	55 (80.9)
Haemophilus Influenzae	32	26 (81.3)	16	16 (100.0)
Haemophilus Parainfluenzae	18	15 (83.3)	17	13 (76.5)
Klebsiella Pneumoniae	13	10 (76.9)	13	11 (84.6)
Gram-Positive Bacteria (aerobes)	61	52 (85.2)	56	49 (87.5)
Steptococcus Pneumoniae	43	37 (86.0)	34	31 (91.2)
PSSP	26	23 (88.5)	22	21 (95.5)
Macrolide Resistant	10	10 (100.0)	5	5 (100.0)
Stephylococcus Aereus	11	8 (72.7)	11	9 (81.8)

*10 or More lsolates for Omadacycline

Neither gastrointestinal side effects nor IV infusion reactions occurred more frequently in the omadacycline arm than in the comparator arm. Cardiovascular signs and symptoms and liver function test abnormalities occurred in both study arms with similar frequency.

This study was recently published in the New England Journal of Medicine (R Stets et al.. Omadacycline for Community-Acquired Bacterial Pneumonia, N Engl J Med 2019; 380:517-527).

Figure 13: TEAEs in CABP Trial

	Omadacycline (N = 382) n(%)	Moxifloxacin (N = 388) n(%)
Subjects with at Least One TEAE	157 (41.1)	188 (48.5)
ALT Increased	14 (3.7)	18 (4.6)
Hypertension	13 (3.4)	11 (2.8)
GGT Increased	10 (2.6)	8 (2.1)
Insomnia	10 (2.6)	8 (2.1)
Vomiting	10 (2.6)	6 (1.5)
Constipation	9 (2.4)	6 (1.5)
Nausea	9 (2.4)	21 (5.4)
AST Increased	8 (2.1)	14 (3.6)
Headache	8 (2.1)	5 (1.3)

Phase III trial – ABSSSI /OASIS-2

Paratek's third Phase III clinical study (OASIS-2) was an oral-only administration of omadycline in ABSSSI compared to oral-only linezolid. Oral, once daily omadycline met the FDA-specified primary efficacy endpoint of statistical non-inferiority in the modified intent-to-treat, or mITT, population (10% non-inferiority margin, 95% confidence interval) compared to oral, twice daily linezolid at the early clinical response, or ECR, 48-72 hours after initiation of therapy. The ECR rates for the omadycline and linezolid treatment arms were 87.5% and 82.5%, respectively. In addition, omadycline met specified co-primary endpoints for the EMA, which are key secondary endpoints for the FDA. For these endpoints, non-inferiority in the mITT and clinically evaluable populations in at the post treatment evaluation, seven to 14 days after end of treatment, omadycline demonstrated a high response rate and met statistical non-inferiority to linezolid for both populations using a pre-specified 95% confidence interval. High success rates were observed with response rates of 84.2% (omadycline) vs. 80.8% (linezolid) and 97.9% (omadycline) vs. 95.5% (linezolid), respectively.

The most common TEAEs in omadycline-treated patients (occurring in ≥ 3% of patients) were gastrointestinal adverse events of omadycline vs. linezolid included: vomiting (16.8% vs. 3.0%), nausea (30.2% vs. 7.6%), diarrhea (4.1% vs. 2.7%). In addition, alanine aminotransferase, or ALT, increase (5.2% with omadycline vs. 3.0% with linezolid), aspartate aminotransferase increases (4.6% with omadycline vs. 3.3 for linezolid) and headache (3.5% with omadycline vs. 2.2% with linezolid). Drug-related TEAEs were 37.8% for omadycline vs. 14.2% for linezolid (including gastrointestinal events). Discontinuation for TEAEs was uncommon, 1.6% for omadycline vs. 0.8% for linezolid. Serious TEAEs occurred in 1.4% of omadycline patients and 1.4% of linezolid patients; only one serious TEAE was considered related to the study drug and the event occurred in a linezolid patient.

Phase II studies

In a small study (N=111) conducted in cSSSI patients omadycline showed comparable efficacy and safety to linezolid IV/PO ± aztreonam. However, the design of the Phase II study (and a truncated Phase III study with 68 patients) was no longer consistent with newer FDA guidance issued for ABSSSI in 2008 which required, among other changes, an early efficacy read-out at 48-72 hours.

In addition, this early omadycline program used a 200 mg oral step-down dose that proved to not be bioequivalent to the 100 mg IV dose. Hence, these data are now considered supportive and cannot be merged easily with the larger pivotal program trials in ABSSSI and CABP that were conducted with FDA guidance and bioequivalent IV to oral step-down dosing.

A Phase II study (IV and oral) in patients with acute pyelonephritis was initiated by Paratek in 2018.

Phase I studies

Omadycline has been evaluated in more than 20 Phase I studies, including food-effect, age and gender, and renal / hepatic insufficiency studies.

Omadycline has a very favorable PK profile. It was absorbed well; its plasma $T_{1/2}$ of 14-20 hours permitted once-daily dosing. The drug was not metabolized and drug-drug interactions were minimal. In contrast to other tetracyclines, which paradoxically display dose-dependent increases in protein binding, 80% of omadycline remained available as free drug. Excretion was via biliary and urinary routes. Data from hepatic and renal impairment studies showed that dose adjustments are not needed for patients with either condition.

In bioequivalence studies, the 300 mg oral dose was found to match the area under the curve of the 100 mg IV dose within the 80-125% range.

Omadycline was negative on hERG testing and had no appreciable effect on cardiac conduction in a Thorough QT trial at supra-therapeutic doses. However, in animal tests and during Phase I, a dose-dependent elevation of blood pressure (systolic and diastolic) and heart rate were observed. Omadycline was found to be an acetylcholine antagonist for muscarinic receptor subtype M2, essentially acting as a vagolytic agent. In subsequent patient studies, these effects were less pronounced or absent and clinically asymptomatic. All Phase II and III studies included systematic cardiovascular pre- and post-dose monitoring of blood pressure and heart rate to further characterize these effects both qualitatively and quantitatively.

An ELF study showed excellent penetration of omadycline into bronchoalveolar lavage fluid and into alveolar macrophages.

A cystitis (uUTI) study was conducted by Paratek to obtain PK information for different oral dosing regimens of omadycline.

Durlobactam (ZL-2402)

Durlobactam is a novel β-lactamase inhibitor of class A, C, and D beta-lactamases. As such it is active against multiple members of the β-lactamases commonly found in Acinetobacter baumannii. In particular, it is a potent inhibitor of several Class D enzymes which confer MDR to many β-lactam antibiotics. In combination with sulbactam, durlobactam reduces the minimum inhibitory concentration, or MIC, against this organism and restores susceptibility to sulbactam. It is being developed by Entasis as SUL-DUR, a combination of durlobactam and sulbactam. The microbiologic efficacy of this combination was demonstrated in large studies of well-characterized MDR Acinetobacter isolates from diverse regions, including Asia. SUL-DUR was bactericidal and active against penem-resistant Acinetobacter organisms. SUL-DUR was synergistic with imipenem, further lowering MICs on in-vitro testing. The FDA has granted SUL-DUR QIDP, Fast Track and Priority Review status.

Durlobactam without sulbactam but in combination with other β-lactams lowered the MICs for E. coli, K. pneumoniae and P. aeruginosa compared to the partner β-lactam antibiotic alone. Entasis has conducted a comprehensive Phase I safety and PK program for durlobactam. Single ascending dose and multiple ascending dose studies showed that durlobactam alone and in combination with sulbactam or imipenem is well tolerated and safe. There were no noticeable drug-drug interactions.

Entasis plans to develop SUL-DUR for the treatment of severe A. baumannii infections. Entasis has finished a Phase II cUTI trial in 2018 and started enrollment in the pivotal Phase III trial in MDR Acinetobacter infections in the second half of 2019.

Background on Acinetobacters

Acinetobacter is one of the most resistant pathogens encountered in clinical practice. It is one of the ESKAPE pathogens, a leading cause of nosocomial infections throughout the world, for which new treatment options are needed as these organisms are MDR to most antibiotics currently available. Approximately 60% of Acinetobacter isolates are carbapenem resistant (so-called CRAB pathogens) and can only be treated with colistin, a rather toxic drug, or tigecycline which is often ineffective.

Of great concern, colistin resistance has been reported in recent years, especially from Asia, in E. coli and in K. pneumoniae. So far, there is only scattered report of mcr-1 resistance in Acinetobacter have been reported but the risk is high that chromosomal and – more ominously – plasmid mediated resistance may spread to other bacteria, especially in an environment with high veterinary colistin use like in China. Recent case reports of successful treatment with experimental phage therapy as a last resort when available antibiotics fail. Severe Acinetobacter infections are associated with mortality rates of 50-60% despite intensive medical care. These infections usually present as blood-stream infections or hospital-acquired pneumonia. Less severe infections of the skin and urinary tract are not uncommon.

The frequency of Acinetobacter infections is on the rise world-wide. In the United States and the European Union, the incidence of infection is between 80,000 and 120,000 patients per year in each region. The incidence is higher in the Asia Pacific region and especially in China where the organism ranks among the most frequent isolates in intensive care unit patients. In 2015, over 180,000 infections were reported from China alone. In Japan, over 30,000 cases were reported for 2015, which is an increase of approximately 50% since 2012.

Background on Sulbactam

Sulbactam, a β-lactam derivative, has been in use since the 1980s. It is a IV BLI used in combination with ampicillin, known in the United States as Unasyn and widely used since 1987. It is an β-lactam with a proven safety record. Sulbactam has antibiotic activity of its own, notably against Acinetobacter. However, β-lactamase-mediated resistance to sulbactam has developed and is now common in Acinetobacter.

Durlobactam is a non-β-lactam BLI of the DBO class. It has structural similarities to avibactam, a BLI recently approved in combination with ceftazidime (Avycaz). However, durlobactam has demonstrated much greater potency against many β-lactamases, especially the Class D OXA enzymes prevalent in Acinetobacter.

Overview of Our License Agreements

Tesaro (now GSK)

In September 2016, we entered into a collaboration, development and license agreement with Tesaro (now GSK) under which we obtained an exclusive sublicense under certain patents and know-how that Tesaro licensed from Merck Corp. and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize Tesaro's proprietary PARP inhibitor, niraparib (ZEJULA), in mainland China, Hong Kong and Macau, or licensed territory, in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). We also obtained the right of first negotiation to obtain a license to develop and commercialize certain follow-on compounds of niraparib being developed by Tesaro (now GSK) in our licensed field and licensed territory. Under the agreement, we agreed not to research, develop or commercialize certain competing products and we also granted Tesaro (now GSK) the right of first refusal to license certain immuno-oncology assets developed by us.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory. We are also responsible for funding all development and commercialization of the licensed products in our licensed territory.

We also agree to take any action or omission reasonably requested by Tesaro (now GSK) that is necessary or advisable to maintain compliance with the terms of the license agreements between Tesaro (now GSK) and each of Merck Corp. and AstraZeneca UK Limited.

Under the terms of the agreement, we made an upfront payment of $15.0 million and accrued a development milestone payment of $3.5 million to Tesaro (now GSK). On top of those, if we achieve other specified regulatory, development and commercialization milestones, we may be additionally required to pay further milestone payments of up to $36.0 million to Tesaro (now GSK). In addition, if we successfully develop and commercialize the licensed products, we will pay Tesaro (now GSK) tiered royalties at percentage rates in the mid- to high-teens on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. In February 2018, we entered into an amendment with Tesaro (now GSK) to eliminate Tesaro's option to co-market niraparib in the licensed territory.

The agreement with Tesaro (now GSK) will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy or insolvency or by mutual agreement of the parties. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to Tesaro (now GSK). Upon early termination of the agreement, we must grant to Tesaro (now GSK) an exclusive license under certain of our intellectual property to develop and commercialize the licensed products outside the licensed territory.

Novocure

In September 2018, we entered into a license and collaboration agreement with Novocure. Under the terms of the agreement, Novocure exclusively licensed to us the rights to perform clinical studies, sublicensable to affiliates and third parties (subject to Novocure's consent), sell, offer for sale and import Tumor Treating Fields products in the field of oncology, each, a licensed product and collectively, the licensed products, in China, Hong Kong, Macau and Taiwan, or the territory. In partial consideration for the license grant to us for the territory, we paid Novocure a non-refundable, upfront license fee in the amount of $15.0 million. We also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $78.0 million, and tiered royalties at percentage rates from ten up to the mid-teens on the net sales of the Licensed Products in the Territory.

We will purchase licensed products exclusively from Novocure at Novocure's fully burdened manufacturing cost. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such licensed product and such region as specified in the agreement. Each party may terminate the agreement upon the material breach of the agreement by the other party, subject to certain cure periods. In addition, we may terminate the agreement for convenience on twelve months' prior notice prior to commercializing a licensed product and on eighteen months' prior notice after commercializing a licensed product, and Novocure may terminate the agreement due to our diligence failure or material FCPA violation, subject to certain cure periods and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the agreement.

Deciphera

In June 2019, we entered into a license agreement with Deciphera. Under the terms of the agreement, Deciphera exclusively licensed to us the rights to perform clinical studies, sublicenseable to affiliates without Deciphera's consent and third parties (subject to Deciphera's consent), sell, offer for sale and import ripretinib, each, a licensed product, in the field of the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in China, Hong Kong, Macau and Taiwan. In partial consideration for the license grant to us for the territory, we paid Deciphera a non-refundable, up-front license fee in the amount of $20.0 million and a milestone payment of $5.0 million. We also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of $180.0 million, and tiered royalties at percentage rates from low- to high-teens on the net sales of the licensed products in the territory.

We will purchase the licensed products exclusively from Deciphera at a certain mark up of Deciphera's fully burdened manufacturing cost. The agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such licensed product and such region as specified in the agreement. Each party may terminate the agreement upon the material breach of a material term of the agreement by the other party, subject to the ability to cure. In addition, we may terminate the agreement for convenience on 180 days' prior notice, and Deciphera may terminate the agreement due to our patent challenge against certain Deciphera's patents, subject to the ability to cure and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the agreement.

Regeneron

In April 2020, we entered into a Collaboration Agreement with a wholly-owned subsidiary of Regeneron Pharmaceuticals, Inc., or Regeneron. Under the terms of the agreement, Regeneron will receive a $30.0 million non-refundable, upfront payment and is eligible to receive up to $160.0 million in additional regulatory and sales milestones. We will contribute to the global development costs for REGN1979 for certain trials and will receive the rights to develop and exclusively commercialize REGN1979 in oncology in mainland China, Hong Kong, Taiwan and Macau. Additionally, we will make payments to Regeneron based on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron will be responsible for the manufacture and supply of REGN1979 for development and commercialization in the region.

MacroGenics

In November 2018, we entered into a collaboration agreement with MacroGenics. Under the terms of the collaboration agreement, MacroGenics exclusively licensed to us regional development and commercialization rights to margetuximab, MGD-013 and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, or the TRIDENT molecule, and, together with margetuximab and MGD0213, each, a licensed product, in China, Hong Kong,

Macau and Taiwan, or the territory. In partial consideration for the license grant to us for the territory, we paid MacroGenics a non-refundable, up-front license fee in the amount of $25.0 million. We also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of $ 1 4 0.0 million, and tiered royalties at percentage rates of mid-teens to 20% for net sales of Margetuximab in the territory, mid-teens for net sales of MGD-013 in the territory and 10% for net sales of TRIDENT molecule in the territory.

As part of the collaborative clinical development effort, we and MacroGenics intend to initiate a global study using combination regimens containing margetuximab in order to maximize potential clinical benefit in gastric cancer, the fifth most common cancer in the world and the second most common in China.

The collaboration agreement continues, on a region-by-region and licensed product-by-licensed product basis, in effect until the expiration of and payment by us of all of our payment obligations applicable to such licensed product and such region as specified in the collaboration agreement. Each party may terminate the collaboration agreement upon the material breach of the collaboration agreement by the other party, subject to certain cure periods. In addition, at any time after November 29, 2020, we may terminate the collaboration agreement for convenience with prior notice to MacroGenics. MacroGenics may terminate the collaboration agreement in its entirety or on a licensed product-by-licensed product basis with prior notice if one or more major safety issues have occurred with respect to such licensed product prior to the first commercial sale of such licensed product in the territory and MacroGenics has discontinued the global development, manufacturing and commercialization activities with respect to such licensed product.

Incyte

In July 2019, we entered into a collaboration and license Agreement with Incyte. Under the terms of the agreement, Incyte exclusively licensed to us the rights to perform clinical studies, sublicenseable to affiliates in China, Hong Kong, Macau and Taiwan without Incyte's consent and other affiliates and third parties (subject to Incyte's consent), sell, offer for sale and import INCMGA0012 (PD-1) in the filed of the treatment, palliation, diagnosis or prevention of diseases in the fields of hematology or oncology in humans in China, Hong Kong, Macau and Taiwan. In partial consideration for the license grant to us for the territory, we paid Incyte a non-refundable, up-front license fee in the amount of $17.5 million. We also agreed to pay certain development, regulatory and commercial milestone payments of up to an aggregate of $60.0 million, and tiered royalties at percentage rates from low- to high-twenties on the net sales of INCMGA0012 (PD-1) in China, Hong Kong, Macau and Taiwan.

We will purchase Licensed Products exclusively from Incyte at Incyte's fully burdened manufacturing cost. The agreement continues, on a region-by-region and Licensed Product-by-Licensed Product basis, in effect until the expiration of and payment by us of all of our royalty payment obligations applicable to such Licensed Product and such region as specified in the agreement. Each party may terminate the agreement upon the material breach of a material term of the agreement by the other party, subject to the ability to cure. In addition, we may terminate the agreement for convenience on 60 days' prior notice, and Incyte may terminate the agreement due to our development or commercialization diligence failures, subject to the ability to cure and dispute resolution mechanisms if disputes arise with respect to such failure or material violation, each as defined in the agreement.

Five Prime

In December 2017, we entered into a collaboration and license agreement with Five Prime, under which we obtained exclusive rights to develop and commercialize Five Prime's proprietary afucosylated FGFR2b antibody known as bemarituzumab (FPA144), and all fragments, conjugates, derivatives and modifications thereof in China, Hong Kong, Macau and Taiwan, or the licensed territory.

We are responsible for (i) developing and commercializing licensed products under a territory development plan (ii) performing certain development activities to support Five Prime's global development and registration of licensed products, including Five Prime's global Phase III registrational trial of bemarituzumab (FPA144) in combination with FOLFOX in front-line gastric and gastroesophageal cancer, or the bemarituzumab (FPA144)-004 Study, in the licensed territory under a global development plan.

Under the terms of the agreement, we made an upfront payment of $5.0 million and a milestone payment of $2.0 million to Five Prime. Additionally, we may be required to pay further development and regulatory milestone payments of up to an aggregate of $37.0 million to Five Prime.

We are also be obligated to pay Five Prime a royalty, on a licensed product-by-licensed product and region-by-region basis, in the high teens or low twenties, depending on the number of patients we enroll in the bemarituzumab (FPA144)-004 study, subject to reduction in certain circumstances, on net sales of each licensed product in the licensed territory until the latest of (i) the 11th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region.

Under the terms of the agreement, provided that we enroll and treat a specified number of patients in the bemarituzumab (FPA144)-004 study in China, we are eligible to receive a low single-digit percentage royalty, on a licensed product-by-licensed product basis on net sales of a licensed product outside the licensed territory until the 10th anniversary of the first commercial sale of each such licensed product outside the licensed territory.

Unless earlier terminated by either party, the agreement will expire on a licensed product-by-licensed product and region-by-region basis upon the expiration of our payment obligations with respect to each licensed product under the agreement. We may terminate the agreement in its entirety at any time with advance written notice. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. Five Prime may terminate the agreement in its entirety with written notice for the material breach of our diligence obligations with respect to development and obtaining marketing approval, and may terminate the agreement on a region-by-region basis for the breach of our diligence obligations with respect to timely commercialization of a licensed product in a region following marketing approval. Five Prime may terminate the agreement in its entirety if we or one of our affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of Five Prime's patents in the licensed territory. Either party also may terminate the agreement in its entirety upon certain insolvency events involving the other party.

Paratek

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda, Ltd., a subsidiary of Paratek, under which we obtained both an exclusive license under certain patents and know-how of Paratek Bermuda Ltd. and an exclusive sub-license under certain intellectual property that Paratek Bermuda Ltd. licensed from Tufts University to develop, manufacture, use, sell, import and commercialize omadacycline (ZL-2401) in mainland China, Hong Kong, Macau and Taiwan, or licensed territory, in the field of all human therapeutic and preventative uses other than biodefense, or the licensed field. Under certain circumstances, our exclusive sub-license to certain intellectual property Paratek Bermuda Ltd. licensed from Tufts University may be converted to a non-exclusive license if Paratek Bermuda Ltd.'s exclusive license from Tufts University is converted to a non-exclusive license under the Tufts Agreement. We also obtained the right of first negotiation to be Paratek Bermuda Ltd.'s partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek Bermuda Ltd. retains the right to manufacture the licensed product in our licensed territory for use outside our licensed territory. We also granted to Paratek Bermuda Ltd. a non-exclusive license to certain of our intellectual property for Paratek Bermuda Ltd. to develop and commercialize licensed products outside of our licensed territory. Under the agreement, we agreed not to commercialize certain competing products in our licensed territory. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory, including making certain regulatory filings within a specified period of time.

Under the terms of the agreement, we made an upfront payment of $7.5 million and a milestone payment of $5.0 million to Paratek Bermuda Ltd. and we may be required to pay further milestone payments of up to an aggregate of $49.5 million to Paratek Bermuda Ltd. for the achievement of certain development and sales milestone events. In addition, we will pay to Paratek Bermuda Ltd. tiered royalties at percentage rates in the range of low- to mid-teens on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The agreement with Paratek Bermuda Ltd. will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to Paratek Bermuda Ltd. Paratek Bermuda Ltd. has the right to terminate the agreement if we challenge its patents. Upon termination of the agreement, our license of certain intellectual property to Paratek Bermuda Ltd. will continue for Paratek Bermuda Ltd. to develop and commercialize licensed products worldwide.

Entasis

In April 2018, we entered into a collaboration and license agreement with Entasis under which we obtained exclusive rights to develop and commercialize Entasis' proprietary compounds known as durlobactam and SUL-DUR, with the possibility of developing and commercializing a combination of such compounds with Imipenem, in mainland China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan, or the territory. Our rights to develop and commercialize the licensed products are limited to the lead product (SUL-DUR) until such product receives FDA approval in the U.S.

Under the terms of the agreement, we are responsible for (i) developing and commercializing the licensed products in the territory under a mutually agreed development plan and (ii) providing Entasis (or its CRO) with clinical and financial support in the territory for the global pivotal Phase III clinical trial of SUL-DUR as set forth in mutually agreed development plans.

We made an upfront payment of $5.0 million and two development milestone payments of $7.0 million to Entasis. Additionally, we may be required to pay Entasis development, regulatory and research milestone payments (other than existing ones) and commercial milestone payments of up to an aggregate of $91.6 million. We are also responsible for a portion of the costs of the global pivotal Phase III clinical trial of SUL-DUR outside of the territory.

We are also obligated to pay Entasis a royalty based on a percentage of net sales of licensed products ranging from the high single digits to low teens, depending on the amount of net sales of licensed products in the territory, subject to reduction in certain circumstances, until, with respect to a licensed product in a region in the territory, the latest of (i) the 10th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region.

Unless earlier terminated by either party, the agreement will expire on a country-by-country basis upon the expiration of our payment obligations applicable to such country under the agreement. We may terminate the agreement in its entirety at any time with advance written notice. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. Entasis may terminate the agreement on a country-by-country basis if we cease to commercialize the licensed products in such country for a certain period of time. Entasis may terminate the agreement in its entirety if we or one of our affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of Entasis's patents in the licensed territory. Either party also may terminate the agreement in its entirety upon certain insolvency events involving the other party.

Bristol-Myers Squibb

In March 2015, we entered into a collaboration and license agreement with BMS, under which we obtained an exclusive license under certain patents and know-how of BMS to develop, manufacture, use, sell, import and commercialize BMS's proprietary multi-targeted kinase inhibitor, brivanib in mainland China, Hong Kong and Macau, or the licensed territory, in the field of diagnosis, prevention, treatment or control of oncology indications, or licensed field, with the exclusive right to expand our licensed territory to include Taiwan and Korea under certain conditions. BMS retains the non-exclusive right to use the licensed compounds to conduct internal research and the exclusive right to use the licensed compounds to manufacture compounds that are not brivanib. Under the agreement, we agreed not to develop and commercialize certain competing products for specified time periods.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory. BMS has the option to elect to co-promote the licensed products in our licensed territory. If BMS exercises its co-promotion option, BMS will pay us an option exercise fee and we will share equally with BMS the operating profits and losses of the licensed products in our licensed territory.

If BMS does not exercise its co-promotion option, we may be required to pay BMS milestone payments for the achievement of certain development and sales milestone events of up to an aggregate of $114.5 million, and also tiered royalties at percentage rates in the mid- to high-teens on the net sales of the licensed products in our licensed territory, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the twelfth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

We also have the right to opt-out of the commercialization of the licensed products in our licensed territory under certain conditions. If we elect to opt-out, BMS will have the right to commercialize the licensed products in our licensed territory and will pay us royalties on the net sales of the licensed products in our licensed territory.

BMS has the option to use the data generated by us from our development of the licensed products to seek regulatory approval of the licensed products outside our licensed territory, and if BMS exercises such option, BMS will be obligated to make certain payments to us, including upfront, milestone and royalty payments.

The agreement with BMS will remain in effect until the expiration of all payment obligations, and may be earlier terminated by either party for the other party's uncured material breach, safety reasons or failure of the development of the licensed products. In addition, we have the right to terminate the agreement for convenience after a certain specified time period upon advance notice to BMS. BMS may also terminate the agreement for our bankruptcy or insolvency.

Sanofi

In July 2015, we entered into a license agreement with Sanofi, under which we obtained an exclusive and worldwide license under certain patents and know-how of Sanofi to develop, manufacture, use, sell, import and commercialize Sanofi's ALK inhibitor, or the licensed compound, or ZL-2302, for any oncology indications in humans. Under the terms of the agreement, we made upfront payments to Sanofi totaling $0.5 million. Due to changes in the competitive landscape, we intend to terminate the license agreement in 2020. If we do not terminate our license agreement with Sanofi, we may be required to make milestone payments to Sanofi of up to an aggregate of $31.0 million for the achievement of certain development and regulatory milestone events and tiered royalties at percentage rates in the range of high single digits to low double digits on the net sales of the licensed products. Upon any termination of the agreement, in addition to other obligations, we must grant to Sanofi an exclusive license under certain of our intellectual property to commercialize the licensed product.

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our management's research, development and commercialization experience provide us with competitive advantages, we face competition from global and China-based biopharmaceutical companies, including specialty pharmaceutical companies, generic and biosimilar drug companies, biologics drug companies, academic institutions, government agencies and research institutions.

For our global product candidates, we expect to face competition from a broad range of global and local pharmaceutical companies. Many of our competitors have significantly greater financial, technical and human resources than we have, and mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future drug candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

Patents and Other Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our drug candidates and our core technologies and other know-how to operate without infringing, misappropriating or otherwise violating on the proprietary rights of others and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We expect that we will seek to protect our proprietary and intellectual property position by, among other methods, licensing or filing our own U.S., international and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties.

Patents

Patents, patent applications and other intellectual property rights are important in the sector in which we operate. We consider on a case-by-case basis filing patent applications with a view to protecting certain innovative products, processes, and methods of treatment. We may also license or acquire rights to patents, patent applications or other intellectual property rights owned by third parties, academic partners or commercial companies which are of interest to us.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our drug candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive or license in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of our patents and patent applications over third-party patents and patent applications. In addition, because of the extensive time required for clinical development and regulatory review of a drug candidate we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information regarding the risks related to our intellectual property, please see "Item 3.D. Risk Factors—Risks Related to Intellectual Property."

ZEJULA

As of December 31, 2019, we exclusively licensed two issued patents in China directed to ZEJULA's free base compound, and salts thereof, and analogues of ZEJULA. These issued patents are projected to expire between 2027 and 2028. We also exclusively licensed one pending patent application in China directed to a salt that covers 4-methylbenzenesulfonate monohydrate, the active pharmaceutical ingredient, or API, of ZEJULA. If this patent application issues as a patent, such patent will be projected to expire in 2029. We have filed an application in China and a PCT application that cover intermediate synthesis process. The claims in China application had been allowed, and the PCT application is in the national phases, and will enter the United States, the European Union, Israel, Japan, Korea and India. Zai owns this PRC application and the PCT application.

Optune (Tumor Treating Fields)

As of December 31, 2019, we licensed eight issued patents in China and Hong Kong that relate to Optune (Tumor Treating Fields). An additional seven patent applications that relate to Optune (Tumor Treating Fields) are pending. We are pursuing patent rights to protect its rights in these technologies and has continued its efforts to secure patent rights in China for its devices and technologies for applying electric fields to a patient for treating a disease or condition, especially diseases that promote tumor growth. We are pursuing patent rights to protect its rights in these technologies.

Ripretinib

As of December 31, 2019, we exclusively licensed one issued patent and two pending patent applications in China directed to dihydronaphthyridines and related compounds, the API of ripretinib. These issued patent and pending patent applications are projected to expire between 2032. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China.

Margetuximab

As of December 31, 2019, we exclusively licensed two pending patent applications in China and one issued patent in Hong Kong. The pending patent applications in this portfolio cover antibody sequences and therapeutic uses of margetuximab. The issued patent and any patents issuing from the currently pending applications are projected to expire in 2029.

INCMGA0012 (PD-1)

As of December 31, 2019, we exclusively licensed two pending patent applications in China, two pending patent applications in Taiwan and one pending patent application in Hong Kong directed to the API of INCMGA0012 (PD-1). If these patent applications issue as patents, such patents will be projected to expire in 2036 to 2039. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong or Taiwan.

MGD-013

As of December 31, 2019, we exclusively licensed three pending patent applications in China, two issued patents in Hong Kong and three pending patent applications in Taiwan. The pending patent applications in this portfolio cover antibody sequences and therapeutic uses of MGD-013. The issued patents and any patents issuing from the currently pending applications are projected to expire between 2035 and 2036 .

Bemarituzumab (FPA144)

As of December 31, 2019, we exclusively licensed one issued patent in China and one issued patent in Hong Kong. These issued patents are directed to certain anti-FGFR2b antibodies, and are projected to expire in 2029. We have also exclusively licensed one pending patent application in China, two pending patent applications in Taiwan, one pending patent application in Hong Kong. If issued, claims of these patent applications are projected to expire between 2034 and 2036. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong and Taiwan.

Omadacycline (ZL-2401)

As of December 31, 2019, we exclusively licensed four issued patents in China directed to omadacycline's compound, formulations and crystal form and one pending patent application in China directed to other crystalline forms of omadacycline. The issued composition of matter patent covering omadacycline is projected to expire in 2021 and the other two issued patents are projected to expire in 2029. If the two patent applications are issued, they are expected to expire in 2029. We have also exclusively licensed two issued patents in Hong Kong and Taiwan, respectively that cover a crystalline salt form of omadacycline, which expire in 2029. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of China, Hong Kong and Taiwan.

Durlobactam

As of December 31, 2019, we exclusively licensed one issued patent in China, one issued patent in Japan, and a corresponding issued patent or pending patent application in each of several additional jurisdictions in the territory covered by our agreement with Entasis, including Australia, Hong Kong, Taiwan and Korea. These issued patents or pending applications are directed to certain beta-lactamase inhibitor compounds, including durlobactam, and are projected to expire in 2033. We have also exclusively licensed a second family of patent applications having one pending patent application in each of China, Japan, Australia, Taiwan, Korea and four other jurisdictions in the territory. If issued, claims of these patent applications are projected to expire in 2035. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the territory of the Entasis Agreement.

Brivanib (ZL-2301)

As of December 31, 2019, we exclusively licensed five issued patents in China, one issued patent in Taiwan and one issued patent in Hong Kong that relate to brivanib. Of these issued patents, one patent in China is a composition-of-matter patent that covers the brivanib compound and its analogues. One patent in China covers the medical use of brivanib. These patents are projected to expire in 2023. Our exclusively licensed patents also include a patent in China that covers a manufacturing process for intermediates useful in the synthesis of brivanib's API. This patent is projected to expire in 2027. In addition, one patent we exclusively licensed in China covers a crystal form of brivanib alaninate and is projected to expire in 2026. The issued patent in Hong Kong that we exclusively licensed is projected to expire in 2023. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than China and Hong Kong.

Undisclosed multi-specific TRIDENT molecule

As of December 31, 2019, we exclusively licensed one pending international patent application and one pending patent application in Taiwan. Patents issuing from the pending applications are projected to expire in 2038.

Patent Term

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, a patent term is 20 years from the earliest filing date of a non-provisional patent application. Under China Patent Law, the term of patent protection starts from the date of application. Patents relating to inventions are effective for twenty years, and utility models and designs are effective for ten years from the date of application.

The above expiration dates are exclusive of any patent term adjustments or patent term extensions that may be available under applicable law. The laws of each jurisdiction vary, and patent term adjustment or patent term extension may not be available in any or all jurisdictions in which we own or license patents. For example, there are currently no patent term adjustments or patent term extensions available for issued patents in China. However, the government recently announced a proposal which is under consideration to allow a five-year patent term extension for innovative drugs if they will be concurrently reviewed for marketing authorizations in and outside China.

Trade Secrets

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. For more information regarding the risks related to our trade secrets, please see "Item 3.D. Risk Factors—Risks Related to Intellectual Property—If we are unable to maintain the confidentiality of our trade secrets, our business and competitive position may be harmed."

Trademarks and domain names

We conduct our business using trademarks with various forms of the "ZAI LAB" and "□□□□" brands, as well as domain names incorporating some or all of these trademarks.

Employees

As of December 31, 2019, we employed a total of 692 full-time employees, including a total of 125 employees with M.D. or Ph.D. degrees. Of our workforce, 300 employees are engaged in research and development and 298 employees are engaged in commercial and sales. None of our employees are represented by a labor union or covered by a collective bargaining agreement.

Raw Materials and Supplies

Currently, we obtain raw materials for our clinical trial activities from multiple suppliers who we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, a risk exists that an interruption to supplies would materially harm our business. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

While we do experience price fluctuations associated with our raw materials, we have not experienced any material disruptions in the supply of these raw materials in the past.

Quality Control and Assurance

We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing and testing of our drug candidates. We have established a strict quality control system in accordance with NMPA regulations. Our laboratories are staffed with highly educated and skilled technicians to ensure quality of all batches of products released. We monitor our operations in real time throughout the entire production process, from inspection of raw and auxiliary materials, to manufacture and delivery of finished products to clinical testing at hospitals. Our quality assurance team is also responsible for ensuring that we are in compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies and managing the internal and external quality performance of the Company.

Regulation

Government Regulation of Pharmaceutical Product Development and Approval

PRC regulation of pharmaceutical product development and approval

Since China's entry into the World Trade Organization in 2001, the PRC government has made significant efforts to standardize regulations, develop its pharmaceutical regulatory system and strengthen intellectual property protection.

In October 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of the PRC Communist Party jointly issued a mandatory plan to further the reform of the review and approval system and encourage the innovation of drugs and medical devices, or the Innovation Opinion. The expedited programs and other advantages under this and other recent reforms encourage drug manufacturers to seek marketing approval in China first and develop drugs in high priority disease areas, such as oncology, or rare disease areas.

To implement the regulatory reform introduced by Innovation Opinion, the Standing Committee of the NPC and the NMPA are currently revising the fundamental law, regulations and rules regulating pharmaceutical products and the industry, which includes the framework law known as the PRC Drug Administration Law. The newly amended PRC Drug Administration Law became effective on December 1, 2019. The NMPA has promulgated two key implementing regulations for the PRC Drug Administration Law: (i) the amended Drug Registration Regulation; and (ii) the amended PRC Drug Manufacturing Regulation. Both will take effect on July 1, 2020. However, as of April 29, 2020, detailed implementing rules on drug classification, patent linkage and patent term extension, among others, have not yet been promulgated.

Regulatory authorities

In China, the newly formed NMPA is the authority under the State Administration for Market Regulation that monitors and supervises the administration of pharmaceutical products, medical appliances and equipment, and cosmetics. The NMPA's predecessor, the CFDA, was established in March 2013 and separated from the Ministry of Health of China, or the MOH, as part of the institutional reform of the State Council. Predecessors of the NMPA also include the former SFDA that was established in March 2003 and the State Drug Administration that was established in August 1998. The primary responsibilities of the NMPA include:

- monitoring and supervising the administration of pharmaceutical products, medical appliances and equipment, as well as cosmetics in China;
- formulating administrative rules and policies concerning the supervision and administration of the pharmaceutical, medical device, and cosmetics industry;
- evaluating, registering and approving of new drugs, generic drugs, imported drugs and traditional Chinese medicine, or TCM;

- approving and issuing permits for the manufacture and export/import of pharmaceutical products, as well as medical appliances and equipment, and approving the establishment of enterprises to be engaged in the manufacture and distribution of pharmaceutical products; and

- examining and evaluating the safety of pharmaceutical products, medical devices, and cosmetics and handling significant accidents involving these products.

The National Health and Family Planning Commission, or NHFPC, is rebranded as the National Health Commission, or NHC. The NHC is an authority at the ministerial level under the State Council and is primarily responsible for national public health. The NHC combines the responsibilities of the former NHFPC, the Leading Group Overseeing Medical and Healthcare Reform under the State Council, the China National Working Commission on Aging, partial responsibilities of the Ministry of Industry and Information Technology in relation to tobacco control, and partial responsibilities from the State Administration of Work Safety in relation to occupational safety. The predecessor of NHFPC is the MOH. Following the establishment of the former SFDA in 2003, the MOH was put in charge of the overall administration of the national health in China excluding the pharmaceutical industry. The NHC performs a variety of tasks in relation to the health industry such as establishing and overseeing the operation of medical institutes, which also serve as clinical trial sites, regulating the licensure of hospitals and producing professional codes of ethics for public medical personnel. The NHC plays a significant role in drug reimbursement. The NHC and its local counterparts at or below provincial-level local governments also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, which is the chief means through which public hospitals and their internal pharmacies acquire drugs. The NHC is also responsible for overseas affairs, such as dealings with overseas companies and governments.

The restructuring at the state, municipal and county level authorities has been mostly completed as of July 2019.

Healthcare System Reform

The PRC government recently promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the Central Committee of the PRC Communist Party and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System. The State Council issued the Notice on the Issuance of the 13 th Five-year Plan on Strengthening the Reform of Healthcare System on December 27, 2016. On April 21, 2016, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2016. Highlights of these healthcare reform policies and regulations include the following:

- One of the main objectives of the reform was to establish a basic healthcare system to cover both urban and rural residents and provide the Chinese people with safe, effective, convenient and affordable healthcare services. As of 2017, basic medical insurance coverage has reached more than 95% of the country's population. By 2020, a basic healthcare system covering both urban and rural residents should be established.

- Another main objective of reform was to improve the healthcare system, through the reform and development of a graded diagnosis and treatment system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision.

- The reforms aimed to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education were to be provided to urban and rural residents. In the meantime, the reforms also encouraged innovations by pharmaceutical companies to eliminate pharmaceutical products that fail to prove definite efficacy and positive risk-benefit ratio.

- The key tasks of the reform in the 13 th five-year period were as follows: (1) to deepen the reform of public hospitals, (2) to accelerate the development of a graded diagnosis and treatment system, (3) to consolidate and improve the universal medical insurance system, (4) to guarantee drug supply, (5) to establish and improve a comprehensive supervision system, (6) to cultivate talented health-care practitioners, (7) to stabilize and perfect the basic public health service equalization system, (8) to advance the construction of health information technology, (9) to accelerate the development of the health services industry generally, and (10) to strengthen organization and implementation.

Drug Administration Laws and Regulations

The PRC Drug Administration Law as promulgated by the Standing Committee of the National People's Congress in 1984 and the Implementing Measures of the PRC Drug Administration Law as promulgated by the MOH in 1989 have laid down the legal framework for the establishment of pharmaceutical manufacturing enterprises and pharmaceutical trading enterprises and for the administration of pharmaceutical products including the development and manufacturing of new drugs and medicinal preparations by medical institutions. The PRC Drug Administration Law also regulates the packaging, trademarks and advertisements of pharmaceutical products in China.

Certain amendments to the PRC Drug Administration Law took effect on December 1, 2001. Subsequent amendments were also made on December 28, 2013, April 24, 2015, and August 26, 2019. They were formulated to strengthen the supervision and administration of pharmaceutical products, and to ensure the quality of pharmaceutical products and the safety of pharmaceutical products for human use. The current PRC Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products. It regulates and prescribes a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products.

According to the current PRC Drug Administration Law, no pharmaceutical products may be produced in China without a pharmaceutical production license. A local manufacturer of pharmaceutical products must obtain a pharmaceutical production license from one of the provincial administration of medical products in order to commence production of pharmaceuticals. Prior to granting such license, the relevant government authority will inspect the manufacturer's production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards.

In August 2019, the Standing Committee of the NPC promulgated the latest Drug Administration Law, or the 2019 Amendment, which became effective in December 2019. The 2019 Amendment brought a series of changes to the drug supervision and administration system, including conditional approvals of drugs, traceability system of drugs, the cancellation of relevant certification in relation to Good Manufacturing Practice, and Good Supply Practice, and the formalization of the drug marketing authorization holder system, or the MAH system, pursuant to which the marketing authorization holder should assume responsibilities for non-clinical studies, clinical trials, manufacturing and marketing, post-marketing studies, monitoring, reporting and handling of adverse reactions of the drug. The 2019 Amendment also stipulates that the state supports the innovation of drugs with clinical value and specific or special effects on human diseases, encourages the development of drugs with new therapeutic mechanisms and have multi-targeted, systematic regulatory and intervention functions on human body and promotes the technological advancement of drugs.

China Implementing Regulations of the Drug Administration Law promulgated by the State Council took effect on September 15, 2002, were amended on February 6, 2016 and March 2, 2019 respectively, and serve to provide detailed implementation regulations for the PRC Drug Administration Law.

Good Laboratories Practice Certification for Nonclinical Research

To improve the quality of animal research, the former SFDA promulgated the Good Laboratories Practice of Pre-clinical Laboratory in 2003, or the GLP 2003, and began to conduct the certification program of the GLP. The GLP 2003 was then abolished and replaced by the Good Laboratories Practice of Pre-clinical Laboratory promulgated in 2017. In April 2007, the former SFDA promulgated the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, providing that the former SFDA (now the NMPA) is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Pre-clinical Laboratory, the former SFDA (now the NMPA) decides whether an institution is qualified for undertaking pharmaceutical nonclinical research upon the evaluation of the institution's organizational administration, personnel, laboratory equipment and facilities and its operation and management of nonclinical pharmaceutical projects. If all requirements are met, a GLP Certification will be issued by the former SFDA (now the NMPA) and published on the government website.

Collecting and Using Patients' Biospecimens and Derived Data

In June 1998, the Ministry of Science and Technology, or MOST, and the former MOH jointly established the Rules for Protecting and Utilizing Human Genetic Resources in China. In July 2015, the MOST issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of China, which provides that foreign-invested sponsors that collect and use patients' biospecimens in clinical trials shall be required to file with the China Human Genetic Resources Administrative Office, or the HGRAO, through its online system.

In October 2017, the MOST issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for collecting and using human genetic resources for the purpose of commercializing a drug in China.

In June 2019, the State Council of PRC issued the Regulation on the Administration of PRC Human Genetic Resources, which formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for international clinical trials using PRC patients' biospecimens at clinical study sites without involving the export of such biospecimens outside of China. Under the new rule, a notification filing specifying the type, quantity and usage of the biospecimens, among others, with the HGRAO is required before conducting such clinical trials. The collection and use of PRC patients' biospecimens in international collaboration in basic scientific research involving export are still subject to the approval of the HGRAO.

Data Privacy and Data Protection

China continues to strengthen its regulation of network security, data protection, and personal information (including personal health information). For example, the Cyber Security Law of China, or the Cyber Security Law, which became effective in 2017, provides China's first national-level network and data security regulation. The Cyber Security Law regulates network operators, a broad category that covers all organizations in China that own, operate or manage computer networks, and requires them to take certain organizational and technical measures to ensure the security of their networks and data stored on their networks. Additional regulations, guidelines, and measures under the framework of the Cyber Security Law are expected to be adopted and require more stringent compliance requirements. Some of these measures have already been published in draft form, including the draft rules on cross-border data transfers published by the Cybersecurity Administration of China in 2017 and 2019, which if enacted, would require a security review before transferring personal health information out of mainland China. The Cyber Security Law, together with other industry-specific laws and regulations, also require us to obtain consent from clinical trial subjects, customers, and employees before collecting their personal information, including personal health information, take measures to keep personal information secure and confidential, and report security breaches involving personal information to competent industry regulators. These areas are expected to receive greater attention and focus from regulators.

Since our subsidiaries located in mainland China operate computer networks as part of their normal operations, we are required to comply with the requirements of the Cyber Security Law. In addition, in the ordinary course of our business, we collect and store personal information, including personal information about our clinical trial subjects, customers, and employees, in mainland China and we may need to share it with our subsidiaries, licensors, partners, or contractors located outside mainland China. China's network and data protection regime is constantly evolving and we continue to face uncertainties as to whether our efforts to comply with these requirements will be sufficient. Although we develop and maintain compliance protocols and controls designed to maintain compliance with these requirements, development and maintenance of these protocols and controls is costly. In addition, our CROs, licensees, and partners are also required by law and our agreements with them to comply with these requirements, but there is always a risk that they may not fully comply with them. If our operations, or the operations of our CROs, licensees, or partners, are found to be in violation of these requirements, we may suffer loss or use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of mainland China, be unable to comply with our contractual requirements, suffer reputational harm, or be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. If any of these were to occur, it could adversely affect our ability to operate our business and our financial results.

Animal Testing Permits

According to Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission in November 1988, as amended in January 2011, July 2013 and March 2017, and Administrative Measures on the Certificate for Animal Experimentation (Trial) promulgated by the State Science and Technology Commission and other regulatory authorities in December 2001, performing experimentation on animals requires a Certificate for Use of Laboratory Animals. Applicants must satisfy the following conditions:

- Laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;
- The environment and facilities for the animals' living and propagating must meet state requirements;
- The animals' feed and water must meet state requirements;
- The animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- The management systems must be effective and efficient; and
- The applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

Administrative measures for drug registration

In July 2007, the former SFDA released the Administrative Measures for Drug Registration which took effect on October 1, 2007. The Administrative Measures for Drug Registration covers (1) definitions of drug registration applications and regulatory responsibilities of the former CFDA; (2) general requirements for drug registration; (3) drug clinical trials; (4) application, examination and approval of drugs; (5) supplemental applications and re-registrations of drugs; (6) inspections; (7) registration standards and specifications; (8) time limit; (9) re-examination; and (10) liabilities and other supplementary provisions.

In January 2020, the SAMR released the Drug Registration Regulation, which will come into effect in July 2020. As compared to the current version, the Drug Registration Regulation provides detailed procedural and substantive requirements for the key regulatory concepts established by the PRC Drug Administration Law, confirms a number of reform actions that have been taken in the past years, including but not limited to: (i) the fully implementation of MAH System and implied approval of the commencement of clinical trial; (ii) implementing associated review of drugs, excipients and packaging materials; and (iii) introducing four procedures for expedited registration of drugs, which are procedures for ground-breaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval.

Regulations on the Clinical Trials and Registration of Drugs

Four Phases of Clinical Trials

According to the Administrative Measures for Drug Registration, a clinical development program consists of Phases I, II, III and IV. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate's therapeutic effectiveness and safety for particular indication(s) in patients, which provides evidence and support for the design of Phase III clinical trials and settles the administrative dose regimen. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase III is used to further verify the drug's therapeutic effectiveness and safety on patients with target indication(s), to evaluate overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc.

Approval Authority for Clinical Trial Applications

According to the Administrative Measures for Drug Registration, upon completion of its pre-clinical research, a research institution must apply for approval of a CTA before conducting clinical trials. As of May 1, 2017, the clinical trial approval can be directly issued by the Center for Drug Evaluation, or the CDE on behalf of the NMPA. This delegation of authority can shorten the approval timeline for the approval of a CTA.

In addition, pursuant to the Innovation Opinion and the Announcement on Adjusting the Evaluation and Approval Procedure of Drug Clinical Trial issued by the NMPA in July 2018, clinical trials may be commenced as long as the applicant has not received any objections from the CDE within 60 business days after the filing of the CTA, as opposed to the lengthier clinical trial pre-approval process, in which an affirmative approval from the NMPA must be obtained before the commencement of clinical trials. Such approval process has been further enacted into the 2019 Amendment.

Special Examination and Approval for Domestic Category 1 Drugs

According to the Administrative Measures for Drug Registration, drug registration applications are divided into three different types, namely Domestic New Drug Application, Domestic Generic Drug Application, and Imported Drug Application. Drugs fall into one of three general types divided by working mechanism, namely chemical medicine, biological product or traditional Chinese or natural medicine. Under the Administrative Measures for Drug Registration, a Category 1 drug refers to a new drug that has never been marketed in any country, and is eligible for special review or fast track approval by the former SFDA (now the NMPA).

In March 2016, the former CFDA issued the Reform Plan for Registration Category of Chemical Medicine, or the Reform Plan, which outlined the reclassifications of drug applications under the Administrative Measures for Drug Registration. Under the Reform Plan, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the Domestic New Drug Application and the Imported Drug Application procedures under the Administrative Measures for Drug Registration, respectively.

According to the Special Examination and Approval of Registration of New Drugs promulgated by the former SFDA on January 7, 2009, the former SFDA conducts special examination and approval for new drug registration applications when:

- (1) the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered;
- (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing home and abroad;
- (3) the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinic treatment; or
- (4) the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval of Registration of New Drugs provide that the applicant may file for special examination and approval at the CTA stage if the drug candidate falls within items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

We believe that our current drug candidates fall within items (2) and (3) above. Therefore, we may file an application for special examination and approval at the CTA stage, which may enable us to pursue a more expedited path to approval in China and bring therapies to patients more quickly.

Priority Review and Approval for Clinical Trial and Registration of Domestic Category 1 Drugs

The Circular Concerning Several Policies on Drug Registration Review and Approval issued by the former CFDA on November 11, 2015 further clarifies the following policies, potentially simplifying and accelerating the approval process of clinical trials: (x) a one-time umbrella approval procedure allowing the overall approval of all phases of clinical trials for a new drug, replacing the phase-by-phase application and approval procedure, will be adopted for new drugs' clinical trial applications; and (y) a fast track drug registration or clinical trial approval pathway for the following applications: (1) registration of innovative new drugs treating AIDS, malignant tumors, serious infectious diseases and rare diseases; (2) registration of pediatric drugs; (3) registration of drugs treating specific or prevalent diseases in elders; (4) registration of drugs listed in national major science and technology projects or national key research and development plan; (5) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or the European Union and are manufactured using the same production line in China; and (8) CTA for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

The Opinions on Encouraging Priority Review and Approval for Drug Innovations promulgated by the former CFDA on December 21, 2017 provides that a fast track clinical trial approval or drug registration pathway will be available to both innovative drugs with distinctive clinical benefits, which have not been sold within or outside China, and drugs using advanced technology, innovative treatment methods or having distinctive treatment advantages.

Drug Clinical Practice Reform and Compliance with GCP

In October 2017, the Chinese government announced an administrative reform of clinical trial institutions. Certification of clinical trial institutions by the former CFDA and the former NHFPC of the PRC is no longer required. Under this reform, a clinical trial institution can be engaged by a drug marketing authorization applicant (i.e., a sponsor) to conduct a drug clinical study after it has been duly recorded with the online platform designated by the NMPA. On November 29, 2019, pursuant to the 2019 Amendment, the NMPA and the NHC jointly released the Rules for Administration of the Drug Clinical Trial Institutions, which became effective on December 1, 2019. The Rules specify requirements for clinical trial institutions and recordal procedures. Pursuant to the Rules, a clinical trial institution should comply with the requirements of the Good Clinical Practice, or GCP, and be capable of undertaking pharmaceutical clinical trials. It should evaluate or engage a third party to evaluate its clinical trial proficiency, facilities and expertise. According to the PRC Implementing Regulations of the Drug Administration Law, a drug marketing authorization applicant should only engage a duly recorded clinical trial institution to carry out a drug clinical trial.

The conduct of clinical trials must adhere to the GCP and the protocols approved by the ethics committees of each study site. Since 2015, the former CFDA has strengthened the enforcement against widespread data integrity issues associated with clinical trials in China. To ensure authenticity and reliability of the clinical data, the former CFDA mandated applicants of the pending drug registration submissions to conduct self-inspection and verification of their clinical trial data. Based on the submitted self-inspection results, the former CFDA also regularly launched onsite clinical trial audits over selected applications and reject those found with data forgery. The GCP audit has been ongoing and was able to curb the number of unreliable NDAs.

In April 2020, the NMPA and the NHC released the Amended GCP, which will take effect on July 1, 2020. Compared to the current GCP, the Amended GCP provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the Amended GCP enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials. We will need to review our current clinical trials and adapt the design and execution of our current clinical trials to any new requirements imposed by the Amended GCP.

The Marketing Authorization Holder System

Under the authorization of the Standing Committee of the National People's Congress, the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism on May 26, 2016, which provides a detailed pilot plan for the MAH System, for drugs in 10 provinces in China. Under the MAH System, domestic drug research and development institutions and individuals in the piloted regions are eligible to be holders of drug registrations without having to become drug manufacturers. Drugs qualified for the MAH System are: (1) new drugs (including but not limited to Category 1 and 2 drugs under the Reform Plan) approved after the implementation of the MAH System; (2)

generic drugs approved as Category 3 or 4 drugs under the Reform Plan; (3) previously approved generics that have passed the equivalence assessments against originator drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the piloted regions, but have been moved out of the piloted regions due to corporate mergers or other reasons. The Pilot Plan was originally set for a 3-year period, and would end in December 2018. Effective as of November 5, 2018, the Standing Committee of the National People's Congress decided to extend the pilot program for another year.

The newly amended PRC Drug Administration Law purports to roll out this MAH system nationwide. Companies and research and development institutions can be drug marketing authorization holders after they receive the drug registration certificates. The drug marketing authorization holder should be responsible for their products throughout the life cycle, including nonclinical studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the PRC Drug Administration Law. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and may engage pharmaceutical distribution enterprises with drug distribution license for the distribution activities. Upon receiving the marketing authorizations from the NMPA, a drug marketing authorization holder may transfer its drug marketing authorization and the transferee should have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality controllability of drugs, and fulfill the obligations of the drug marketing authorization holder.

Administrative Protection and Monitoring Periods for New Drugs

According to the Administrative Measures for Drug Registration, the PRC Implementing Regulations of the Drug Administration Law and the Reform Plan, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of not more than five years for Category 1 new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs.

During the monitoring period of a new drug, the NMPA will not accept other applications for new drugs containing the same active ingredient. This renders an actual five-year exclusivity protection for Category 1 new drugs. The only exception is that the NMPA will continue to handle any application if, prior to the commencement of the monitoring period, the NMPA has already approved the applicant's clinical trial for a similar new drug. If such application conforms to the relevant provisions, the NMPA may approve such applicant to manufacture or import the similar new drug during the remainder of the monitoring period. The Drug Registration Regulation, which will come into effect in July 2020, omits the provisions relating to the administrative exclusivity created by the new drug monitoring period.

Non-Inferiority Standard

In China, a drug may receive regulatory approval without showing superiority in its primary endpoint. Rather, a drug may be approved for use if it shows non-inferiority in its primary endpoint and superiority in one of its secondary endpoints.

New Drug Application

When Phases I, II and III of the clinical trials have been completed, the applicant may apply to the NMPA for approval of an NDA. The NMPA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the NMPA. We must obtain approval of an NDA before our drugs can be manufactured and sold in the China market.

According to the Opinions on Encouraging Priority Review and Approval for Drug Innovations, for new drugs which are developed for severe, life-threatening diseases currently lacking effective treatment and have great significance for meeting clinical needs, if, based on early-stage clinical trial data, the clinical benefits of such drugs can be reasonably predicted or decided and such drugs have distinctive advantages comparing with existing treatments, such new drugs may obtain a conditional approval for marketing before the completion of Phase III clinical trials undertaken to confirm its therapeutic effectiveness. Such conditional approval process has been further enacted into the 2019 Amendment.

International Multi-Center Clinical Trials Regulations

On January 30, 2015, the former CFDA promulgated Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Tentative), or the Multi-Center Clinical Trial Guidelines, which took effect as of March 1, 2015, aiming to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to NMPA for approval of an NDA, such international multi-center clinical trials shall satisfy, in addition to the requirements set forth in the PRC Drug Administration Law and its implementation regulations, Administrative Measures for Drug Registration and relevant laws and regulations, the following requirements:

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;
- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the drug under clinical trial, and satisfy the statistical and relevant legal requirements; and
- The onshore and offshore international multi-center clinical trial research centers shall be subject to on-site inspections by competent PRC governmental agencies.

International multi-center clinical trials shall follow international prevailing GCP principles and ethics requirements. Applications shall ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers shall have the qualification and capability to perform relevant clinical trials; and an ethics committee shall continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the international multi-center clinical trial, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researchers and clinical trial organizations on the NMPA's drug clinical trial information platform.

Data derived from international multi-center clinical trials can be used for the NDAs with the NMPA. When using international multi-center clinical trial data to support NDAs in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

Leveraging the clinical trial data derived from international multi-center clinical trials conducted by our partners, we may avoid unnecessary repetitive clinical trials and thus further accelerate the NDA process in China.

In October, 2017, the former CFDA released the Decision on Adjusting Items concerning the Administration of Imported Drug Registration, which includes the following key points:

- If the International Multicenter Clinical Trial, or IMCCT, of a drug is conducted in China, the IMCCT drug does not need to be approved or entered into either a Phase II or III clinical trial in a foreign country, except for preventive biological products. Phase I IMCCT is permissible in China.
- If the IMCCT is conducted in China, the application for drug marketing authorization can be submitted directly after the completion of the IMCCT.
- With respect to clinical trial and market authorization applications for imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required.
- With respect to drug applications that have been accepted before the release of this Decision, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from IMCCT.

Trial Exemptions and Acceptance of Foreign Clinical Trial Data

On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, or Guidance Principles, as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of foreign clinical trials must meet the authenticity, completeness, accuracy and traceability requirements, and such data must be obtained in consistency with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Clinical trial sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically, in 2018, the NMPA and NHC issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent or treat serious life-threatening illnesses for which there is either no effective therapy in China or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

Drug Technology Transfer Regulations

On August 19, 2009, the former SFDA promulgated the Administrative Regulations for Technology Transfer Registration of Drugs to standardize the registration process of drug technology transfer, which includes application for, and evaluation, examination, approval and monitoring of, drug technology transfer. Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer and the application for drug registration by the transferee according to the provisions in the new regulations. Drug technology transfer includes new drug technology transfer and drug production technology transfer.

Conditions for the Application for New Drug Technology Transfer

Applications for new drug technology transfer may be submitted prior to the expiration date of the monitoring period of the new drugs with respect to:

- drugs with new drug certificates only; or
- drugs with new drug certificates and drug approval numbers.

For drugs with new drug certificates only and not yet in the monitoring period, or drug substances with new drug certificates, applications for new drug technology transfer should be submitted prior to the respective expiration date of the monitoring periods for each drug registration category set forth in the new regulations and after the issue date of the new drug certificates.

Conditions for the Application of Drug Production Technology Transfer

Applications for drug production technology transfer may be submitted if:

- the transferor holds new drug certificates or both new drug certificates and drug approval numbers, and the monitoring period has expired or there is no monitoring period; or
- with respect to drugs without new drug certificates, both the transferor and the transferee are legally qualified drug manufacturing enterprises, one of which holds over 50% of the equity interests in the other, or both of which are majority-owned subsidiaries of the same drug manufacturing enterprise.

With respect to imported drugs with imported drug licenses, the original applicants for the imported drug registration may transfer these drugs to domestic drug manufacturing enterprises.

Application for, and Examination and Approval of, Drug Technology Transfer

Applications for drug technology transfer should be submitted to the provincial administration of medical products where the transferee is located. If the transferor and the transferee are located in different provinces, the provincial administration of medical products where the transferor is located should provide examination opinions. The provincial administration of medical products where the transferee is located is responsible for examining application materials for technology transfer and organizing inspections on the production facilities of the transferee. Drug control institutes are responsible for testing three batches of drug samples.

The CDE should further review the application materials, provide technical evaluation opinions and form a comprehensive evaluation opinion based on the site inspection reports and the testing results of the samples. The NMPA should determine whether to approve the application according to the comprehensive evaluation opinion of the CDE. An approval letter of supplementary application and a drug approval number will be issued to qualified applications. A Clinical Trial Authorization will be issued when necessary. For rejected applications, a notification letter of the examination opinions will be issued with the reasons for rejection.

Permits and Licenses for Manufacturing of Drugs

Pharmaceutical Manufacturing Permit

To manufacture pharmaceutical products in the PRC, a pharmaceutical manufacturing enterprise must first obtain a Pharmaceutical Manufacturing Permit issued by the relevant pharmaceutical administrative authorities at the provincial level where the enterprise is located. Among other things, such a permit must set forth the permit number, the name, legal representative and registered address of the enterprise, the site and scope of production, issuing institution, date of issuance and effective period.

Each Pharmaceutical Manufacturing Permit issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a Pharmaceutical Manufacturing Permit is subject to review by the relevant regulatory authorities on an annual basis. The enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to reassessment by the issuing authorities in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

Business Licenses

In addition to a Pharmaceutical Manufacturing permit, the manufacturing enterprise must also obtain a business license from the Administration of Market Regulation at the local level. The name, legal representative and registered address of the enterprise specified in the business license must be identical to that set forth in the Pharmaceutical Manufacturing Permit.

GMP Requirements

The World Health Organization encourages the adoption of good manufacturing practice, or GMP, standards in pharmaceutical production in order to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final products.

Pursuant to the newly amended PRC Drug Administration Law, the GMP certification has been cancelled. A GMP certification previously certifies that a manufacturer's factory and quality management system have met certain criteria for engaging in the planning and manufacturing of drug products, which address institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, maintenance of sales records and manner of handling customer complaints and adverse reaction reports. In January 2011, the former MOH issued an updated set of GMP standards, also known as the new GMP, to replace the previous version issued in 1998. There are also five annexes to the new GMP issued by the former SFDA in February 2011, with detailed requirements for the manufacture of sterile drugs, drug/substances/APIs, biologics, blood products and traditional Chinese medicines. Several additional annexes were published in the next few years in succession, including but not limited to annexes with respect to the requirements for IT systems, radiopharmaceuticals, biochemical drugs, etc.

With the cancellation of GMP certification, drug manufacturing enterprises are still required to strictly comply with GMP requirements. The NMPA and its provincial branches are authorized to monitor the continued compliance of pharmaceutical manufacturers, for example, by a follow-up inspection of implementation of the GMP requirements. Failure to continuously comply with the statutory requirements may lead to rectification orders imposed on the manufacturers. Penalties for breach of GMP compliance can vary depending on the degree of seriousness. Administrative sanctions range from a rectification notice to monetary fines, suspension of production and business operation, and revocation of the pharmaceutical manufacturing permit.

U.S. Regulation of Pharmaceutical Product Development and Approval

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining marketing approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions. These sanctions could include, among other actions, FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement-related letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or DOJ, or other governmental entities. Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's GLP regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable good clinical practices, or GCPs and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review and review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced to assess compliance with the FDA's cGMP;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA; and
- payment of user fees and FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Pre-clinical Studies

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, or NCEs, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the pre-clinical tests must comply with federal regulations, including GLPs

and the U.S. Department of Agriculture's Animal Welfare Act. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

Clinical Studies

The clinical stage of development involves the administration of the drug product to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are accurate, and that the rights, safety, and well-being of study participants are protected. GCPs also include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. For example, information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical trials.

- Phase I: The drug is initially introduced into a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase II: The drug is administered to a limited patient population to determine dose tolerance and optimal dosage required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.

- Phase III: The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase IV clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical

trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and FDA Review Process

The results of non-clinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2020, the user fee for an application requiring clinical data, such as an NDA, is approximately $2.9 million. PDUFA also imposes an annual prescription drug program fee for human drugs of approximately $325,000. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA conducts a preliminary review of an NDA within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of an NDA and respond to the applicant within 10 months from the filing date for a standard NDA and, and within six months from the filing date for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may re-analyze the clinical trial data, which can result in extensive discussions between the FDA and us during the review process.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its API will be produced, it may issue

an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL usually describes all of the specific deficiencies in the NDA identified by the FDA. The CRL may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient populations or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of a drug or biological product outweigh its risks. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Pediatric Trials

Under the Pediatric Research Equity Act of 2003, a NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With the enactment of FDASIA in 2012 , a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials, and/or other clinical development programs.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but the product will be entitled to orphan product exclusivity, meaning that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

FDA regulations also require that approved products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, the activities of pharmaceutical manufacturers are subject to federal and state laws designed to prevent "fraud and abuse" in the healthcare industry. The laws generally limit financial interactions between manufacturers and health care providers or other participants in the healthcare industry and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Pharmaceutical manufacturers are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require tracking and reporting of certain drug prices. Manufacturers are subject to fines and other penalties if such prices are not reported accurately. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects manufacturers to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, exclusion from participation in government healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Rest of the World Regulation of Pharmaceutical Product Development and Approval

For other countries outside of China and the United States, such as countries in Europe, Latin America or other parts of Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with applicable GCP requirements and the applicable regulatory requirements and ethical principles.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Coverage and Reimbursement

PRC Coverage and Reimbursement

Historically, most Chinese healthcare costs had been borne by patients out-of-pocket, which had limited the growth of more expensive pharmaceutical products. However, in recent years the number of people covered by government and private insurance has increased. According to the PRC National Bureau of Statistics, as of December 2018, approximately 1.3 billion urban employees and residents in China were enrolled in the national medical insurance program, representing a coverage rate of 95% of the total population. The PRC government has announced a plan to give every person in China access to basic healthcare by year 2020.

Reimbursement under the National Medical Insurance Program

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. The State Council expects the pilot Urban Resident Basic Medical Insurance to cover the whole nation by 2010.

Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the Medical Insurance Catalogue. The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee, jointly issued by several authorities including the Ministry of Labor and Social Security and the Ministry of Finance, among others, on May 12, 1999, provides that a pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements:

- it is set forth in the Pharmacopoeia of the PRC;
- it meets the standards promulgated by the NMPA; and
- if imported, it is approved by the NMPA for import.

Factors that affect the inclusion of a pharmaceutical product in the Medical Insurance Catalogue include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public.

The PRC Ministry of Human Resources and Social Security, together with other government authorities, previously had the power to determine the medicines included in the NRDL. In February 2017, the PRC Ministry of Human Resources and Social Security released the 2017 NRDL. The 2017 NRDL expands its scope and covers 2,535 drugs in total, including 339 drugs that are newly added. The 2017 NRDL reflects an emphasis on innovative drugs and drugs that treat cancer and other serious diseases. For instance, most of the innovative chemical drugs and biological products approved in China between 2008 and the first half of 2016 have been included in the 2017 NRDL or its candidate list. The NRDL was further expanded in October 2018 after the newly created NHSA, the successor agency to Ministry of Human Resources and Social Security, finalized the price negotiations with drug manufacturers for 18 oncology drugs. 10 of the 18 oncology drugs were approved after 2017. 17 of the 18 products were included in the NRDL. In August 2019, the PRC Ministry of Human Resources and Social Security released the 2019 NRDL. In November 2019, NHSA organized another round of price negotiation with drug companies for 119 new drugs that had not been included in the NRDL at the time of the negotiation, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation; subsequently, the NRDL was expanded to include the 70 new drugs.

Medicines included in the NRDL are divided into two parts, Part A and Part B.

Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price. The percentage of reimbursement for Part B medicines differs from region to region in the PRC.

The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the national medical insurance program in a calendar year is capped at the amounts in such participant's individual account under such program. The amount in a participant's account varies, depending on the amount of contributions from the participant and his or her employer.

According to the 2019 NRDL, all provinces shall implement the 2019 NRDL in a strict manner and shall not have the discretion to formulate the catalogue or increase the drugs of Part B in any form or adjust the scope of limited payment. For those drugs that were already added to Part B of the provincial catalogue in accordance with the 2017 NRDL, the drugs shall be gradually removed within 3 years.

National List of Essential Drugs

On August 18, 2009, the former MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Drugs and the Guidelines on the Implementation of the National List of Essential Drugs System, which aimed to promote essential medicines sold to consumers at fair prices in the PRC and ensured that the general public in the PRC has equal access to the drugs contained in the National List of Essential Drugs. The former MOH promulgated the National List of Essential Drugs (Catalog for the Basic Healthcare Institutions) on August 18, 2009, a revised National List of Essential Drugs on March

13, 2013 and another revised National List of Essential Drugs on September 30, 2018 which became effective on November 1, 2018. According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in National List of Essential Drugs. The drugs listed in National List of Essential Drugs shall be purchased by centralized tender process and shall be subject to the price control by NDRC. Drugs listed in the National List of Essential Drugs are all listed in the Medical Insurance Catalogue. Historically, the entire amount of the purchase price of such drugs would be entitled to reimbursement. The recent revision in 2018 included several novel drugs, and their reimbursement ratios are subject to further negotiations between the drug manufacturers and local administration of healthcare security at the provincial level.

Commercial Insurance

On October 25, 2016, the State Council and the Communist Party of China jointly issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

Price Controls

Instead of direct price controls which were historically used in China but abolished in June 2016, the government regulates prices mainly by establishing a price negotiations, consolidated procurement mechanism, and revising medical insurance reimbursement standards as discussed below.

Price Negotiations

The Chinese government has initiated several rounds of price negotiations with manufacturers of patented drugs, drugs with an exclusive source of supply and oncology drugs since 2016. The average percentage of price reduction has been over 50%. Once the government agreed with the drug manufacturers on the supply prices, the drugs would be automatically listed in the NRDL and qualified for public hospital purchase.

Centralized Procurement and Tenders

The Guiding Opinions concerning the Urban Medical and Health System Reform, promulgated on February 21, 2000, aims to regulate the purchasing process of pharmaceutical products by medical institution. The MOH and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on July 7, 2000 and the Notice on Further Improvement on the Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on August 8, 2001, medical institutions established by county or higher level government or state-owned enterprises (including state-controlled enterprises) are required to implement centralized tender procurement of drugs.

The former MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation), or the Centralised Procurement Regulations, on March 13, 2002, and promulgated Sample Document for Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation), or the Centralized Tender Sample Document in November 2001, to implement the tender process requirements and ensure the requirements are followed uniformly throughout the country. The Centralized Tender Regulations and the Centralized Tender Sample Document provide rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On January 17, 2009, the former MOH, the former SFDA and other four national departments jointly promulgated the Opinions on Further Regulating Centralized Procurement of Drugs by Medical Institutions. According to the notice, public hospitals owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalogue of drugs subject to centralized

procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by public medical institutions shall be covered by the catalogue of drugs subject to centralized procurement. On July 7, 2010, the former MOH and six other ministries and commissions jointly promulgated the Notice on Printing and Distributing the Working Regulations of Medical Institutions for Centralized Procurement of Drugs to further regulate the centralized procurement of drugs and clarify the code of conduct of the parties in centralized drug procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralized tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

"4+7" Volume-based Drug Procurement and Tenders

In June 2018, the State Council decided to launch a new round of drug pricing and procurement reform. This reform is implemented mainly by the NHSA, a new agency established in 2018 as part of the institutional restructuring with a mandate for pricing and procurement of drugs and disposables. The NHC supports the reform by introducing policy that encourages purchasing and prescribing of the selected drug, and by managing the supplier's behavior. The NMPA is responsible for the quality assurance of the drug.

On November 15, 2018, the Joint Procurement Office, the procurement alliance formed by representatives of procurement agencies in 11 pilot cities established to oversee the bidding and procurement process, published the Paper on Drug Centralized Procurement in "4+7"Regions, launching the national pilot scheme for centralized volume-based drug procurement and tenders. According to the papers, the initial procurement of 31 generic drugs was implemented in 4 municipalities, namely Beijing, Shanghai, Tianjin and Chongqing, and 7 cities, namely Shenyang, Guangzhou, Shenzhen, Xi'an, Dalian, Chengdu, and Xiamen. This pilot program is thus also referred to as the "4+7" procurement scheme. On January 17, 2019, the General Office of the State Council published a circular on National Pilot Program for Centralized Procurement and Use of Drug, which provides detailed implementing measures for the nation-wide centralized drug procurement and tender scheme.

The "4+7" pilot program puts special emphasis on procurement volume guarantee. Public hospitals in pilot regions are encouraged to form a group procurement organization to increase the negotiation leverage. The committed volume will be shared by all qualified bid-winners, and public hospitals should prioritize their use of drugs purchased through the volume-based procurement in order to realize the volume commitment. Under this program, a company is provided with a substantial volume guarantee. The selected drugs must pass the generic drug consistency evaluation on quality and effectiveness. The reform policy is aimed to lower drug costs for patients, reduce transaction costs for enterprises, regulate drug use of hospitals, and improve the centralized drug procurement and pricing system. The centralized volume-based procurement is open to all approved enterprises that manufacture drugs on the government-set procurement list in China. Clinical effects, adverse reactions, and batch stability of the drugs are considered, and their quality consistency with the originator drugs will be the main criteria for evaluation. Production capacity and stability of the supplier are also considered.

On December 17, 2018, the preliminary results of the "4+7" centralized volume-based procurement were announced: 25 out of 31 generic drugs were selected, of which there are 3 originator drugs and 22 generics. As of December 2019, many provinces have published regional implementation measures, expanding the pilot program. On January 17, 2020, the results of the second round of the national centralized volume-based procurement and tender program were published: the average price reduction reached more than 50%, and the highest reduction has reached 90%.

Two-invoice System

In addition to the centralized tender process, the Chinese government also rolled out a "two-invoice system" nationwide in 2018. In the two-invoice system, in principle there can be no more than two invoices issued for drug products supplied by manufacturers to public hospitals. To satisfy with this requirement, many drug manufacturers have reduced the tiers of distributors, or converted drug distributors into contracted service organizations. This excludes the

sale of products invoiced from the manufacturer to its wholly-owned or controlled distributors, or for imported drugs, to its exclusive distributor, or from a distributor to its wholly-owned or controlled subsidiary (or between its wholly-owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. The reduction in distribution tiers resulted in a decrease in distribution mark-ups, hence the supply prices to public hospitals would also be reduced. Compliance with the two-invoice system is a prerequisite for pharmaceutical companies to participate in the tender and procurement processes of public hospitals, which currently provide most of PRC healthcare services. Manufacturers and distributors that fail to implement the two-invoice system may lose their qualifications to participate in the tender and procurement process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals. The two-invoice system has been implemented in all provinces, each with its own regional implementation rules.

Medical Insurance Reimbursement Standards

The Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents issued by the State Council on January 3, 2016, call for the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangement who participate in the basic medical insurance for urban employees.

According to the Main Tasks of Healthcare System Reform in 2016 issued by the General Office of the State Council on April 21, 2016, the key tasks of the medical insurance reform are: (1) to advance the establishment of the mechanisms of stable and sustainable financing and security level adjustment, (2) to advance the integration of the basic medical insurance systems for urban and rural residents, (3) to consolidate and improve the system for serious illness insurance for urban and rural residents, (4) to reform medical insurance payment methods, and (5) to advance the development of commercial health insurance.

The General Office of the State Council further announced a master plan for the medical insurance reimbursement reform in June 2017. The main objectives are to implement a diversified reimbursement mechanism including DRGs, per-capita caps, and per-bed-day caps. These new reimbursement methods will be rolled out nationwide by 2020 to replace the current reimbursement method that is based on service category and product price. Local administration of healthcare security will introduce a total budget control for their jurisdictions and decide the amount of reimbursement to public hospitals based on hospitals' performance and the spending targets of individual basic medical insurance funds. In June 2019, the NHSA, the Ministry of Finance, the NHC and the National Administration of Traditional Chinese Medicine jointly issued the Notice on the National List of Pilot Cities for the DRG Payment Mechanism, identifying 30 cities as pilot cities for the DRG payment pilot program, proposing to further the medical insurance reimbursement reform. To further standardize payment in the national Basic Medical Insurance schemes, in October 2019, the NHSA issued two key technical documents for a pilot project that introduces DRGs—the Technical Guideline of the Classification and Payment for China Healthcare Security Diagnosis Related Groups (CHS-DRG) and the CHS-DRG Classification Plan. According to the classification plan, patients will be sorted into 26 major diagnostic categories and 376 adjacent diagnosis-related groups. DRG-based settlement is currently only applicable to expenses of inpatient care incurred by the insureds at designated hospitals participating in the DRG payment pilot programs and payable by regional medical insurance fund under the national Basic Medical Insurance schemes. DRG-based payments are made directly to the participating medical institutions, while the covered benefits enjoyed by the insureds, under the current public insurance schemes, are not affected by such settlement.

U.S. Coverage and Reimbursement

Successful sales of our drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. These third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures

could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could have a material adverse effect on our sales, results of operations and financial condition.

Health care reform initiatives have resulted in significant changes to the coverage, reimbursement and delivery of health care, including drugs. Health care reform efforts are likely to continue and such efforts have included, and may include in the future, attempts to repeal prior healthcare reform.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2029 unless additional Congressional action is taken. If we obtain approval to market a drug candidate in the United States, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Other Healthcare Laws

Other PRC Healthcare Laws

Advertising of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes promulgated in December 2019 and became effective in March 2020, an enterprise seeking to advertise its pharmaceutical products must apply for an advertisement approval number. The advertisement approval number is issued by the relevant local administrative authority. The validity term of the advertisement approval number for drugs shall be consistent with the shortest validity term of the production registration certificate, filing certificate or production license. If no valid term is prescribed in the production registration certificate, filing certificate or production license, the valid term of the advertisement approval number shall be two years. The content of an approved advertisement may not be altered without prior approval.

Insert Sheet and Labels of Pharmaceutical Products

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the former SFDA. A drug insert sheet should include the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use if drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage and adverse reaction.

Packaging of Pharmaceutical Products

According to the Measures for The Administration of Pharmaceutical Packaging effective on September 1, 1988, pharmaceutical packaging must comply with the national and industry standards. If no national or industry standards are available, the enterprise can formulate its own standards and put into implementation after obtaining the approval of the administration of medical products or bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its own packaging standard. Drugs that have not developed and received approval for packing standards must not be sold or traded in China (except for drugs for the military).

Other U.S. Healthcare Laws

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and transparency laws, such as the following:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians and teaching hospitals (and other healthcare professionals starting in 2021) to the federal government for re-disclosure to the public; and
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If and when we become subject to such laws, efforts to ensure that our activities comply with applicable healthcare laws may involve substantial costs. Many of these laws and their implementing regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we could be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business.

Other Significant PRC Regulation Affecting Our Business Activities in China

PRC Regulation of Foreign Investment

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC, or the PRC Company Law, which was adopted by the Standing Committee of the NPC in December 1993, implemented in July 1994, and subsequently amended in December 1999, August 2004, October 2005, December 2013 and October 2018. Under the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies. Pursuant to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.

Investment activities in the PRC by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the Special Administrative Measures (Negative List) for Foreign Investment Access (2019), or the Negative List, which was promulgated by the Ministry of Commerce, or the MOFCOM and National Development and Reform Commission, or the NDRC on June 30, 2019 and took effect on July 30, 2019. The Negative List set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 13 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

Foreign Investment Law of the People's Republic of China, or the Foreign Investment Law was promulgated by the NPC in March 2019 and become effective in January 2020. After the Foreign Investment Law came into force, the Law on Wholly Foreign- Owned Enterprises, the Law on Sino-foreign Equity Joint Ventures and the Law on Sino-foreign Contractual Joint Ventures have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law: 1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; 2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) investing by foreign investors in new projects in China alone or jointly with other investors; 4) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law of the PRC, which came into effect in January 2020. After the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulation on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law, Provisional Regulations on the Duration of Sino- Foreign Equity Joint Venture Enterprise, the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law and the Regulations on Implementing the Sino-foreign Cooperative Joint Venture Enterprise Law have been repealed simultaneously.

In December 2019, the MOFCOM and the State Administration for Market Regulation issued the Measures for the Reporting of Foreign Investment Information, which came into effect in January 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Investment Enterprises has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

PRC Regulation of Commercial Bribery

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of failure to monitor their operating activities.

PRC Regulation of Product Liability

In addition to the strict new drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the PRC, or the PRC Civil Law, promulgated on April

12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

On February 22, 1993, the Product Quality Law of the PRC, or the Product Quality Law, was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised by the Ninth National People's Congress on July 8, 2000, by the Eleventh National People's Congress on August 27, 2009 and by the Thirteenth National People's Congress on December 29, 2018. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep it confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

PRC Tort Law

Under the Tort Law of the PRC which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as issuance of a warning, recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages.

PRC Regulation of Intellectual Property Rights

China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

Patents

Pursuant to the PRC Patent Law, most recently amended in December 2008, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten years from the date of application. The PRC Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the SIPO. Normally, the SIPO publishes an

application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the SIPO for a substantive examination within three years from the date of application.

Article 20 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offences such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, and if the loss suffered by the patent holder arising from the infringement cannot be determined, the damages for infringement shall be calculated as the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

Medical Patent Compulsory License

According to the PRC Patent Law, for the purpose of public health, the SIPO may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded.

Exemptions for Unlicensed Manufacture, Use, Sale or Import of Patented Products

The PRC Patent Law provides five exceptions for unauthorized manufacture, use, sale or import of patented products. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope;
- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;

- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or
- Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, uses or imports patented drugs or patented medical equipment for the abovementioned person.

However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in PRC Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

Trade Secrets

According to the PRC Anti-Unfair Competition Law promulgated by the Standing Committee of the NPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019 respectively, the term "trade secrets" refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders.

Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, intimidation, solicitation or coercion; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the fact that an employee or former employee of the right owner of trade secrets or any other entity or individual conducts any of the illegal acts above mentioned, but still accepts, publishes, uses or allows any other to use such secrets, such practice shall be deemed as infringement of trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB100,000 to RMB500,000, where the circumstance is serious, the fine shall be between RMB500,000 to RMB3,000,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a Chinese court for loss and damages incurred due to the misappropriation.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

Trademarks and Domain Names

Trademark. According to the Trademark Law of the PRC, promulgated by the Standing Committee of the NPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its implementation rules, the PRC Trademark Office of the National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout the PRC. The Trademark Law has adopted a "first-to-file" principle with respect to trademark registration. As of December 31, 2019, we had 25 registered trademarks and 9 trademark applications pending in China, and 15 registered trademarks and 35 trademark applications pending outside China.

Domain Name. Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology in August 2017 and effective from November 2017, and the Implementing Rules on Registration of Domain Names issued by China Internet Network Information Center in September 2002, and amended in June 2009 and May 2012. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names. We have registered zaibio.com, zaibiotech.com, zailaboratory.com, zailab.com.cn, zaimedicine.com and zaipharma.com.

PRC Regulation of Labor Protection

Under the Labor Law of the PRC, effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the PRC Employment Contract Law, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the PRC.

Pursuant to the Law of Manufacturing Safety of the PRC effective on November 1, 2002 and amended on August 27, 2009 and August 31, 2014, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable PRC laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011 and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds which became effective on January 22, 1999 and amended on March 24, 2019, Interim Measures concerning the Maternity Insurance of Employees which become effective on January 1, 1995, and the Regulations on Work-related Injury Insurance which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Regulations Relating to Foreign Exchange Registration of Offshore Investment by PRC Residents

In July 2014, SAFE issued the SAFE Circular 37, and its implementation guidelines, which abolished and superseded the SAFE Circular 75. Pursuant to SAFE Circular 37 and its implementation guidelines, PRC residents (including PRC institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle, or SPV, directly established or indirectly controlled by PRC residents for the purposes of offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such PRC residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a PRC resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the PRC individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or PRC residents to penalties under PRC foreign exchange administration regulations.

Regulations Relating to Employee Stock Incentive Plan

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE on March 28, 2007. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any

stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Dividend Distribution

Pursuant to the PRC Company Law and Foreign Investment Law, and Regulations on Implementing the Foreign Investment Law, foreign investors may freely remit into or out of China, in renminbi or any other foreign currency, their capital contributions, profits, capital gains, income from asset disposal, intellectual property royalties, lawfully acquired compensation, indemnity or liquidation income and so on within the territory of China.

In January 2017, the SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Regulations Relating to Foreign Exchange

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, or SAFE Circular No. 142, regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into RMB by restricting how the converted RMB may be used. SAFE Circular No. 142 provides that the RMB capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within China. SAFE also strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such RMB capital may not be changed without SAFE's approval, and such RMB capital may not in any case be used to repay RMB loans if the proceeds of such loans have not been used. In March 2015, SAFE issued SAFE Circular No. 19, which took effective and replaced SAFE Circular No. 142 on June 1, 2015. Although SAFE Circular No. 19 allows for the use of RMB converted from the foreign currency-denominated capital for equity investments in China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted RMB for purposes beyond the business scope, for entrusted loans or for inter-company RMB loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to nonassociated enterprises. Violations of SAFE Circular 19 or Circular 16 could result in administrative penalties.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e.g. profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment, or SAFE Circular No. 13, which took effect on June 1, 2015. SAFE Circular No. 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment.

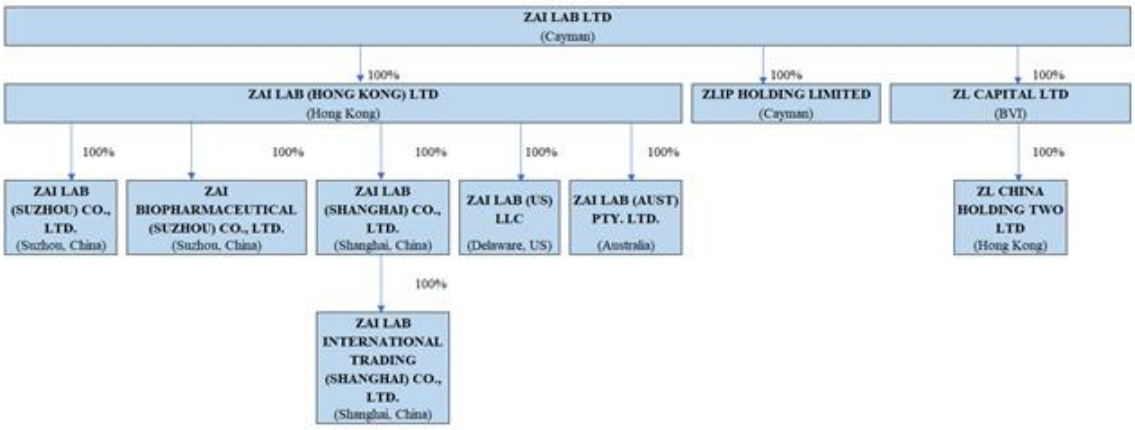
Other PRC National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control in all material aspects. We believe that we are currently in compliance with these laws and regulations; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

C. Organizational Structure

The following diagram illustrates our corporate structure, including our principal subsidiaries, as of the date of this Annual Report on Form 20-F:



D. Property, Plant and Equipment

We are headquartered in Shanghai where we have our main administrative and laboratory offices, which is 3,632 square meters in size. The lease for this facility expires in 2023. We also have a 2,475 square meter commercial office for in Shanghai, the lease for which expires in 2022, and a 493 square meter office in Beijing, the lease for which expires in 2020. We have a 445 square meter commercial office in Hong Kong, the leases for which expire in 2022. We also have a 2,652 square feet administrative office and an 18,707 square feet laboratory office in San Francisco, the leases for which expire in 2021 and 2026, respectively. We also have an administrative office in Boston. In early 2017, we built a small molecule drug product facility in Suzhou, China capable of supporting clinical and commercial production and in 2018, we built a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. The cost to complete the small molecule facility was approximately $6.7 million and was paid with cash on hand. The construction of the large molecule facility was completed in 2018, which cost approximately $12.9 million and was financed with cash. We believe our current facilities are sufficient to meet our near-term needs.

E. Land Use Right

In 2019, we acquired land use rights of 50,851 square meters in Suzhou for the purpose of constructing and operating the research center and biologics manufacturing facility in Suzhou. The terms of the land use rights are 30 years.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with "Item 3.A. Selected Financial Data" and our consolidated financial statements appearing elsewhere in this Annual Report on Form F-20. This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this annual report are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. In evaluating our business, you should carefully consider the information provided under "Item 3.D. Risk Factors." Actual results could differ materially from those projected in the forward-looking statements. The terms "Company", "Zai Lab", "we", "our" or "us" as used herein refer to Zai Lab Limited and its consolidated subsidiaries unless otherwise stated or indicated by context.

A. Operating Results.

Overview

We are an innovative, research-based, commercial-stage biopharmaceutical company focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China market, including in the fields of oncology, autoimmune and infectious diseases therapies. Our mission is to leverage our expertise and insight to address the expanding needs of patients in China and to utilize our China-based competencies to improve the lives of patients worldwide.

Since our founding in 2013 until December 31, 2019, we have constructed a broad and validated innovative pipeline consisting of two commercial products and eight clinical-stage drug assets with potentially differentiated profiles, in addition to other assets, through partnerships with global biopharmaceutical companies. In April 2020, our portfolio was expanded to eleven drug assets with the addition of REGN1979. Following the addition of REGN1979, our clinical-stage portfolio now includes seven late-stage clinical assets targeting large, fast growing segments of China's pharmaceutical market. Across our broader portfolio, we currently have over 25 ongoing or planned clinical trials. We believe that our leadership team's extensive global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, with opportunities to bring innovative products to market in China efficiently.

Our consolidated net loss attributable to ordinary shareholders for the year ended December 31, 2017, 2018 and 2019 was $50.4 million, $139.1 million and $195.1 million, respectively.

Basis of Presentation

Our consolidated statement of operations data for the years ended December 31, 2017, 2018 and 2019 and our consolidated statement of financial position data as of December 31, 2017, 2018 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. Our consolidated financial statements appearing elsewhere in this Annual Report on Form 20-F have been prepared in accordance with U.S. GAAP.

Factors Affecting our Results of Operations

Innovation Platform

Research and Development Expenses

We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been steadily advancing and expanding, with seven late-stage clinical drug candidates being investigated. For more information on the nature of the efforts and steps necessary to develop our drug candidates, see "Business" and "Regulation."

To date, we have financed our activities primarily through private placements, our initial public offering in September 2017 and various follow-on offerings. Through December 31, 2019, we have raised approximately $164.6 million in private equity financing and approximately $513.4 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering and our subsequent follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $32.4 million, $97.5 million and $191.0 million, for the years ended December 31, 2017, 2018 and 2019, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our seven late-stage clinical drug candidates and continue research and development of our pre-clinical-stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. These expenditures include:

- expenses incurred for payments to CROs, investigators and clinical trial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits and equity compensation expense;
- expenses for licensors;
- the cost of acquiring, developing, and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include office leases and other overhead expenses;
- costs associated with pre-clinical activities and regulatory operations;
- expenses associated with the construction and maintenance of our manufacturing facilities; and
- costs associated with operating as a public company.

For more information on the research and development expenses incurred for the development of our drug candidates, see "Key Components of Results of Operations—Research and Development Expenses."

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for commercial and administrative personnel. Other selling, general and administrative expenses include product distribution and promotion costs, professional service fees for legal, intellectual property, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support increases in our commercial and research and development activities and as we continue to commercialize, develop, and manufacture our products and drug assets. These increases will likely include increased headcount, increased share compensation charges, increased product distribution and promotion costs, expanded infrastructure and increased costs for insurance. We also incur increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

Our Ability to Commercialize Our Drug Candidates

All of our drug candidates are still in development in China (including, with respect to ZEJULA, for indications not yet approved in China). As of December 31, 2019, ten of our drug candidates are in clinical development and various others are in pre-clinical development in China. Our ability to generate revenue from our drug candidates is dependent on their receipt of regulatory approval for and successful commercialization of such products, which may never occur. Certain of our drug candidates may require additional pre-clinical and/or clinical development, regulatory approval in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

Our License Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant drug product under these agreements as well as tiered royalties based on the net sales of the licensed products. These expenses are recorded in research and development expense in our consolidated financial statements and totalled $8.0 million, $59.2 million and $58.7 million for the years ended December 31, 2017, 2018 and 2019, respectively.

Key Components of Results of Operations

Taxation

Cayman Islands

Zai Lab Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands. For more information, see “Taxation—Material Cayman Islands Taxation.”

People’s Republic of China

Our subsidiaries incorporated in China are governed by the EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years. For more information, see “Taxation—Material People’s Republic of China Taxation.”

Results of Operations

The following table sets forth a summary of our consolidated results of operations for the periods indicated. This information should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Year ended December 31,		
(in thousands, except share and per share data)	2019	2018	2017
Comprehensive Loss Data:			
Revenue	$ 12,985	$ 129	$ —
Expenses:			
Cost of sales	(3,749)	(43)	—
Research and development	(142,221)	(120,278)	(39,342)
Selling, general and administrative	(70,211)	(21,576)	(12,049)
Loss from operations	(203,196)	(141,768)	(51,391)
Interest income	8,232	3,261	527
Interest expenses	(293)	(40)	—
Changes in fair value of warrants	—	—	200
Other income, net	938	59	530
Loss before income tax and share of loss from equity method investment	(194,319)	(138,488)	(50,134)
Income tax expense	—	—	—
Share of loss from equity method investment	(752)	(587)	(250)
Net loss attributable to ordinary shareholders	$ (195,071)	$ (139,075)	$ (50,384)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	64,369,490	52,609,810	21,752,757
Net loss per share, basic and diluted	$ (3.03)	$ (2.64)	$ (2.32)

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended December 31,			
(in thousands)	2019	%	2018	%
Research and development expenses:				
Personnel compensation and related costs	$ 30,820	21.6	$ 16,755	13.9
Licensing fees	58,682	41.3	59,152	49.2
Payment to CROs/CMOs/Investigators	36,814	25.9	32,282	26.8
Other costs	15,905	11.2	12,089	10.1
Total	$ 142,221	100.0	$ 120,278	100.0

Research and development expenses increased by $21.9 million to $142.2 million for year ended December 31, 2019 from $120.3 million for year ended December 31, 2018. The increase in research and development expenses included the following:

- $14.1 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the year ended December 31, 2019 and the grants of new share options and vesting of restricted shares to certain employees;
- $4.5 million for increased payment to CROs/CMOs/Investigators in fiscal year 2019 as we advanced our drug candidate pipeline; and
- $3.8 million for increased lab consumables and professional service expenses.

The following table summarizes our research and development expenses by program for the years ended December 31, 2019 and 2018, respectively:

	Year ended December 31,			
(in thousands)	2019	%	2018	%
Research and development expenses:				
Clinical programs	$ 96,442	67.8	$ 89,556	74.5
Pre-clinical programs	8,268	5.8	8,102	6.7
Unallocated research and development expenses	37,511	26.4	22,620	18.8
Total	$ 142,221	100.0	$ 120,278	100.0

During the year ended December 31, 2019, 67.8% and 5.8% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the year ended December 31, 2018, 74.5% and 6.7% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. ZEJULA represented approximately 17% and 13% of our external research and development expense, which includes payments to CROs, CMOs and investigators, for the year ended December 31, 2019 and 2018, respectively. Omadacycline (ZL-2401) represented approximately 7% and 12% of our external research and development expense, which includes licensing fees and payment to CROs, CMOs and investigators, for the year ended December 31, 2019 and 2018. bemarituzumab (FPA144) represented approximately 5% and 12%, of our external research and development expense, which includes licensing fees and payment to CROs, CMOs and investigators, for the year ended December 31, 2019 and 2018; ZL-1306 and ZL-2307 represented approximately 17% and 25% of our external research and development expense, which includes licensing fees and payment to CROs, CMOs and investigators, for the year ended December 31, 2019, respectively. No other programs represented a significant amount of research and development expense for the years ended December 31, 2019 or 2018. Though we manage our external research and development expenses by program we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.

Selling, General and Administrative Expenses

The following table sets forth the components of our selling, general and administrative expenses for the years indicated.

	Year ended December 31,			
(in thousands)	2019	%	2018	%
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	$ 43,572	62.1	$ 13,410	62.2
Professional service fees	2,887	4.1	3,266	15.1
Other costs	23,752	33.8	4,900	22.7
Total	$ 70,211	100.0	$ 21,576	100.0

Selling, general and administrative expenses increased by $48.6 million to $70.2 million for year ended December 31, 2019 from $21.6 million for year ended December 31, 2018. The increase in general and administrative expenses included the following:

- $30.2 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during year ended December 31, 2019 and the grants of new share options and vesting of restricted shares to certain employees; and
- $18.9 million for increased selling, rental, and travel expenses primary attributable to the commercial operation in Hong Kong and PRC for the year ended December 31, 2019.

Interest Income

Interest income increased by $5.0 million for year ended December 31, 2019 primary attributable to interest income on higher cash and short-term investments balance in 2019.

Interest Expenses

Interest expenses increased by $0.3 million for year ended December 31, 2019 primary attributable to more short-term borrowings balance in 2019.

Share of loss from equity method investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd., or JING, an entity that will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. We account for our investment using the equity method of accounting because we do not control the investee but have the ability to exercise significant influence over the operating and financial policies of the investee. An investment loss of $0.8 million and $0.6 million related to this investment was recorded for the year ended December 31, 2019 and 2018, respectively.

Other Income, net

Other income, net increased by $0.9 million for year ended December 31, 2019 primarily as a result of an increase in governmental subsidies.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $195.1 million for the year ended December 31, 2019 compared to net loss attributable to ordinary shareholders of $139.1 million for the year ended December 31, 2018.

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the years indicated.

	Year ended December 31,			
(in thousands)	2018	%	2017	%
Research and development expenses:				
Personnel compensation and related costs	$ 16,755	13.9	$ 9,370	23.8
Licensing fees	59,152	49.2	7,948	20.2
Payment to CROs/CMOs/Investigators	32,282	26.8	14,993	38.1
Other costs	12,089	10.1	7,031	17.9
Total	$ 120,278	100.0	$ 39,342	100.0

Research and development expenses increased by $81.0 million to $120.3 million for year ended December 31, 2018 from $39.3 million for year ended December 31, 2017. The increase in research and development expenses included the following:

- $7.4 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the year ended December 31, 2018 and the grants of new share options and vesting of restricted shares to certain employees;
- $51.2 million for increased licensing fees in connection with the upfront and milestone fee paid for licensing agreement (see “Item 4. Information on the Company—Overview of Our License Agreements” for further information);
- $17.3 million for increased payment to CROs/CMOs/Investigators in fiscal year 2018 as we advanced our drug candidate pipeline; and
- $5.1 million for increased lab consumables and professional service expenses.

The following table summarizes our research and development expenses by program for the years ended December 31, 2018 and December 31, 2017, respectively:

	Year ended December 31,			
(in thousands)	2018	%	2017	%
Research and development expenses:				
Clinical programs	$ 89,556	74.5	$ 12,614	32.1
Pre-clinical programs	8,102	6.7	14,755	37.5
Unallocated research and development expenses	22,620	18.8	11,973	30.4
Total	$ 120,278	100.0	$ 39,342	100.0

During the year ended December 31, 2018, 74.5% and 6.7% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the year ended December 31, 2017, 32.1% and 37.5% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. ZEJULA represented approximately 13% and 43% of our external research and development expense, which includes payments to CROs, CMOs and investigators, for the year ended December 31, 2018 and 2017, respectively. Omadacycline (ZL-2401) represented approximately 12% and 45% of our external research and development expense, which includes licensing fees and payment to CROs, CMOs and investigators, for the year ended December 31, 2018 and 2017. Bemarituzumab (FPA144), Optune and MacroGenics projects represented approximately 12%, 14% and 25% of our external research and development expense, which includes licensing fees and payment to CROs, CMOs and investigators, for the year ended December 31, 2018, respectively. No other programs represented a significant amount of research and development expense for the years ended December 31, 2018 or 2017. Though we manage our external research and development expenses by program we do not allocate our internal research and development expenses by program, because our employees and internal resources may be engaged in projects for multiple programs at any time.

Selling, General and Administrative Expenses

The following table sets forth the components of our selling, general and administrative expenses for the years indicated.

	Year ended December 31,			
(in thousands)	2018	%	2017	%
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	$ 13,410	62.2	$ 7,331	60.9
Professional service fees	3,266	15.1	2,977	24.7
Other costs	4,900	22.7	1,741	14.4
Total	$ 21,576	100.0	$ 12,049	100.0

Selling, general and administrative expenses increased by $9.6 million to $21.6 million for year ended December 31, 2018 from $12.0 million for year ended December 31, 2017. The increase in general and administrative expenses included the following:

- $6.1 million for increased personnel compensation and related costs which was primarily attributable to increased administrative personnel costs, due to hiring of more personnel during year ended December 31, 2018 and the grants of new share options and vesting of restricted shares to certain employees; and
- $3.2 million for increased other costs due to the increase of selling, rental, and travel expenses in fiscal year 2018. No selling expenses were incurred during year ended December 31, 2017.

Interest Income

Interest income, net increased by $2.7 million for year ended December 31, 2018 due to higher cash and short-term investments balance in 2018.

Interest Expenses

Interest expenses were due to short-term borrowings in 2018.

Share of loss from equity method investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. We account for our investment using the equity method of accounting because we do not control the investee but have the ability to exercise significant influence over the operating and financial policies of the investee. An investment loss of $586,551 and $249,652 related to this investment was recorded for the year ended December 31, 2018 and 2017, respectively.

Other Income, net

Other income decreased by $0.5 million for year ended December 31, 2018 primarily as a result of an increase of $1.5 million foreign currency exchange loss, and net of an increase of $1.0 million in governmental subsidies.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $139.1 million for the year ended December 31, 2018 compared to net loss attributable to ordinary shareholders of $50.4 million for the year ended December 31, 2017.

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our financial statements in conformity with U.S. GAAP, which requires us to make judgments, estimates and assumptions. We continually evaluate these estimates and assumptions based on the most recently available information, our own historical experiences and various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from our expectations as a result of changes in our estimates. Some of our accounting policies require a higher degree of judgment than others in their application and require us to make significant accounting estimates.

The selection of critical accounting policies, the judgments and other uncertainties affecting application of those policies and the sensitivity of reported results to changes in conditions and assumptions are factors that should be considered when reviewing our financial statements. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

Revenue recognition

In May 2014, the Financial Accounting Standards Board, or FASB, issued a comprehensive new standard which amends revenue recognition principles. In 2018, we adopted of ASC Topic 606, or ASC 606, Revenue from Contracts with Customers, in recognition of revenue. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Our revenue is all from product sales. We recognize revenue from product sales when we have satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the consumers. Cost of sales mainly consists of the purchase price of products and royalty fee.

The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Therefore we do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised good to the customer and receipt of payment will be one year or less.

We started to generate product sales revenue since year 2018. For the year ended December 31, 2019, our product revenues were generated from the sale of ZEJULA and OPTUNE (Tumor Treating Fields) to customers, which are typically healthcare providers such as oncology centers. For the year ended December 31, 2018, our product revenues were generated from the sale of ZEJULA to customers, which are typically healthcare providers such as oncology centers. We utilize a distributor in Hong Kong for warehousing services. Based on the nature of the arrangement, we have determined that the distributor is a principal in the transaction since we are primarily responsible for fulfilling the promise to provide the products to the customers, maintain inventory risk until delivery to the customers and have latitude in establishing the price.

Revenue was recognized at the amount to which we expected to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the distributor is recognized in operating expenses.

Share-Based Compensation

We grant share options to eligible employees, management and directors and account for these share-based awards in accordance with ASC Topic 718, *Compensation-Stock Compensation* , or ASC 718.

Share-based awards are measured at the grant date fair value and recognized as an expense (i) immediately at grant date if no vesting conditions are required or (ii) using a graded vesting method over the requisite service period, which is the vesting period. See Note 16 to the consolidated financial statements included elsewhere in this Annual Report on Form 20-F for further details on the assumptions used to estimate the fair value of share-based awards granted in prior periods.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed.

We determined the fair value of the stock options granted to employees. Before 2018, the binomial option pricing model was applied in determining the estimated fair value of the options granted to employees. In 2018, we changed to use the Black-Scholes option valuation model since we expected the Black-Scholes option valuation model provide a better estimate of fair value. A change in the valuation technique is a change in accounting estimate for purposes of applying ASC 250, and shall be applied prospectively to new awards.

Before January 2019, we have accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 505, Equity-Based Payments to Non-Employees. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if we had paid cash for the services provided by the nonemployees.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718 (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The amendments in this ASU are effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, Revenue from Contracts with Customers. We adopted this ASU on January 1, 2019. The adoption of this standard did not have a material effect on our financial statements.

Fair Value Measurements

We apply ASC Topic 820, *Fair Value Measurements and Disclosures* , or ASC 820, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Include other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches, for example, to measuring the fair value of assets and liabilities: (1) market approach, (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of our company primarily include cash, cash equivalents and restricted cash , short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities. As of each reporting date, the carrying values of cash and cash equivalents, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities approximated their fair values due to the short-term maturity of these instruments , and the carrying value of restricted cash approximates its fair value based on the nature of the assessment of the ability to recover these amounts.

Fair Value of Our Ordinary Shares

Prior to our initial public offering in September 2017, we were a private company with no quoted market prices for our ordinary shares. We have therefore needed to make estimates of the fair value of our ordinary shares at various dates for the following purposes:

- determining the fair value of our ordinary shares at the date of issuance and the dates of subsequent measurement of convertible instruments as one of the inputs in determining the intrinsic value of the beneficial conversion feature, if any; and
- determining the fair value of our ordinary shares at the date of the grant of a share-based compensation award to our employees and non-employees as one of the inputs in determining the grant date fair value of the award.

In determining the fair value of our ordinary shares as of various valuation dates, we first applied an income approach, specifically a discounted cash flow, or DCF, analysis based on our projected cash flows using management’s best estimates as of the valuation date and the market approach by referring to transaction prices of our private equity financing transactions with independent third parties to conclude on the equity value. We then applied the option-pricing method to allocate the equity value between preferred shares and ordinary shares. The determination of the equity value requires complex and subjective judgments to be made regarding prospects of the industry and the products at the respective valuation dates, our projected financial and operating results, our unique business risks and the liquidity of our shares.

The income approach involves applying appropriate discount rates to estimated cash flows that are based on earnings forecasts. However, these fair values are inherently uncertain and highly subjective. The major assumptions utilized in DCF analysis include:

Financial projection . The projected cash flows include among other things, an analysis of projected revenue growth, gross margins, effective tax rates, capital expenditures, working capital requirements and depreciation and amortization. The assumptions used in deriving the fair values are consistent with our business plan. These assumptions include no material changes in the existing political, legal and economic conditions in China; our ability to retain competent management and key personnel to support our ongoing operations; and no material deviation in historical industry trends and market conditions from current forecasts. These assumptions are inherently uncertain.

Discount Rates . The discount rates were based on the weighted average cost of capital and ranged from 16%-25% where the cost of equity was determined based on a Capital Asset Pricing Model, which includes a consideration of the factors including risk-free rate, comparative industry risk, equity risk premium, company size and non-systemic risk factors.

Discount for Lack of Marketability, or DLOM . DLOM reflects the fact that our shares were privately-held shares. DLOM was quantified by various valuation techniques, such as the Black-Scholes option pricing model. Under this method, the cost of the put option, which could be used to hedge the price change before the privately held shares can be sold, was considered as a basis to determine the DLOM. This option pricing method is one of the methods commonly used in estimating DLOM. The key assumptions of such model include risk-free rates, timing of a liquidity event, and estimated volatility of our shares. The farther the valuation date is from an expected liquidity event, the higher the put option value and thus the higher the implied DLOM. The lower DLOM is used for the valuation, the higher is the determined fair value of the ordinary shares.

The equity value of our company determined at the respective valuation dates based on the income approach under the above assumptions and the market approach referring to transaction price of our private equity financing transactions with independent third parties was allocated between the preferred shares and ordinary shares. The option-pricing method was used to allocate equity value, taking into account the guidance prescribed by the AICPA Audit and Accounting Practice Aid, " *Valuation of Privately-Held Company Equity Securities Issued as Compensation* ." The method treats common stock and preferred stock as call options on the enterprise's value, with exercise prices based on the liquidation preference of the preferred stock.

The option-pricing method involves making estimates of the anticipated timing and probability of a potential liquidity event, such as a sale of our company, an initial public offering, a redemption event (for Series C preferred shares issued in June 2017) and estimates of risk free rate and the volatility of our equity securities. The anticipated timing and probability were based on the plans of our board of directors and management. The risk free rate is adopted based on the United States Treasury bond yield with a maturity commensurate with the expected time to liquidity, adjusted by country risk premium between China and the United States. Estimating the volatility of the share price of a privately held company is complex because there is no readily available market for the shares. We estimated the volatility of our shares to be 70% based on the historical volatilities of comparable publicly traded companies engaged in similar lines of business. Had we used different estimates of volatility, the allocations between preferred and ordinary shares would have been different.

After our initial public offering in September 2017, the closing market price of the underlying shares on the applicable grant date is used to determine the fair value of our ordinary shares.

Income Taxes

Current income taxes are provided on the basis of net income for financial reporting purposes, adjusted for income and expense items which are not assessable or deductible for income tax purposes, in accordance with the regulations of the relevant tax jurisdictions. We follow the liability method of accounting for income taxes.

Under this method, deferred tax assets and liabilities are determined based on the temporary differences between the financial statements carrying amounts and tax bases of assets and liabilities by applying enacted statutory tax rates that will be in effect in the period in which the temporary differences are expected to reverse. We record a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in our consolidated financial statements in the period of change.

In accordance with the provisions of ASC 740, *Income Taxes* , we recognize in our financial statements the benefit of a tax position if the tax position is "more likely than not" to prevail based on the facts and technical merits of the position. Tax positions that meet the "more likely than not" recognition threshold are measured at the largest amount

of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. We estimate our liability for unrecognized tax benefits which are periodically assessed and may be affected by changing interpretations of laws, rulings by tax authorities, changes and/or developments with respect to tax audits, and expiration of the statute of limitations. The ultimate outcome for a particular tax position may not be determined with certainty prior to the conclusion of a tax audit and, in some cases, appeal or litigation process.

We consider positive and negative evidence when determining whether some portion or all of our deferred tax assets will not be realized. This assessment considers, among other matters, the nature, frequency and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, our historical results of operations, and our tax planning strategies. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the level of our historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe it is more likely than not that we will not realize the deferred tax assets resulted from the tax loss carried forward in the future periods.

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts, circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of December 31, 2018 and 2019, we did not have any significant unrecognized uncertain tax positions.

B. Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We incurred net losses of $195.1 million, $139.1 million and $50.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $444.7 million. Our primary use of cash is to fund research and development costs. Our operating activities used $191.0 million, $97.5 million and $32.4 million of cash flows during the years ended December 31, 2019, 2018 and 2017, respectively. Historically, we have financed our operations principally through proceeds from private placements as well as proceeds from our initial public offering and subsequent follow-on offerings. As of December 31, 2019, we had cash and cash equivalents and short-term investments of $275.9 million. In January 2020, we raised $280.6 million in net proceeds from our subsequent follow-on offering of 6,300,000 ADSs. Our expenditures as a company principally focused on research and development, are largely discretionary and as such our current losses and cash used in operations do not present immediate going concern issues. Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of April 2020, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in this report are issued. However, in order to bring to fruition our research and development objectives the company will ultimately need additional funding sources and there can be no assurances that they will be made available.

Our ability to pay dividends may depend on receiving distributions of funds from our PRC subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by our PRC subsidiaries only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of our PRC subsidiaries. In accordance with the relevant applicable PRC laws and regulations, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the board of directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. Our PRC subsidiaries were established as domestic enterprises and therefore are subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2019, 2018 and 2017, no appropriation to statutory reserves was made because our PRC subsidiaries had substantial losses during such periods. As a result of relevant applicable PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as a general reserve fund, our PRC subsidiaries are restricted in their ability to transfer a portion of its net assets. Foreign exchange and other regulations in China may further restrict our PRC

subsidiaries from transferring funds to us in the form of dividends, loans and advances. As of December 31, 2019, amounts restricted are the paid-in capital of our PRC subsidiaries, which amounted to $155.9 million.

The following table provides information regarding our cash flows for the years ended December 31, 2019, 2018 and 2017:

	Year ended December 31,		
(in thousands)	2019	2018	2017
Net cash (used in) operating activities	$ (191,011)	$ (97,538)	$ (32,367)
Net cash (used in) investing activities	(14,892)	(212,554)	(10,434)
Net cash provided by financing activities	219,302	144,147	187,860
Effect of foreign exchange rate changes	91	(763)	652
Net increases(decrease) in cash, cash equivalents and restricted cash	$ 13,490	$ (166,708)	$ 145,711

Net cash used in operating activities

During the year ended December 31, 2019, our operating activities used $191.0 million of cash, which resulted principally from our net loss of $195.1 million, adjusted for non-cash charges of $27.3 million, and by cash used in our operating assets and liabilities of $23.2 million. Our net non-cash charges during the year ended December 31, 2019 primarily consisted of $3.8 million depreciation expense, $20.3 million share-based compensation expense and $2.8 million noncash lease expense.

During the year ended December 31, 2018, our operating activities used $97.5 million of cash, which resulted principally from our net loss of $139.1 million, adjusted for non-cash charges of $14.2 million, and by cash provided by our operating assets and liabilities of $27.4 million. Our net non-cash charges during the year ended December 31, 2018 primarily consisted of $1.6 million depreciation expense, $12.2 million share-based compensation expense and a $0.6 million share of loss from equity method investment and offset by a $0.3 million amortization of deferred income.

During the year ended December 31, 2017, our operating activities used $32.4 million of cash, which resulted principally from our net loss of $50.4 million, adjusted for non-cash charges of $10.5 million, and by cash provided in our operating assets and liabilities of $7.5 million. Our net non-cash charges during the year ended December 31, 2017 primarily consisted of $0.5 million depreciation expense, $9.9 million share-based compensation expense, $0.2 million share of loss from equity method investment and $0.2 million gain from changes in fair value of warrants.

Net cash used in investing activities

Net cash used in investing activities was $14.9 million for the year ended December 31, 2019 compared to $212.6 million for the year ended December 31, 2018. The decrease in cash used in investing activities was primary due to the proceeds from maturity of short-term investments, net of purchases of short-term investments.

Net cash used in investing activities was $212.6 million for the year ended December 31, 2018 compared to $10.4 million for the year ended December 31, 2017. The increase in cash used in investing activities was due to purchases of short-term investments, construction of our large molecule facility and other investments in 2018.

Net cash provided by financing activities

Net cash provided by financing activities was $219.3 million for the year ended December 31, 2019 compared to $144.1 million for the year ended December 31, 2018. The cash provided by financing activities was mainly attributable to the issuance of ADSs in our subsequent follow-on offering in 2019.

Net cash provided by financing activities was $144.1 million for the year ended December 31, 2018 compared to $187.9 million for the year ended December 31, 2017. The cash provided by financing activities was mainly attributable to the issuance of ADSs in our subsequent follow-on offering in 2018.

C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are given in the “Business” and “Operating and Financial Review and Prospects” sections of this annual report above.

D. Trend Information.

Other than as described elsewhere in this Annual Report on Form 20-F, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

E. Off-balance Sheet Arrangements.

We currently do not engage in trading activities involving non-exchange traded contracts or interest rate swap transactions or foreign currency forward contracts. In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

F. Tabular Disclosure of Contractual Obligations.

The following table sets forth our contractual obligations as of December 31, 2019. Amounts we pay in future periods may vary from those reflected in the table.

(in thousands)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Purchase Obligations	$ 692	$ 692	$ —	$ —	$ —
Operating Lease Obligations	16,043	4,595	6,949	2,712	1,787

We also have obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones as well as tiered royalties on net sales. We have not included these commitments on our balance sheet or in the table above because the commitments are cancellable if the milestones are not complete and achievement and timing of these obligations are not fixed or determinable.

Recently Issued Accounting Standards

In February 2016, the FASB issued ASC 842 which supersedes the lease recognition requirements in ASC 840, Leases, or ASC 840. The most prominent of the changes in ASC 842 is the recognition of right-of-use, or ROU, assets and lease liabilities by lessees for those leases classified as operating leases. Consistent with ASC 840, leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. In July 2018, the FASB issued an accounting standard update which amended ASC 842 and offered an additional (and optional) transition method by which entities could elect not to recast the comparative periods presented in financial statements in the period of adoption.

We adopted the new standard on January 1, 2019, using the optional adoption method whereby we did not adjust comparative period financial statements. Consequently, prior period balances and disclosures have not been restated. We elected the package of transition provisions available for expired or existing contracts, which allowed us to carry forward our historical assessments of (i) whether contracts are or contain leases, (ii) lease classification and (iii) initial direct costs. For leases in place upon adoption, we used the remaining lease term as of January 1, 2019 in determining the incremental borrowing rate, or IBR. For the initial measurement of the lease liabilities for leases commencing on or after January 1, 2019, the IBR at the lease commencement date was applied.

Our lease portfolio consists entirely of operating leases, the adoption of ASU 2016-02 resulted in the initial recognition of ROU assets of $7.1 million and related lease liabilities of $7.0 million on the consolidated balance sheet at January 1, 2019. Upon adoption, we reclassified $0.1 million prepaid rent to operating ROU assets. Our leases do not contain any material residual value guarantees or material restrictive covenants. Additionally, the adoption of ASU 2016-02 did not materially affect the consolidated statements of income or the consolidated statements of cash flows.

For the impact on the consolidated balance sheet upon adoption of ASU 2016-02, please see Note 2(ac) to our audited consolidated financial statements in this Annual Report on Form 20-F.

In June 2016, the FASB released ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)* : Measurement of Credit Losses on Financial Instruments. ASU 2016-13 replaces the existing impairment model for most financial assets from an incurred loss impairment model to a current expected credit loss model, which requires an entity to recognize an impairment allowance equal to its current estimate of all contractual cash flows the entity does not expect to collect. ASU 2016-13 also requires credit losses relating to AFS debt securities to be recognized through an allowance for credit losses. In April 2019, the FASB issued ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments Credit Losses, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825 Financial Instruments, the amendments of which clarify the modification of accounting for available for sale debt securities excluding applicable accrued interest, which must be individually assessed for credit losses when fair value is less than the amortized cost basis. In May 2019, the FASB issued ASU 2019-05, Financial Instruments— *Credit Losses* (Topic 326)— *Targeted Transition Relief* , which is the final version of Proposed Accounting Standards Update 2019-10— *Targeted Transition Relief* for Topic 326, Financial Instruments—Credit Losses, which has been deleted. This update provides entities with an option to irrevocably elect the fair value option applied on an instrument-by-instrument basis for certain financial assets upon the adoption of Topic 326. The fair value option election does not apply to held-to-maturity debt securities. An entity that elects the fair value option should subsequently apply the guidance in Subtopics 820-10, Fair Value Measurement-Overall, and 825-10. In December 2019, FASB issued ASU No. 2019-11, Codification Improvements to Topic 326, *Financial Instruments—Credit Losses* . This update introduced an expected credit loss model for the impairment of financial assets measured at amortized cost basis. In March 2020, the FASB issued ASU No. 2020-03, Codification Improvements to Financial Instruments. This update clarifies that the contractual term of a net investment in a lease determined in accordance with Topic 842 should be the contractual term used to measure expected credit losses under Topic 326. The standards are to be applied using a modified retrospective approach and are effective for interim periods and fiscal years beginning after December 15, 2019, with early adoption permitted. We do not anticipate the adoption of this ASU to have a material impact to its financial statements for its existing business.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)* : Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for interim periods and fiscal years beginning after December 15, 2019, with early adoption permitted. We do not expect the requirements of ASU 2018-13 will have a material impact on the consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)* : Clarifying the Interaction between Topic 808 and Topic 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The update is effective in fiscal years beginning after December 15, 2019, and interim periods therein, and early adoption is permitted for entities that have adopted ASC 606. This guidance should be applied retrospectively to the date of initial application of Topic 606. We are currently evaluating the impact on its financial statements of adopting this guidance.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, Income taxes, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. We are currently evaluating the impact on its financial statements of adopting this guidance.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

Our Executive Officers and Directors

Below is a list of the names and ages of our directors, officers, other key employees and scientific advisors as of March 31, 2020, and a brief account of the business experience of each of them. The business address for our directors and officers is c/o Zai Lab Limited, 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210.

Name	Age	Position(s)
Executive Officers		
Ying (Samantha) Du	55	Director, Chairman and Chief Executive Officer
Tao Fu	48	Director, President & Chief Operating Officer
Yongjiang Hei	57	Chief Medical Officer, Oncology
Harald Reinhart	68	Chief Medical Officer, Autoimmune and Infectious Diseases
Billy Cho	42	Chief Financial Officer
William Liang	49	Chief Commercial Officer
Valeria Fantin	49	Chief Scientific Officer
Non-Management Directors		
Kai-Xian Chen	74	Director
Nisa Leung	49	Director
William Lis	55	Director
Peter Wirth	69	Director; Senior Advisor
John Diekman	77	Director
Leon O. Moulder, Jr.	62	Director
Other Key Employees		
Ning Xu	55	Executive Vice President, Head of Clinical and Regulatory
James Yan	56	Executive Vice President, Preclinical Development and Program & Portfolio Management
Jonathan Wang	38	Senior Vice President, Head of Business Development
Scientific Advisors		
Lieping Chen	62	Scientific Advisor
Richard A. Flavell	74	Scientific Advisor
Neal Rosen	69	Scientific Advisor
Timothy Yap	45	Scientific Advisor
Alex A. Adjei	64	Scientific Advisor

Executive Officers

Ying (Samantha) Du , Ph.D. co-founded our company and has been our Director, Chairman and Chief Executive Officer since our inception. Prior to founding our company, Dr. Du spent two years as Managing Director of healthcare investments at Sequoia Capital China, where she led four investments. From 2001 to 2011, Dr. Du was founder and Chief Executive Officer of Hutchison Medi-Pharma and the co-founder and Chief Scientific Officer of Hutchison China MediTech Limited, a Nasdaq-listed biopharmaceutical company, where she pioneered China-based global biopharmaceutical innovation by bringing five internally-discovered innovative drug candidates into clinical trials, including two global Phase III ready drug candidates. Dr. Du began her career with Pfizer in the United States in 1994, where she was involved in the development and launch of two global drugs. While at Pfizer, she was responsible for Pfizer's global metabolic licensing program on the scientific side. She received a Ph.D. in biochemistry from the University of Cincinnati. Dr. Du has also been involved with and chaired several Chinese regulatory and government related committees.

Tao Fu has been our Director since 2017 and has served as our company's President and Chief Operating Officer since September 2018. Prior to joining our company, he was Executive Vice President, Chief Commercial and Business Officer of Portola Pharmaceuticals, Inc., a publicly traded biotechnology company specializing in cardiovascular disease, hematological disorders and cancer from June 2015 to September 2018. Prior to joining Portola in June 2015, Mr. Fu was Vice President, business development, head of M&A and alliance management at BMS. Mr. Fu led all M&A, divestiture, strategic transaction and venture investment opportunities as well as alliance management for BMS. Between 2003 and 2015, Mr. Fu worked at Johnson & Johnson in a number of roles, most recently as Vice President, business development, where he was responsible for global M&A activities in the pharmaceutical sector. Prior to joining Johnson & Johnson, Mr. Fu held managerial positions with Scios Inc., a biotechnology company in California; McKinsey &Company, a global management consulting firm; and Becton Dickinson, a leading medical device company. Mr. Fu received a master of science in cell biology from the University of Rochester, and a master of business administration in finance and marketing from Vanderbilt University. Mr. Fu did his undergraduate studies in biology at Tsinghua University and is a Chartered Financial Analyst (CFA).

Yongjiang Hei, M.D., Ph.D. has been our Chief Medical Officer, oncology since 2018. Prior to joining our company, Dr. Hei was the Chief Medical Officer at Qilu Pharmaceuticals responsible for the overall strategy and operations of clinical development programs in all therapeutic areas. Dr. Hei joined Qilu from the San Diego-based biotechnology company Ambrx, where he served as the Chief Medical Officer responsible for the clinical strategy and operations, focusing on antibody-drug conjugates and bispecific antibodies. Prior to Ambrx, Dr. Hei had worked at Amgen for approximately 10 years as the Executive Medical Director in oncology global development and medical affairs. In particular, he was the Global Development Leader for numerous oncology pipeline molecules and marketed products including small molecules such as Motesanib as well as biologics such as conatumumab and Vectibix. Additionally, during his tenure at Amgen, Dr. Hei spent three years in China as the Medical Head to build the clinical medical teams and establish product development and clinical operation capabilities for Amgen China. Before Amgen, Dr. Hei served as the U.S. Medical Director for Roche, and Senior Global Brand Medical Director/Executive Director for Novartis Oncology where he led the development and execution of medical plans and expanded investigator-initiated clinical research. In addition, Dr. Hei supported regulatory filings and submissions at the FDA, PMDA (Japan), EMA, and the CFDA.

Harald Reinhart , M.D. has been our Chief Medical Officer, autoimmune and infectious diseases since 2017. He is currently adjunct clinical professor of infectious diseases at the Yale School of Medicine. Prior to joining our company, Dr. Reinhart worked at Shionogi US as Head of Clinical Development & Medical Affairs, where he directed a broad portfolio of antibiotics, diabetes, allergy and pain medications and guided a woman's health product through Phase III, NDA and FDA approval. Between 2003 and 2011, Dr. Reinhart held senior roles at Novartis, including Vice President and Global Project Leader of Infectious Disease, Transplantation and Immunology. He oversaw successful filings of SNDAs and NDAs for Coartem, Famvir, Sebivo, and Cubicin, managed clinical development groups in the U.S. and E.U., and supervised the transitioning of projects from research into clinical development. From 1991 until 2003 he worked at Bayer in anti-infectives and diabetes. He was International Clinical Project Manager for ciprofloxacin and acarbose and in charge of numerous successful sNDA filings. He also oversaw the strategic development of several early phase antibacterial and antiviral projects. Dr. Reinhart received his medical degree from the University of Würzburg in Germany. He completed his medical specialty training in the United States with board certifications in internal medicine and infectious diseases.

Billy Cho , M.B.A., M.A. joined our company as our Chief Financial Officer in March 2018. Prior to joining our company, Mr. Cho served as Managing Director and Head of Asia Healthcare Investment Banking at Citigroup. Based in Hong Kong since 2011, Mr. Cho was responsible for healthcare client coverage at Citigroup across the Asia Pacific region and led many biopharma transactions in China, including Zai Lab's U.S. initial public offering. Prior to this, he was based in New York in healthcare M&A investment banking and also spent time in corporate development for a pharmaceutical services company. Mr. Cho started his career at Ernst & Young performing financial audits of U.S.-based healthcare companies. Mr. Cho earned his M.B.A. from the Wharton School of the University of Pennsylvania and M.A. in Accounting from University of Virginia.

William Liang , M.D. joined our company as our Chief Commercial Officer in June 2018. Prior to joining our company, Mr. Liang served as Vice President at AstraZeneca heading up the Oncology Business Unit in China. Under his leadership, AstraZeneca built a top performing oncology franchise in China by significantly outgrowing the market with many successful product launches, including setting a new benchmark for the successful market launch of Tagrisso. During his tenure, Mr. Liang expanded his team from approximately 500 to 2,000 professionals and introduced a patient-centric business model to establish AstraZeneca's oncology leadership position in China. Prior to AstraZeneca, he was Vice President of Oncology at BMS in China, where he rebuilt the oncology sales team to achieve substantial sales growth. Previously, he spent over 13 years in senior commercial roles at Roche, where he began his career and ultimately achieved the position of China Business Unit Director of Oncology. Mr. Liang received his Medical Degree in Clinical Medicine from Fudan University and his Executive MBA degree from the China Europe International Business School.

Valeria Fantin, Ph.D. joined our company as our Chief Scientific Officer in June 2019. Prior to joining Zai Lab, Dr. Fantin was the Chief Scientific Officer at ORIC Pharmaceuticals, where she was responsible for building the research team and establishing a pipeline targeting mechanisms of therapy resistance in cancer, including driving the GR antagonist ORIC-101 from discovery to the clinic. Before ORIC, Dr. Fantin was Vice President of Tumor Cell Biology at Pfizer, where she was responsible for advancing small molecules and biologics from target validation to Phase II proof-of-concept across signaling, metabolism, epigenetics and immuno-oncology. Dr. Fantin contributed to the development of the first in class CDK4/6 inhibitor palbociclib (IBRANCE®), as well as the discovery of the brain-penetrant ALK inhibitor lorlatinib (LORBRENA®) and several compounds currently in Ph1/Ph2 studies. Prior to that, Dr. Fantin held leadership positions at Agios Pharmaceuticals where she created and advanced an exploratory program of novel cancer metabolism targets into drug discovery and led the execution of the company's flagship isocitrate dehydrogenase program that provided the scientific foundation for the recently FDA approved IDH2 and IDH1 inhibitors enasidenib (IDHIFA®) and ivosidenib (TIBSOVO®), respectively. Her earlier work as a researcher at Merck Research Laboratories focused on epigenetics and kinase drug discovery projects, where she contributed to the development of the first in class HDAC inhibitor vorinostat (ZOLINZA®). Dr. Fantin completed postdoctoral training in cancer metabolism and signal transduction at Harvard Medical School and the Howard Hughes Medical Institute and earned her Ph.D. in molecular and cellular biology from Dartmouth Medical School.

Non-Management Directors

Kai-Xian Chen , Ph.D. has been our Director since August 2018. From 2007 to 2017, he served as a member of the National Committee of the Chinese People's Political Consultative Conference. From 2005 to 2014, Professor Chen served as President of Shanghai University of Traditional Chinese Medicine. From 2011 to 2018, Professor Chen served as President of the Shanghai Association for Science and Technology. Prior to that, from 1993 to 2004, Professor Chen served as Deputy Director and later, Director of Shanghai Institute of Materia Medica, or SIMM, Chinese Academy of Sciences. Professor Chen has as also served as Principal Scientist for two National Basic Research Programs by the MOST. Since 2001, professor Chen has served successively as the member of the Chief Specialists Board and the deputy Chief Technical Officer of the major science and technology projects "innovative drugs and modernization of traditional Chinese medicine" and "Innovative Drug Research & Development ", where he participated in the organization and promotion of new drug research and development for China's 10th -13th Five Year Plans. In 1999, Professor Chen was elected as a member of the Chinese Academy of Sciences. Prior to that, from 1985 to 1988, he conducted postdoctoral research at Institut de Biologie Physico-Chimique in Paris. Professor Chen started his academic career at SIMM as an Associate Professor, where he later reached the level of Full Professor. Professor Chen received his Master and Ph.D. Degree at the Chinese Academy of Science, and his Bachelor of Science from Fudan University.

Nisa Leung has been our Director since 2014. Ms. Leung is a Managing Partner at Qiming Venture Partners, where she leads its health care investments. In addition to serving on our board of directors, Ms. Leung is also a member of the board of directors of CanSino Biotechnology, a vaccine developer; dMed, a Shanghai-based CRO consulting startup; Gan & Lee Pharmaceuticals, a developer of insulin analog; Nurotron Biotechnology, a developer of neurostimulation systems; and Venus Medtech, a developer of interventional artificial cardiac valve systems. Ms. Leung received a Master of Business Administration from the Stanford Graduate School of Business.

William Li s has been our independent Director since October 2018. He has 28 years of biopharmaceutical experience. He is the Executive Chairman, and interim CEO of Jasper Therapeutics, Inc where he led the company's 2019 Series A financing. Previously, Mr. Lis served as Chief Executive Officer and a Director of Portola Pharmaceuticals, Inc. from 2009 until 2018 after serving as Chief Operating Officer. Under his leadership, Portola successfully grew from a discovery-stage company to a fully integrated research and development and commercial organization, and independently discovered and developed Andexxa® and Bevyxxa® through commercial launch, and advanced cerdulatinib into clinical development. He led corporate partnerships and private and public financings including an initial public offering in 2013. The company grew into a multi-billion valuation company during his tenure. Mr. Lis held executive positions at Scios, Inc. (a Johnson & Johnson company) where he last served as Sr. Vice President of Business Development and New Product Development, having led efforts for the in-licensing, development and pre-commercial launch for Xarelto®; He also held positions of increasing responsibility at Millennium Pharmaceuticals, Inc. (previously COR Therapeutics, Inc.) and Rhone Poulenc Rorer in sales, marketing, medical affairs and business development. He was involved in the U.S. commercial launch of several products, including Integrilin®, Lovenox® and Rilutek®. Mr. Lis served as a member of the Bio Board of Directors for Emerging Companies and is currently an independent Director of Eidos Therapeutics, Inc. and Zai Laboratories, Inc. Mr. Lis holds a B.S. from the University of Maryland.

Peter Wirth has been our Director since 2017 and has been our senior advisor since 2015. He is chairman of FORMA Therapeutics Holdings LLC, a small molecule drug discovery company; executive chairman of ZappRx, a digital health care company; chair of the board of directors at Syros Pharmaceuticals, a Nasdaq-listed biopharmaceutical company; and a venture partner at Quan Capital Management, LLC, a global venture capital firm. From 2011 to 2014, Mr. Wirth served as President and Director of Lysosomal Therapeutics, Inc., a biopharmaceutical company focused on small molecule research. From 1996 to 2011, Mr. Wirth served as a senior executive at Genzyme, which is now part of Sanofi, and most recently as its Executive Vice President of legal and corporate development, Chief Risk Officer and corporate secretary. During the last five years, Mr. Wirth also served as a director of Synageva BioPharma Corp., a biopharmaceutical company which is now owned by Nasdaq-listed Alexion Pharmaceuticals. Mr. Wirth received a law degree from Harvard Law School.

John D. Diekman , Ph.D. has been our independent Director since 2017. Dr. Diekman is founding partner of 5AM Ventures, where he has served since 2002. He is chairman of the board of directors of IDEAYA Biosciences, Inc., an oncology target discovery company; director of Cleave Therapeutics, Inc., a cancer therapeutic company; and Wildcat Discovery Technologies, Inc., a technology company that discovers materials for energy storage applications; charter trustee of Princeton University; chairman of the board of directors of The Scripps Research Institute; and a member of the advisory board of the Schaeffer Center for Health Policy and Economics at the University of Southern California. During the last five years, Dr. Diekman also served as director of Calibrium LLC, a biopharmaceutical research company focused on diabetes and other metabolic diseases; Cellular Research, Inc., a single-cell genomics startup; and PhaseRx Inc., a biopharmaceutical company developing mRNA treatments for life-threatening inherited liver diseases in children. Dr. Diekman holds an A.B. in Organic Chemistry from Princeton University and a Ph.D. in Chemistry from Stanford University.

Leon O. Moulder, Jr. has been our independent Director since January 2020. Mr. Moulder is the Founding General Partner of Tellus BioVentures, LLC, an early-stage life sciences investment fund. He most recently served as Chief Executive Officer and Director of Tesaro, Inc. since cofounding the company in 2010. Acquired by GSK in January 2019, Tesaro was a fully-integrated Boston based oncology-focused biopharmaceutical company with operations in North America and Europe. He previously served as President and Chief Executive Officer of Abraxis BioScience, Inc., prior to the company's eventual acquisition by Celgene Corporation in 2010. Prior to that, from 2008, Mr. Moulder served as Vice Chairman of Eisai Corporation of North America following Eisai's acquisition of MGI PHARMA, where he served as President and Chief Executive Officer beginning in 2003 and previously as Executive Vice President since 1999. This followed him serving as a member of the founding management team of a venture-stage biotech company in 1997. Mr. Moulder began his career as a clinical pharmacist followed by a seventeen year career at predecessor companies of Sanofi, beginning with Marion Laboratories in 1981. Mr. Moulder is a Temple University

Trustee, Chair of the Trustee Committee for Research and Chair of the Temple University Japan (TESS) Board. He is a Council Member for both the University of Chicago Booth School of Business and the Polsky Center for Entrepreneurship and Innovation. Mr . Moulder is Chair of the Board of Directors of Trevena, Inc. and previously served on the Boards of Cubist Pharmaceuticals and the Biotechnology Innovation Organization (BIO). Mr. Moulder received a Pharmacy degree from Temple University in 1980 and an MBA from The University of Chicago Booth School of Business in 1997.

Other Key Employees and Advisors

Ning Xu , M.D. has been our executive Vice President, head of clinical operations and regulatory affairs since 2014. Prior to joining our company, he served as Vice President, head of clinical development service at Covance China. Before joining Covance, Dr. Xu served as a senior medical and regulatory affairs executive at Johnson & Johnson and GSK. Dr. Xu received a medical degree from Peking Union Medical College and a master of business administration from the University of Illinois at Chicago. Dr. Xu also completed a postdoctoral fellowship at the Medical School, University of Illinois at Chicago. Between 2011 and 2015, he was the chairman of the Advisory Council of DIA China and a Director of DIA Global.

James Yan , Ph.D. has been our executive Vice President, pre-clinical development and program & portfolio management since 2015. Prior to joining our company, Dr. Yan was the head of the Covance early development Shanghai site, where he was responsible for all aspects of the business. Between 2009 and 2011, Dr. Yan served as the head of drug safety evaluation and program management of Hutchison Medi-Pharma. Prior to Hutchison Medi-Pharma, Dr. Yan had significant experience at Pfizer in the United States. Over the course of his career, Dr. Yan was been involved in many IND and NDA filings for multiple drug candidates and gained substantial experience working with regulatory agencies in several countries. Dr. Yan received a Ph.D. from Peking Union Medical University and completed post-doctoral training at the University of Chicago's Ben-May Institute for Cancer Research. He is a diplomat of the American Board of Toxicology, a council member of the China Society of Toxicology and a member of the Drug Toxicity and Drug Safety Evaluation Committee.

Jonathan Wang has been our senior Vice President, head of business development since 2014. Prior to joining our company, Mr. Wang was an investment professional at OrbiMed, where he was responsible for China healthcare investment and portfolio management. From 2005 to 2011, Mr. Wang worked as a consultant at the Boston Consulting Group in China, where he specialized in pharmaceutical and healthcare engagements, assisting multinational and local companies with their China strategy. Previously, Mr. Wang also gained financial transactional experience at Goldman Sachs Investment Banking. Mr. Wang received a master of business administration in healthcare management from Wharton Business School.

Lieping Chen , M.D., Ph.D. has served on our Scientific Advisory Board since 2019. Dr. Chen is the United Technologies Corporation Professor in Cancer Research, Co-Director of the Cancer Immunology Program at the Yale Cancer Center and a Professor of Immunobiology, Dermatology and Medicine (Medical Oncology) at the Yale University School of Medicine. Dr. Chen studies cell membrane proteins which control lymphocyte functions and translates his laboratory findings for the treatment of human diseases including cancer. Dr. Chen has published more than 350 research articles, review and book chapters. He has received several awards and professional recognitions including William B. Coley Award (2014), Warren Alpert Foundation Prize (2017) and Giants of Cancer Care (2018).

Richard A. Flavell , Ph.D., FRS has served on our Scientific Advisory Board since 2017. Since 2002, Dr. Flavell has been the Sterling Professor of Immunobiology at Yale University School of Medicine. Prior to joining the Yale faculty in 1988, Dr. Flavell was the President and Chief Scientific Officer of Biogen Research Corporation. Dr. Flavell received a Ph.D. in biochemistry from the University of Hull, England, and performed postdoctoral work in Amsterdam and Zurich. He is an Investigator of the Howard Hughes Medical Institute, a fellow of the Royal Society, a member of the National Academy of Sciences, and a member of the Institute of Medicine of the National Academies. He has published over 800 papers and has received many awards, including the Invitrogen Meritorious Career Award from the American Association of Immunologists.

Neal Rosen , M.D., Ph.D. has served on our Scientific Advisory Board since 2016. Dr. Rosen is a Member of the Department of Medicine and a Member of the Molecular Pharmacology and Chemistry Program at Memorial Sloan Kettering Cancer Center, where he serves as Head of Developmental Therapeutics. He is also a Professor of Pharmacology, Cell Biology and Medicine at Cornell University Medical School. He has played an important role in the development of tyrosine kinase-mediated signaling inhibitors and has pioneered the concept that cancer cells are dependent on cellular machinery for protein folding. Dr. Rosen received a medical degree and a Ph.D. in Molecular Biology from the Albert Einstein College of Medicine. He completed a residency in Internal Medicine at the Brigham and Women's Hospital and post-doctoral training and a fellowship in Medical Oncology at the National Cancer Institute, where he served on the senior staff prior to joining the faculty of Memorial Sloan Kettering Cancer Center. He was the recipient of the NIH/NCI Outstanding Investigator Award in 2016.

Timothy Yap, M.D., Ph.D. has served on our Scientific Advisory Board since 2019. Dr. Yap is an Associate Professor in the Department of Investigational Cancer Therapeutics and Medical Director of The Institute for Applied Cancer Science at The University of Texas MD Anderson Cancer Center, Houston, TX. Previously, he was a Consultant Medical Oncologist and NIHR BRC Clinician Scientist jointly in the Phase I Drug Development Unit, Lung Cancer Unit and Cancer Biomarkers Laboratory at the Royal Marsden Hospital and the Institute of Cancer Research (ICR). Dr. Yap earned his medical degree from Imperial College London and completed his general medical training in Oxford. Dr. Yap undertook a Clinical Fellowship in the Phase I Drug Development Unit at the Royal Marsden Hospital and completed his Ph.D. in Molecular Pharmacology in the Division of Cancer Therapeutics in the ICR.

Alex A. Adjei, M.D., Ph.D., FACP has served on our Scientific Advisory Board since 2019. Dr. Adjei is a Consultant in Oncology, Professor of Oncology and Professor of Pharmacology at Mayo Clinic and Mayo College of Medicine, in Rochester, MN. Dr. Adjei oversees oncology drug development as well as lung cancer research and treatment across all 3 Mayo Clinic sites, and is co-Leader of the Developmental Therapeutics program at Mayo Cancer Center. Dr. Adjei has served on a number of U.S. National Cancer Institute committees. From 2007 to 2013, he was Chair of the NIH Study Section NCRR Clinical Research Review Committee, reviewing CTSAs. From 2010 to 2014, he was a Member of the Clinical Oncology Study Section (CONC), and from 2013 to 2017, he was a member of NCI IRG Subcommittee A, reviewing Cancer Centers. He is currently co-chair of the Thoracic Malignancies Steering Committee of NCI. He has also served on various committees of professional societies (AACR, ASCO, ESMO, IASLC). Dr. Adjei is currently serving on the Committee on Diagnosing and Treating Adult Cancers of the U.S. National Academies of Sciences, Engineering and Medicine, tasked with providing a report on this topic to the U.S. government (Social Security Administration). He is the Editor-in-Chief of the Journal of Thoracic Oncology, and the inaugural Editor-in-Chief of JTO Clinical and Research Reports. Dr. Adjei's research is focused on experimental therapeutics and clinical drug development. He has been the principal investigator for over 70 early phase clinical trials. He has served on scientific advisory boards for a large number of pharmaceutical companies including Pfizer, Novartis, Bayer, Boehringer-Ingelheim, Merck AG, Daiichi-Sankyo, Amgen, Millenium, Onyx and Roche among others, and have served as Scientific advisor to a number of small and start-up companies such as Exelixis, Array Biopharma, Chiron, Nektar, Merrimack, Cagent, Cleveland BioLabs, Zeno Pharmaceuticals and Swiss Rockets. He received the first American Society of Clinical Oncology Drug Development Research Professorship 2012 to 2017, in recognition of his mentorship and his work in cancer drug development. He has authored 280 publications dealing primarily with pre-clinical pharmacology and phase I trials as well as novel therapies for lung cancer.

B. Compensation

Employment Arrangements with Our Executive Officers

We have entered into employment agreements with each of our executive officers. Dr. Du is employed by Zai Lab Limited, pursuant to an amended and restated employment agreement that became effective December 1, 2018. Dr. Du also is a party to an employment agreement with Zai Lab (Shanghai) Co., Ltd. In addition, Dr. Du has entered into an agreement with our U.S. subsidiary, Zai Lab (US) LLC, pursuant to which a portion of her base salary will be paid by Zai Lab (US) LLC based on the level of services that she provides this entity. Dr. Fu, Dr. Reinhart and Dr. Fantin are each employed by Zai Lab (US) LLC pursuant to employment agreements and amended and restated employment agreements that became effective on January 25, 2019, December 1, 2018 and June 3, 2019, respectively. Dr. Hei is employed by Zai Lab (US) LLC and also party to an employment agreement with Zai Lab (Shanghai) Co., Ltd. Mr. Cho is employed by Zai Lab (Hong Kong) Limited. Mr. Liang is employed by Zai Lab (Shanghai) Co. Ltd.

Employment Agreements with Executive Officers at Zai Lab (Hong Kong) Limited, Zai Lab (US) LLC and Zai Lab Limited

Under the terms of the Zai Lab (Hong Kong) Limited, Zai Lab (US) LLC and Zai Lab Limited employment agreements with our executive officers, we may terminate an executive officer's employment at any time, with or without "cause," by giving such executive officer a notice of termination. In the event of a voluntary termination other than for "good reason" or a termination by the company for cause, the executive officer will receive the unpaid portion of his or her base salary, computed pro rata to the date of termination, plus reimbursement for unpaid business expenses ("accrued compensation"). In the event of a termination without "cause" or a resignation of the executive officer for "good reason," the executive officer, other than Dr. Du, will receive (i) accrued compensation, (ii) a separation benefit consisting of either six or twelve months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over such period following the effective date of such officer's termination of employment, depending on service, (iii) a pro-rated portion of the executive officer's target bonus (other than Mr. Cho, Dr. Fantin and Dr. Hei) and (iv) any additional compensation that may be required by applicable law (the "Severance Benefits"). In the event that Dr. Du's employment is terminated without "cause" or she resigns for "good reason", Dr. Du will receive (i) the accrued compensation, (ii) a separation benefit consisting of eighteen months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the eighteen-month period following the effective date of her termination of employment, (iii) a pro-rated portion of her target bonus, (iv) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to Dr. Du prior to such termination (the "Equity Acceleration") and (v) any additional compensation that may be required by applicable law (the "Du Severance Benefits"). In the event the employment of an executive officer, other than Dr. Du, is terminated without "cause" or the executive officer resigns for "good reason" within twelve months following a change in control (as defined in the executive officer's employment agreement), the executive officer is entitled to receive (i) accrued compensation, (ii) a separation benefit consisting of twelve months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over such period following the effective date of such officer's termination of employment, depending on service, (iii) a pro-rated portion of the executive officer's target bonus, (iv) any additional compensation that may be required by applicable law and (v) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to the executive officer prior to such termination. In the event Dr. Du's employment is terminated without "cause" or she resigns for "good reason" within twelve months following a change in control (as defined in her employment agreement), in addition to the Equity Acceleration, Dr. Du is entitled to receive (i) the accrued compensation, (ii) a separation benefit consisting of eighteen months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the eighteen-month period following the effective date of her termination of employment and (iii) an additional lump-sum payment equal to the sum of (x) six (6) months' base salary, (y) two times her target bonus and (z) six months of the company's portion of monthly premiums for health, dental, and vision insurance coverage.

For purposes of the employment agreements described above, "cause" generally means (1) the executive officer's repeated drunkenness or use of illegal drugs (or, in the case of Mr. Fu and Dr. Fantin, the executive officer's drunkenness or use of illegal drugs) which adversely interferes with the performance of the executive officer's obligations and duties in the company, (2) the conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws, (3) the executive officer's gross mismanagement of the business and affairs of the company or of its subsidiaries that directly results in a material loss to the company and for which the company has reasonable proof was committed by the executive officer, (4) the executive officer's material violation of any terms of the employment agreement or the restrictive covenants agreement between him or her and the company, or (5) a conclusive finding by an independent fact finder appointed by the board of directors for any willful misconduct, dishonesty or acts of moral turpitude by the executive, which is materially detrimental to the interests and well-being of the company, including, without limitation harm to its business or reputation. For this purpose, "good reason" means (1) any material diminution of the executive officer's duties or responsibilities (except in connection with a termination for cause, or by reason of death or "disability") or an assignment of duties or responsibilities that are materially inconsistent with the executive officer's position, (2) any material breach of the employment agreement by the company which is not cured within ten (10) business days after written notice is given to the company, or (3) relocation of the executive officer's from the place of the assignment by the company (for Samantha Du, relocation from the place of assignment of the founder by the company, for Mr. Cho, Dr. Hei, Dr. Fantin, relocation from the place of initial assignment by the company, and for Mr. Fu and Dr. Reinhart, relocation from the place of assignment by the company), without consent, to a location more than thirty (30) kilometers from the original employment location, other than temporary relocations of no longer than six (6) calendar months.

In the event of termination of employment by reason of death or disability, the executive officer is entitled to receive the accrued compensation, a payment equal to one month's base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage plus any other additional compensation required by law and, with respect to Dr. Du only, the Equity Acceleration. For purposes of the employment agreements, "disability" means the executive officer is incapacitated or disabled by accident, sickness or otherwise, so as to render him or her mentally or physically incapable of performing the services under the employment agreement for a period of ninety (90) or more consecutive days, or for ninety (90) days during any six (6) month period.

As a condition to receiving payments during an applicable severance period, the executive officer must execute a release of claims that is satisfactory to the company.

Each executive officer has generally agreed to assign to us or our designee all rights and titles to any inventions created while he or she is performing services within the scope of employment with us or utilizing our facilities. Each executive officer has also agreed, during his or her employment with us and thereafter, not to use, disclose or transfer any confidential information of our company other than as authorized by us within the scope of his or her duties. Moreover, each of our executive officers has agreed to execute the company's compliance agreement regarding confidentiality, trade secrets, intellectual property and competitive activities, which subjects the executive to certain restrictive covenant obligations, including an agreement by the executive, for the term of his or her employment and for a period of one to two years thereafter, not to (i) directly or indirectly, compete with our business within any country where we conduct or, at the time of his or her employment, are actively engaged in planning to conduct, our business (for Dr. Hei, Dr. Fantin and Mr. Fu, this restriction is limited to their period of employment) or (ii) solicit for any employees of our company or orders from any person, firm or company which was at any time during the twelve months prior to termination of such employment a customer or supplier of our company, or to modify its business relationship with our company in a manner adverse thereto.

Employment Agreements with Executive Officers at Zai Lab (Shanghai) Co., Ltd.

Dr. Du, Dr. Hei and Mr. Liang are each party to a service agreement with Zai Lab (Shanghai) Co., Ltd. The employment agreements with Zai Lab (Shanghai) Co., Ltd. provide that we engage each executive officer on a fixed term. (Dr. Du's agreement with Zai Lab (Shanghai) Co. Ltd. does not have a fixed term). We provide labor protection and work conditions that comply with the safety and sanitation requirements stipulated by the relevant PRC laws. Relevant executive officers (except non-PRC nationals) and the company contribute to statutory social insurance and other benefits.

During any probation period, we may immediately terminate an executive's employment agreement without payment of severance or other liability if the executive fails to meet the company's recruiting requirements. Outside any probation period, we may terminate an executive officer's employment with Zai Lab (Shanghai) Co., Ltd. by providing the executive with thirty (30) days' notice or one month's base salary in lieu of such notice and a severance benefit in accordance with local law if (i) the executive is ill or suffers any injury that is not work-related, and fails to perform the original work after the prescribed treatment period or fails to perform other work arranged by the company, (ii) the executive is not qualified for the job, and still fails to be qualified for the job after training is given or the position is adjusted, (iii) there is a significant change to the objective circumstances on which this contract is based, resulting in the failure to perform this contract, and after the consultations by both parties, no agreement can be reached in respect of the modification of the content of this contract, (iv) the company needs to terminate employees during any reorganization to avoid bankruptcy, or because it experiences serious difficulties in production or operation, and (v) other circumstances prescribed by PRC laws or regulation. In addition, we may terminate the executive's employment without notice or payment if (i) the executive seriously or continuously violates, or violates several times, the employment rules and policies of the company, (ii) the executive commits serious dereliction in the performance of his or her duties, or practices graft, or engages in malpractice to seek private benefit, as applicable, in either case causing severe damage to the interests of the company, (iii) the executive commits fraud or uses coercive measures or takes advantage of the company's vulnerability to make it enter into this contract or to make amendments thereto against the company's will, (iv) the executive is prosecuted for criminal liability, or (v) under other circumstances as permitted by PRC laws and regulations. Each executive officer may voluntarily terminate his or her contract without cause with thirty (30) days' prior notice to us. In the event the employment of Mr. Liang is terminated without "cause" or resigns for "good reason" within twelve months following a change in control (as defined in his employment agreement). Mr. Liang is entitled to receive (i) the accrued compensation, (ii) a separation benefit consisting of twelve months' base pay and payment of the company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the twelve-month period following the effective date of his termination of employment, (iii) a pro-rated portion of Mr. Liang's target bonus, (iv) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to the executive officer prior to such termination and (v) any additional compensation that may be required by applicable law.

Each executive officer has agreed to comply with our rules and policies regarding confidentiality and, during his or her employment with us and thereafter, has agreed not to use or disclose any confidential information of our company other than as authorized by us within the scope of his or her duties. Moreover, each of our executive officers has agreed that during his or her employment and for two years after his or her employment with us at Zai Lab (Shanghai) Co., Ltd., he or she will not work for another company or individual that is in competition with us directly or indirectly or provide services to any company or individual that is in competition with us, and will not setup or operate any business which is in competition with us directly or indirectly, or with any other third party, or through any other form. Each of our executive officers is entitled to receive monthly compensation during their 24-month non-compete period in an amount equal to 30% of their respective average monthly salaries received during the 12 months immediately preceding the termination of their employment. Each of the executives has agreed that, during employment and within one year after the termination thereof, certain "works for hire," as defined in the agreements, shall belong to the company.

In addition, we have been advised by our PRC counsel, Zhong Lun Law Firm, that notwithstanding any provision to the contrary in our employment agreements at Zai Lab (Shanghai) Co., Ltd., we may still be required to make severance payments upon termination without cause to comply with the PRC labor laws and other relevant PRC regulations, which entitle employees to severance payments in case of early termination.

Compensation of Directors and Executive Officers

In the year ended December 31, 2019, we paid aggregate salaries, bonuses and benefits (excluding equity-based grants) of approximately $4.92 million to our executive officers. Executive officers are eligible to receive an annual incentive bonus, as determined by our board of directors, based on achievement of pre-established individual, departmental and company performance goals. Other than 401(k) and social insurance benefits that we provide to our U.S. executive officers, we do not otherwise separately set aside any amounts for pensions, retirement or other benefits for our executive officers, other than pursuant to relevant statutory requirements, and health and life insurance. In the year ended December 31, 2019, we paid aggregate cash retainers (excluding equity-based grants and consulting fees) of approximately $282,418 to our non-employee directors pursuant to our non-employee director compensation policy, described below. For information regarding equity-based grants to our executive officers and directors, see "—2017 Equity Incentive Plan."

2017 Equity Incentive Plan

The following summary describes the material terms of the Zai Lab Limited 2017 Equity Incentive Plan (the "2017 Equity Plan"), which is the only equity plan under which the Company currently grants equity awards. This summary is not a complete description of all provisions of our 2017 Equity Plan and is qualified in its entirety by reference to our 2017 Equity Plan, which has been previously filed as an exhibit to our registration statement on Form F-1.

Purposes . The purposes of our 2017 Equity Plan are to attract, retain and reward key employees and directors of, and consultants and advisors to, the Company and its subsidiaries, to incentivize them to generate shareholder value, to enable them to participate in the growth of the Company and to align their interests with the interests of our shareholders.

Administration. Our 2017 Equity Plan is administered by our compensation committee, which has the discretionary authority to interpret our 2017 Equity Plan, determine eligibility for and grant awards, determine, modify and waive the terms and conditions of any award, determine the form of settlement of awards, designate whether an award will be over, or with respect to, ordinary shares or ADSs, prescribe forms, rules and procedures relating to our 2017 Equity Plan and awards and otherwise do all things necessary or desirable to carry out the purposes of our 2017 Equity Plan. Our compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board of directors and, to the extent permitted by law, officers of the Company, and may delegate to employees and other persons such ministerial tasks as it deems appropriate. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable.

Eligibility. Key employees, directors, consultants and advisors of the Company and its subsidiaries are eligible to participate in our 2017 Equity Plan. Eligibility for stock options intended to be incentive stock options, or ISOs, is limited to employees of the Company or certain affiliates. Eligibility for stock options, other than ISOs, and stock appreciation rights, or SARs, is limited to individuals who are providing direct services on the date of grant of the award to the Company or certain affiliates.

Authorized shares. Subject to adjustment as described below, the maximum number of shares that may be delivered in satisfaction of awards under our 2017 Equity Plan is 1,924,327 shares, plus an annual increase, to be added as of January 1st of each year from January 1, 2018 to January 1, 2027, equal to the lesser of (i) four percent (4%) of the number of shares outstanding as of the close of business on the immediately preceding December 31st; and (ii) the number of shares determined by our board of directors on or prior to such date for such year. For purposes of our 2017 Equity Plan, "share" means a share of our common stock (an "ordinary share"), unless there are ADSs representing ordinary shares available, in which case "share" means the number of ADSs equal to an ordinary share. If the ratio of ADSs to ordinary shares is not 1:1, then (a) the maximum number of shares that may be delivered under our 2017 Equity Plan, (b) all award adjustments made pursuant to our 2017 Equity Plan; and (c) all awards designated as awards over ordinary shares will automatically be adjusted to reflect the ratio of the ADSs to ordinary shares, as reasonably determined by the Administrator. Up to the total number of shares available for awards under the plan may be delivered in satisfaction of ISOs.

Subject to applicable laws, shares delivered under our 2017 Equity Plan may be newly issued ordinary shares, previously issued ordinary shares acquired by us or ADSs. Any shares underlying awards that are settled or that expire, become unexercisable, terminate or are forfeited or repurchased by us, in each case without the delivery of shares, will again be available for issuance under our 2017 Equity Plan. In addition, the number of shares delivered in satisfaction of awards will be determined net of shares withheld by us in payment of the exercise price or purchase price of an award or in satisfaction of tax withholding requirements with respect to an award.

Individual limits. The maximum number of shares subject to share options that may be granted to any participant in our 2017 Equity Plan in any calendar year is 577,298 shares and the maximum number of shares subject to SARs that may be granted to any participant in any calendar year is 288,649 shares. The maximum number of shares subject to awards other than share options and SARs that may be granted to any participant in any calendar year is 288,649 shares.

Director limits. In addition to the individual limits described above, the maximum grant date fair value of awards granted under our 2017 Equity Plan to any non-employee director of the Company in respect of his or her service as a director with respect to any calendar year may not exceed $500,000, assuming maximum payout.

Types of awards. Our 2017 Equity Plan provides for the grant of share options, SARs, restricted and unrestricted shares and share units, performance awards, and other awards that are convertible into or otherwise based on our shares. Dividend equivalents may also be provided in connection with awards under our 2017 Equity Plan.

1. *Stock options and SARs.* The Administrator may grant share options, including ISOs, and SARs. A share option is a right entitling the holder to acquire shares upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price of each share option, and the base value of each SAR, granted under our 2017 Equity Plan shall be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, share options and SARs granted under our 2017 Equity Plan may not be repriced or substituted for with new share options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any share options or SARs that have a per share exercise or base price greater than the fair market value of a share on the date of such cancellation, in each case, without shareholder approval. Each share option and SAR will have a maximum term of not more than ten years from the date of grant (or five years, in the case of certain ISOs).

2. *Restricted and unrestricted shares and share units.* The Administrator may grant awards of shares, share units, restricted shares and restricted share units. A share unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted share unit is a share unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted shares are shares that are subject to restrictions requiring that they be redelivered or offered for sale to the Company if specified conditions are not satisfied.

3. *Performance awards.* The Administrator may grant performance awards, which are awards subject to performance criteria.

4. *Other stock-based awards.* The Administrator may grant other awards that are convertible into or otherwise based on shares, subject to such terms and conditions as it determines.

5. *Substitute awards.* The Administrator may grant substitute awards, which may have terms and conditions that are inconsistent with the terms and conditions of our 2017 Equity Plan.

Vesting; terms of awards. The Administrator determines the terms of all awards granted under our 2017 Equity Plan, including the time or times an award vests or becomes exercisable, the terms on which an award remains exercisable, and the effect of termination of a participant's employment or service on an award. The Administrator may at any time accelerate the vesting or exercisability of an award.

Transferability of awards. Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

Section 162(m). During a transition period following the completion of our initial public offering, the Administrator may grant awards under our 2017 Equity Plan that are exempt from Section 162(m) of the Code and its requirements under a special transition rule.

Effect of certain transactions. In the event of certain covered transactions (including the consummation of a merger, consolidation, or the sale of substantially all of the Company's assets or shares, a change in ownership of the Company's shares, or the dissolution or liquidation of the Company), the Administrator may, with respect to outstanding awards, provide for (in each case, on such terms and subject to such conditions as it deems appropriate):

1. The assumption, substitution or continuation of some or all awards (or any portion thereof) by the acquirer or surviving entity;

2. The acceleration of exercisability or delivery of shares in respect of any award, in full or in part; and/or

3. The cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the Administrator may otherwise determine, each award will automatically terminate immediately upon the consummation of the covered transaction, other than awards that are substituted for or assumed.

Adjustment provisions. In the event of certain corporate transactions, including an extraordinary cash dividend, share dividend, share split or combination of shares (including a reverse share split), recapitalization or other change in our capital structure, the Administrator shall make appropriate adjustments to the maximum number of shares that may be issued under our 2017 Equity Plan, the individual award limits, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of, outstanding awards, and any other provisions affected by such event.

Clawback. The Administrator may provide that any outstanding award or the proceeds of any award or shares acquired thereunder will be subject to forfeiture and disgorgement to the Company if the participant to whom the award was granted violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

Amendments and termination. The Administrator may at any time amend our 2017 Equity Plan or any outstanding award and may at any time terminate our 2017 Equity Plan as to future grants. However, except as expressly provided in our 2017 Equity Plan, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent (unless the Administrator expressly reserved the right to do so at the time the award was granted). Any amendments to our 2017 Equity Plan will be conditioned on shareholder approval to the extent required by law or applicable stock exchange requirements.

Outstanding awards . The following table summarizes the outstanding share options and restricted shares held by our directors and executive officers, as well as by their affiliates, as of March 31, 2020.

Name	Ordinary shares* underlying outstanding awards, which represent options unless otherwise indicated		Purchase price ($/share)		Exercise price ($/share)	Date of grant(1)
Samantha Du	216,666		N/A	US$	0.60	March 5, 2015
	1,739,166		N/A	US$	0.60	October 22, 2015
	604,376		N/A	US$	1.20	March 9, 2016
	922,184		N/A	US$	1.74	August 25, 2016
	350,000		N/A	US$	20.90	March 28, 2018
	300,000		N/A	US$	38.93	March 8, 2019
	250,000		N/A	US$	44.94	March 12, 2020
Harald Reinhart	33,334		N/A	US$	3.00	May 12, 2017
	100,000		N/A	US$	18.00	September 20, 2017
	100,000		N/A	US$	20.90	March 28, 2018
	50,000		N/A	US$	17.99	November 16, 2018
Billy Cho	400,000		N/A	US$	21.84	March 2, 2018
	80,000	(2)	N/A		N/A	March 2, 2018
	30,000		N/A	US$	44.94	March 12, 2020
William Liang	375,000		N/A	US$	23.80	June 4, 2018
	116,106	(2)	N/A		N/A	June 4, 2018
	30,000		N/A	US$	44.94	March 12, 2020
Yongjiang Hei	375,000		N/A	US$	22.00	August 6, 2018
	121,977	(2)	N/A		N/A	August 6, 2018
Valeria Fantin	200,000		N/A	US$	27.23	June 3, 2019
	50,000	(2)	N/A		N/A	June 3, 2019
	20,000		N/A	US$	44.94	March 12, 2020
Peter Wirth	12,500	(2)	N/A		N/A	January 1, 2018
	12,500	(2)	N/A		N/A	January 10, 2019
	10,000	(2)	N/A		N/A	January 1, 2020
Tao Fu	25,000	(2)	N/A		N/A	September 20, 2017
	2,000	(2)	N/A		N/A	January 1, 2018
	500,000		N/A	US$	18.92	September 24, 2018
	200,000	(2)	N/A		N/A	September 24, 2018
John Diekman	25,000	(2)	N/A		N/A	September 20, 2017
	12,500	(2)	N/A		N/A	January 1, 2018
	12,500	(2)	N/A		N/A	January 10, 2019
	10,000	(2)	N/A		N/A	January 1, 2020
Kaixian Chen	7,345	(2)	N/A		N/A	August 30, 2018
	7,767	(2)	N/A		N/A	January 10, 2019
	10,000	(2)	N/A		N/A	January 1, 2020
William Lis	12,500	(2)	N/A		N/A	October 8, 2018
	12,500	(2)	N/A		N/A	January 10, 2019
	10,000	(2)	N/A		N/A	January 1, 2020
Leon O. Moulder. Jr	10,000	(2)	N/A		N/A	January 13, 2020

(1) Options expire on or before the 10-year anniversary of the grant date.

(2) Represents restricted shares.

Other Compensation Programs

2017 Cash Bonus Plan

Our board of directors has adopted and our shareholders have approved the Zai Lab Limited 2017 Cash Bonus Plan, or our Cash Plan. Annual award opportunities for executive officers and key employees of the Company and its subsidiaries are granted under our Cash Plan. The following summary describes the material terms of our Cash Plan. This summary is not a complete description of all provisions of our Cash Plan and is qualified in its entirety by reference to our Cash Plan, which is filed as an exhibit to this Annual Report on Form 20-F.

Administration. Our Cash Plan will be administered by our compensation committee and its delegates. As used in this summary, the term "Administrator" refers to our compensation committee and its authorized delegates, as applicable. The Administrator will have the discretionary authority to interpret our Cash Plan, determine eligibility for and grant awards, determine, modify or waive the terms and conditions of any award, prescribe forms, rules and procedures relating to our Cash Plan and awards, and otherwise do all things necessary or appropriate to carry out the purposes of our Cash Plan.

Eligibility and participation. Executive officers and key employees of the Company and its subsidiaries will be eligible to participate in our Cash Plan and will be selected from time to time by the Administrator to participate in the plan.

Awards. For each award granted under our Cash Plan, the Administrator will establish the performance criteria applicable to the award, the amount or amounts payable if the performance criteria are achieved and such other terms and conditions as the Administrator deems appropriate.

Performance criteria. Awards under our Cash Plan will be made based on, and subject to achieving, specified criteria established by the Administrator, including measures of performance relating to any, or any combination of, the following (measured either absolutely or comparatively (including, without limitation, by reference to an index or indices or the performance of one or more companies) and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof and subject to such adjustments, if any, as the Administrator specifies): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; share or ADS price; shareholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or strategic business criteria, consisting of one or more objectives based on: meeting specified market penetration or value added, product development or introduction (including, without limitation any clinical trial accomplishments, regulatory or other filings or approvals, or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, patent application or issuance goals.

Payments under an award; individual limits. A participant will be entitled to payment under an award only if all conditions to payment have been satisfied in accordance with our Cash Plan and the terms of the award. Following the end of a performance period, the Administrator will determine whether and to what extent the applicable performance criteria have been satisfied and will determine the amount payable under each award.

Recovery of compensation. Payments in respect of an award will be subject to forfeiture and disgorgement to the Company if the participant to whom the award was granted violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

Amendment and termination. The Administrator may amend or terminate our Cash Plan at any time, except that any amendment or termination that would materially and adversely affect a participant's rights under an award will require the consent of the affected participant, unless the Administrator expressly reserved the right to so amend the award at the time of grant.

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy under which each member of our board of directors who is not an employee of the Company or one of our affiliates (each a "non-employee director") will be eligible to receive an annual cash retainer payment of $50,000. In addition, each non-employee director who was appointed to our board of directors following the adoption of this policy and whose appointment was effective prior to our IPO received an award of 25,000 restricted shares under our 2017 Equity Plan, which vests ratably on each of the first three anniversaries of the date of grant, subject to continued service as a member of our board of directors through such date. In addition to this initial grant,in calendar years 2018 and 2019, non-employee directors received an annual grant of 12,500 restricted shares under our 2017 Equity Plan, which vested in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date. Commencing in calendar year 2020, non-employee directors will receive an annual grant of 10,000 restricted shares under our 2017 Equity Plan, which vest in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date.

In addition, the non-employee director compensation policy provides for the following additional annual cash retainer payments for the members and chairpersons of our board committees: audit committee chair, $20,000; audit committee member, $10,000; compensation committee chair, $15,000; compensation committee member, $7,500; nominating committee chair, $10,000; nominating committee member, $5,000; compliance committee chair, $10,000; and compliance committee member, $5,000.

Composition of Our Board

Our board of directors consists of eight directors, of whom four qualify as independent directors under the rules and regulations of the SEC and Nasdaq Stock Market. Our directors hold office until they are removed from office by special resolution at an annual general meeting of the shareholders or by a vote of the board of directors. In addition, a director will cease to be a director it the director (i) dies, becomes bankrupt or makes any arrangement or composition with his or her creditors, (ii) is found to be or becomes of unsound mind or (iii) resigns his office by notice in writing to the Company. For information regarding the period during which our officers and directors have served in their respective positions, please see "Item 6.A. Directors and Senior Management."

Duties of Directors

Under Cayman Islands law, all of our directors owe us fiduciary duties, including a duty of loyalty, a duty to act honestly and a duty to act in good faith and in a manner they believe to be in our best interests. Our directors also have a duty to exercise the skill they actually possess and such care and diligence that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended articles of association, as amended and restated from time to time. We have the right to seek damages if a duty owed by any of our directors is breached.

Board Committees

Our board of directors has established an audit committee, a compensation committee, a nominating and corporate governance committee and a compliance committee.

Audit Committee

Our audit committee consists of John Diekman, William Lis and Leon O. Moulder, Jr., with Mr. Diekman serving as chairman of the committee. We have determined that Mr. Lis qualifies as a financial expert as set forth under the applicable rules of the SEC and that Mr. Lis, Dr. Diekman and Mr. Moulder each satisfy the independence requirements under the rules of the Nasdaq Stock Market and under Rule 10A-3 of the Exchange Act.

The audit committee oversees our accounting and financial reporting processes and the audits of our financial statements. Our audit committee is responsible for, among other things:

- selecting, and evaluating the qualifications, performance and independence of, the independent auditor;
- approving or, as permitted, pre-approving auditing and non-auditing services permitted to be performed by the independent auditor;

- considering the adequacy of our internal accounting controls and audit procedures;
- reviewing with the independent auditor any audit problems or difficulties and management's response;
- reviewing and approving related party transactions;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;
- establishing procedures for the receipt, retention and treatment of complaints received from our employees regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- meeting separately, periodically, with management, internal auditors and the independent auditor; and
- reporting regularly to the full board of directors.

Compensation Committee

Our compensation committee consists of Peter Wirth, Nisa Leung and Leon O. Moulder, Jr., with Mr. Wirth serving as chairman of the committee.

Our compensation committee is responsible for, among other things:

- reviewing, evaluating and, if necessary, revising our overall compensation policies;
- reviewing and evaluating the performance of our directors and executive officers and determining the compensation of our executive officers;
- reviewing and approving our executive officers' employment agreements with us;
- determining performance targets for our executive officers with respect to our incentive compensation plan and equity-based compensation plans;
- administering our equity-based compensation plans in accordance with the terms thereof; and
- carrying out such other matters that are specifically delegated to the compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Samantha Du, Nisa Leung and John Diekman, with Dr. Du serving as chairman of the committee.

Our nominating and corporate governance committee is responsible for, among other things:

- electing the board nominees for election by the shareholders or appointment by the board;
- periodically reviewing with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and
- advising the board periodically with regards to significant developments in corporate governance law and practices as well as our compliance with applicable laws and regulations, and making recommendations to the board on corporate governance matters.

Compliance Committee

Our compliance committee consisted of William Lis, Peter Wirth and Tao Fu, with Mr. Lis serving as chairman of the committee.

Our compliance committee is responsible for, among other things:

- overseeing the Company's policies and practices for complying with laws, regulations and internal procedures (other than regarding financial reporting matters);
- overseeing the Company's compliance program and evaluate its effectiveness and adequacy, review and approve the internal compliance audit plan and receive periodic updates from the Chief Compliance Officer on major compliance-related activities;
- reviewing the Company's policies and practices regarding issues that have the potential to seriously impact the Company's business operations and reputation;
- reviewing and monitoring efforts to promote an ethical culture;
- overseeing the mechanisms for employees to seek guidance and report concerns regarding matters of compliance with laws, regulations and industry standards; and
- exercising such other powers and perform such other duties as the Board may from time to time delegate to it.

On November 14, 2019, our board of directors resolved that the audit committee would take responsibility for the compliance-related duties and obligations of the board of directors and the compliance committee was subsequently dissolved.

Code of Ethics

Our board of directors has adopted a code of ethics to set standards for our directors, officers and employees as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the reports and documents that we file or submit to the applicable stock exchanges, and in any other public communications; (iii) compliance with applicable governmental and regulatory laws, rules, codes and regulations; (iv) prompt internal reporting of any violations of the code of ethics; and (v) accountability for adherence to the code of ethics.

Complaints Procedures

Our board of directors has adopted procedures for the confidential receipt, retention, and treatment of complaints from, or concerns raised by, employees regarding accounting, internal accounting controls and auditing matters as well as illegal or unethical matters. The complaint procedures are reviewed by the audit committee from time to time as warranted to ensure their continuing compliance with applicable laws and listing standards as well as their effectiveness.

D. Employees

As of December 31, 2019, 2018 and 2017, we had 692, 309 and 88 full-time employees, respectively. In 2020, as of March 31, 2020, we hired an additional 60 employees. None of our employees is represented by a labor union or covered by a collective bargaining agreement. The number of employees by function as of the end of the period for our fiscal years ended December 31, 2019, 2018 and 2017 was as follows:

By Function	2019	2018	2017
Research and Development	300	183	52
Commercial	298	55	—
Manufacturing	54	46	20
General and Administrative	40	25	16
Total	692	309	88

E. Share Ownership.

We had 74,675,511 ordinary shares outstanding as of March 31, 2020. The following table and accompanying footnotes set forth information relating to the beneficial ownership of our ordinary shares as of March 31, 2020 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our directors;
- each of our executive officers; and
- all of our executive officers and directors as a group.

Our major shareholders do not have voting rights that are different from our shareholders in general. Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary Shares Beneficially Owned	
Name of beneficial owner†	**Number**	**Percent**
Executive Officers and Directors:		
Samantha Du(1)	6,667,961	8.6%
Tao Fu(2)	342,666	*
Harald Reinhart(3)	106,666	*
Yongjiang Hei(4)	96,977	*
Billy Cho(5)	180,000	*
William Liang(6)	91,106	*
Valeria Fantin	—	*
Peter Wirth(7)	325,000	*
John Diekman(8)	41,666	*
Nisa Leung	—	*
Kai-Xian Chen(9)	15,112	*
William Lis(10)	25,000	*
Leon O. Moulder, Jr	—	*
All Executive Officers and Directors as a Group	7,708,154	9.8%
Beneficial Owners of 5% or More of our Ordinary Shares:		
QM 11 Limited(11)	9,072,932	12.1%
FMR, LLC(12)	6,737,550	9.0%
Capital Group(13)	5,844,200	7.8%
The Z Trust(14)	4,619,930	6.2%
Investment funds affiliated with Advantech Capital(15)	4,551,772	6.1%

* The person beneficially owns less than 1% of our outstanding ordinary shares.

† The business address of all directors and officers is 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210.

(1) Includes 3,047,705 ordinary shares issuable to Dr. Du upon exercise of vested options and options exercisable within 60 days of March 31, 2020 and 36,820 ADSs purchased by Dr. Du in multiple open market transactions. Includes 2,583,603 ordinary shares held by certain holders of ordinary shares, including Zai management and their affiliates. Although Dr. Du does not have any pecuniary interest in these ordinary shares, these shareholders have granted Dr. Du the right to vote their shares and, therefore, she may be deemed to be the beneficial owner of the ordinary shares held by these shareholders.

(2) Includes 100,000 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2020 and 58,666 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2019; and 184,000 shares held by Mr. Fu's wife.
(3) Includes 106,666 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2019.
(4) Includes 75,000 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2020 and 21,977 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(5) Includes 160,000 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2020, and 20,000 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(6) Includes 75,000 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2020 and 16,106 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(7) Includes 25,000 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(8) Includes 41,666 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(9) Includes 15,112 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(10) Includes 25,000 vested restricted shares and restricted shares will be vested within 60 days of March 31, 2020.
(11) Based on a Schedule 13G/A filed on February 14, 2020. The address for QM 11 Limited is Units 4206-06 Gloucester Tower, The Landmark, Central, Hong Kong.
(12) Based on a Schedule 13G/A filed on February 7, 2020. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly-owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02110.
(13) Consists of (i) 4,028,500 ordinary shares held by American Funds New World Fund, (ii) 1,356,900 ordinary shares held by American Funds SMALLCAP World Fund and (iii) 458,800 ordinary shares held by American Funds Insurance Series – New World Fund. The address for Capital Group is 333 South Hope Street, Los Angeles, CA 90071.
(14) The address for The Z Trust is 66 Mount Vernon St #2, Boston, MA.
(15) Based on a Schedule 13G/A filed on February 11, 2020. Consists of (i) 4,246,791 ordinary shares held by Maxway Investment Limited and (ii) 304,981 ordinary shares held by Harbor Front Investment Limited. The address for Maxway Investment Limited and Harbor Front Investment Limited is c/o DMS House, 20 Genesis Close, George Town, Grand Cayman, KY1-1103, Cayman Islands.

As of March 31, 2020, based on public filings with the SEC, there are no major shareholders owning 5% or more of our ordinary shares or ADSs representing ordinary shares, except as described above. As of March 31, 2020, we had eleven holders of record with addresses in the United States, including Citibank, N.A., depositary of our ADS program, which held 59,318,351 ordinary shares as of that date.

To our knowledge, except as disclosed above, we are not owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any other natural or legal person or persons, severally or jointly. To our knowledge, there are no arrangements the operation of which may at a subsequent date result in us undergoing a change in control. Our major shareholders do not have different voting rights than any of our other shareholders.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders.

Please refer to "Item 6.E. Directors, Senior Management and Employees—Share Ownership."

B. Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2019 with any members of our board of directors or executive officers and beneficial holders of more than 5% of our ordinary shares:

Agreements and Transactions with Shareholders

Registration Rights Agreement

We have entered into a shareholders agreement in January 2016, or the Registration Rights Agreement, with certain of our shareholders, in which we granted certain demand registration rights, piggyback registration rights and F-3 registration rights to holders of our registrable securities.

Other Relationships

Voting Proxy

Certain holders of our ordinary shares, which hold 2,583,603 ordinary shares, have granted Dr. Du the right to vote their ordinary shares.

Quan Venture Partners I, L.L.C.

Quan Venture Fund I, L.P., or Quan Fund, is a Cayman Islands exempted limited partnership organized in April 2017 to make capital investments in global public and private companies with a particular focus on the healthcare industry. Quan Fund's general partner, which is responsible for investment and divestment decisions related to the Quan Fund, is Quan Venture Partners I, L.L.C., or Quan GP, a Cayman Islands limited liability company. Dr. Du is a manager of Quan GP. In the first half of 2017, we sold our interests in three entities to the Quan Fund, for a total consideration of approximately $0.5 million.

MEDx (Suzhou) Translational Medicine Co., Ltd. (formerly known as Qiagen (Suzhou) Translational Medicine Co., Ltd)

An immediate family member of Dr. Du is owner of MEDx (Suzhou) Translational Medicine Co., Ltd., or MEDx. We incurred $0.2 million and $0.1 million in research and development expenses to MEDx for drug research and development services for the years ended December 31, 2019 and 2018, respectively.

Agreements with Our Directors and Executive Officers

Compensation of Directors and Executive Officers

See "Item 6.B. Directors, Senior Management and Employees—Compensation—Compensation of Directors and Executive Officers" for a discussion of our compensation of directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see "Item 6.B. Directors, Senior Management and Employees—Compensation—Employment Arrangements with Our Executive Officers."

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. We also maintain a general liability insurance policy which covers certain liabilities of our directors and executive officers arising out of claims based on acts or omissions in their capabilities as directors or officers.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Financial Statements and Other Financial Information

See "Item 18 Financial Statements."

A.7 Legal Proceedings

We are, from time to time, subject to claims and suits arising in the ordinary course of business. Although the outcome of these and other claims cannot be predicted with certainty, management does not believe that the ultimate resolution of these matters will have a material adverse effect on our financial position or on our results of operations. We are not currently a party to, nor is our property the subject of, any material legal proceedings.

A.8 Dividend Policy

We have never declared or paid dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not have any present plan to pay any dividends. The declaration and payment of any dividends in the future will be determined by our board of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions.

B. Significant Changes

We have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

ITEM 9. THE OFFER AND LISTING

A. Offering and Listing Details

The principal host market for our ADSs is the Nasdaq Global Market.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs have been listed on the Nasdaq Global Market since September 20, 2017 under the symbol "ZLAB."

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

We are a Cayman Islands company and our affairs are governed by our fourth memorandum and articles of association and the Companies Law.

The following are summaries of material provisions of our fourth amended and restated memorandum and articles of association that became effective immediately prior to the completion of our initial public offering in September 2017, insofar as they relate to the material terms of our ordinary shares.

Registered Office and Objects

Our registered office in the Cayman Islands is located at Harbour Place 2nd Floor, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands, or at such other location within the Cayman Islands as our board of directors may from time to time decide. The objects for which our company is established are unrestricted and we have full power and authority to carry out any object not prohibited by the Companies Law, as amended from time to time, or any other law of the Cayman Islands.

Board of Directors

See "Item 6.C. Directors, Senior Management and Employees—Board Practices."

Ordinary Shares

General. Our authorized share capital consists of $5,000.00 divided into 83,333,333 ordinary shares, with a par value of $0.00006 each. Our ordinary shares are issued in registered form, and are issued when registered in our register of members. Certificates representing the ordinary shares are issued in registered form. Our shareholders who are non-residents of the Cayman Islands may freely hold and transfer their ordinary shares.

Dividends. The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. Our fourth amended and restated articles of association provide that dividends may be declared and paid out of our profits, realized or unrealized, or from any reserve set aside from profits which our board of directors determine is no longer needed. Dividends may also be declared and paid out of share premium account or any other fund or account which can be authorized for this purpose in accordance with the Companies Law. Holders of ordinary shares will be entitled to the same amount of dividends, if declared.

Voting rights. In respect of all matters subject to a shareholders' vote, each ordinary share is entitled to one vote. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one or more shareholders present in person or by proxy and who together hold not less than 10% of the nominal value of the total issued voting shares of our company. Each holder of our ordinary shares is entitled to have one vote for each ordinary share registered in his or her name on our register of members.

A quorum required for a meeting of shareholders consists of one or more shareholders who hold at least one-third of all voting power of our share capital in issue at the date of the meeting present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. Shareholders' meetings may be held annually. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Extraordinary general meetings may be called by a majority of our board of directors or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than one-third of the aggregate voting power of our company. Advance notice of at least seven days is required for the convening of our annual general meeting and other general meetings unless such notice is waived in accordance with our articles of association.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to all issued and outstanding shares cast at a meeting, while a special resolution also requires the affirmative vote of no less than two-thirds of the votes cast attaching to the issued and outstanding shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our fourth amended and restated memorandum and articles of association.

Transfer of ordinary shares. Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four;
- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Nasdaq Stock Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on 14 days' notice being given by advertisement in one or more newspapers or by electronic means, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year.

Liquidation. On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares), assets available for distribution among the holders of ordinary shares shall be distributed by a liquidator who may divide our assets for distribution among our shareholders in his discretion. The liquidator also may vest all or part of our assets in trust. None of our shareholders may be compelled to accept any shares subject to liability.

Calls on ordinary shares and forfeiture of ordinary shares. Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their ordinary shares in a notice served to such shareholders at least 14 clear days prior to the specified time of payment. The ordinary shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption of ordinary shares. The Companies Law and fourth amended and restated articles of association permit us to purchase our own shares. In accordance with our fourth amended and restated articles of association and provided the necessary shareholders or board approval have been obtained, we may issue shares on terms that are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner, including out of capital, as may be determined by our board of directors.

Variations of rights of shares. All or any of the special rights attached to any class of shares may, subject to the provisions of the Companies Law, be varied with the written consent of the holders of a majority of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

Inspection of books and records. Holders of our ordinary shares have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we will provide our shareholders with annual audited financial statements.

Issuance of additional shares. Our fourth amended and restated memorandum of association authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our fourth amended and restated memorandum of association also authorizes our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights and voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Anti-Takeover provisions. Some provisions of our fourth amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

Exempted company. We are an exempted company with limited liability under the Companies Law. The Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company" or elsewhere in this Annual Report on Form 20-F.

D. Exchange Controls

See "Item 4.B. Information on the Company—Business—Regulation—Regulations Relating to Foreign Exchange Registration of Offshore Investment by PRC Residents."

E. Taxation

The following is a discussion of the material Cayman Islands, People's Republic of China and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decisions to acquire ADSs.

Material Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Material People's Republic of China Taxation

We are a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of China with a "de facto management body" within China is considered a "resident enterprise," and will be subject to the EIT on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State Administration of Taxation issued SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, all offshore enterprises controlled by a PRC enterprise or a PRC enterprise will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China only if all of the following conditions are met:

(i) the primary location of the day-to-day operational management is in China;

(ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in China;

(iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and

(iv) at least 50% of voting board members or senior executives habitually reside in China.

We believe that none of Zai Lab Limited and its subsidiaries outside of China is a PRC resident enterprise for PRC tax purposes. Zai Lab Limited is not controlled by a PRC enterprise or PRC enterprise group, and we do not believe that Zai Lab Limited meets all of the conditions above. Zai Lab Limited is a company incorporated outside China. As a holding company, some of its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside China. For the same reasons, we believe our other subsidiaries outside of China are also not PRC resident enterprises. However, the tax resident status of an enterprise is subject to determination by China tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body."

If China tax authorities determine that Zai Lab Limited is a PRC resident enterprise for EIT purposes, we may be required to withhold tax at a rate of 10% on dividends we pay to our shareholders, including holders of our ADSs, that are non-resident enterprises. In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to a 10% PRC withholding tax on gains realized on the sale or other disposition of ADS or ordinary shares, if such income is treated as sourced from within China. Furthermore, gains derived by our non-PRC individual shareholders from the sale of our shares and ADSs may be subject to a 20% PRC withholding tax. It is unclear whether our non-PRC individual shareholders (including our ADS holders) would be subject to any PRC tax (including

withholding tax) on dividends received by such non-PRC individual shareholders in the event we are determined to be a PRC resident enterprise. If any PRC tax were to apply to dividends realized by non-PRC individuals, it will generally apply at a rate of 20%. China tax liability may be reduced under applicable tax treaties. However, it is unclear whether non-PRC shareholders of Zai Lab Limited would be able to claim the benefits of any tax treaty between their country of tax residence and China in the event that Zai Lab Limited is treated as a PRC resident enterprise.

See "Item 3.D. Risk Factors—Risks Related to Doing Business in China—If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders."

Pursuant to the EIT Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in China, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement between mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of China enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in China resident enterprise; and (ii) it must have directly owned such percentage in China resident enterprise throughout the 12 months prior to receiving the dividends. Furthermore, the Announcement of the State Administration of Taxation on Promulgating the Administrative Measures for Tax Convention Treatment for Non-resident Taxpayers, which became effective in November 2015, require that non-resident enterprises may be entitled to the reduced tax rate itself when filing a tax return or making a withholding declaration through a withholding agent. There are also other conditions for enjoying the reduced tax rate according to other relevant tax rules and regulations. Accordingly, our subsidiary Zai Lab (Hong Kong) Limited may be able to enjoy the 5% tax rate for the dividends it receives from its PRC incorporated subsidiaries if they satisfy the conditions prescribed under SAT Circular 81 and other relevant tax rules and regulations and obtain the approvals as required. However, according to SAT Circular 81, if the relevant tax authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

If our Cayman Islands holding company, Zai Lab Limited, is not deemed to be a PRC resident enterprise, holders of our ADSs and ordinary shares who are not PRC residents will not be subject to PRC income tax on dividends distributed by us or gains realized from the sale or other disposition of our shares or ADSs.

Material United States Federal Income Tax Consideration

The following discussion, subject to the limitations set forth below, describes the material U.S. federal income tax consequences for a U.S. Holder (as defined below) of the acquisition, ownership and disposition of ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire our ADSs. This discussion is limited to U.S. Holders who hold such ADSs as capital assets (generally, property held for investment). This discussion is based on Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between China and the United States, or the U.S.-PRC Tax Treaty, each as available and in effect on the date hereof, all of which are subject to change or differing interpretations, possibly with retroactive effect, which could affect the tax consequences described herein. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

For purposes of this summary, a "U.S. Holder" is a beneficial owner of an ADS that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States or any state thereof, or the District of Columbia;

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) it has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court can exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

Except as explicitly set forth below, this summary does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders subject to special rules, including:

- banks or other financial institutions;
- insurance companies;
- real estate investment trusts;
- regulated investment companies
- grantor trusts;
- tax-exempt organizations;
- persons holding ADSs through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- dealers or traders in securities, commodities or currencies;
- persons whose functional currency is not the U.S. dollar;
- certain former citizens and former long-term residents of the United States;
- persons holding ADSs as part of a position in a straddle or as part of a hedging, conversion or integrated transaction for U.S. federal income tax purposes; or
- direct, indirect or constructive owners of 10% or more of our total combined voting power or value.

In addition, this summary does not address the 3.8% Medicare contribution tax imposed on certain net investment income, the U.S. federal estate and gift tax or the alternative minimum tax consequences of the acquisition, ownership, and disposition of ADSs. We have not received nor do we expect to seek a ruling from the U.S. Internal Revenue Service, or the IRS, regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Moreover, on December 22, 2017, President Trump signed into law new legislation that significantly revises the Code. The overall impact of the new federal tax law is uncertain and the impact of this tax reform on holders of our ADSs is also uncertain and could be adverse. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of ADSs.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership should consult its own tax advisors as to the U.S. federal income tax consequences of acquiring, owning and disposing of ADSs.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEIR SITUATIONS AS WELL AS THE APPLICATION OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S. OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.

ADSs

A U.S. Holder of ADSs will generally be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that such ADSs represent. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depositary or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of non-U.S. withholding taxes (if any), and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

Taxation of Dividends

As described in "Item 8. Financial Information—A.8 Dividend Policy," we do not currently anticipate paying any distributions on our ADSs in the foreseeable future. However, subject to the discussion below in "—Passive Foreign Investment Company Considerations," to the extent there are any distributions made with respect to our ADSs, the gross amount of any distribution on the ADSs (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the ADSs and thereafter as capital gain. However, because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax accounting principles, U.S. Holders should expect to treat distributions paid with respect to the ADSs as dividends. Dividends paid to corporate U.S. Holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. This discussion assumes that distributions on the ADSs, if any, will be paid in U.S. dollars.

Dividends paid to a non-corporate U.S. Holder by a "qualified foreign corporation" may be subject to reduced rates of U.S. federal income taxation if certain holding period and other requirements are met. A qualified foreign corporation generally includes a foreign corporation (other than a PFIC) if (1) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (2) it is eligible for benefits under a comprehensive U.S. income tax treaty that includes an exchange of information program and which the U.S. Treasury Department has determined is satisfactory for these purposes.

Our ADSs are listed on the Nasdaq Global Market, which is an established securities market in the United States. IRS guidance indicates that the ADSs will be readily tradable for these purposes.

The United States does not have a comprehensive income tax treaty with the Cayman Islands. However, in the event that we were deemed to be a PRC resident enterprise under the EIT Law (see "—Material People's Republic of China Taxation" above), although no assurance can be given, we might be considered eligible for the benefits of the U.S.-PRC Tax Treaty, and if we were eligible for such benefits, dividends paid on the ADSs, regardless of whether the ADSs are readily tradable on an established securities market in the United States, would be eligible for the reduced rates of U.S. federal income taxation, subject to applicable limitations. U.S. Holders should consult their own tax advisors regarding the availability of the reduced tax rates on dividends in light of their particular circumstances.

Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

In the event that we were deemed to be a PRC resident enterprise under the EIT Law (see "—People's Republic of China Taxation" above), ADS holders might be subject to PRC withholding taxes on dividends paid with respect to ADSs. In that case, subject to certain conditions and limitations, such PRC withholding tax may be treated as a foreign tax eligible for credit against a U.S. Holder's U.S. federal income tax liability under the U.S. foreign tax credit rules. For purposes of calculating the U.S. foreign tax credit, dividends paid on the ADSs will be treated as income from sources outside the United States and will generally constitute passive category income. If a U.S. Holder is eligible for U.S.-PRC Tax Treaty benefits, any PRC taxes on dividends will not be creditable against such U.S. Holder's U.S. federal income tax liability to the extent such tax is withheld at a rate exceeding the applicable U.S.-PRC Tax Treaty rate. An eligible

U.S. Holder who does not elect to claim a foreign tax credit for PRC tax withheld may instead be eligible to claim a deduction, for U.S. federal income tax purposes, in respect of such withholding but only for the year in which such U.S. Holder elects to do so for all creditable foreign income taxes. The U.S. foreign tax credit rules are complex. U.S. Holders should consult their own tax advisors regarding the foreign tax credit or deduction rules in light of their particular circumstances.

Taxation of Capital Gains

Subject to the discussion below in "—Passive Foreign Investment Company Considerations" below, upon the sale, exchange, or other taxable disposition of ADSs, a U.S. Holder generally will recognize gain or loss on the taxable sale or exchange in an amount equal to the difference between the amount realized on such sale or exchange and the U.S. Holder's adjusted tax basis in the ADSs. The initial tax basis of ADSs to a U.S. Holder will generally be the U.S. Holder's U.S. dollar purchase price for the ADS.

Subject to the discussion below in "—Passive Foreign Investment Company Considerations" below, such gain or loss will be capital gain or loss. Under current law, capital gains of non-corporate U.S. Holders derived with respect to capital assets held for more than one year are generally eligible for reduced rates of taxation. The deductibility of capital losses is subject to limitations. Capital gain or loss, if any, recognized by a U.S. Holder generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders are encouraged to consult their own tax advisors regarding the availability of the U.S. foreign tax credit in consideration of their particular circumstances.

If we were treated as a PRC resident enterprise for EIT Law purposes and PRC tax were imposed on any gain (see "—Material People's Republic of China Taxation" above), and if a U.S. Holder is eligible for the benefits of the U.S.-PRC Tax Treaty, the holder may be able to treat such gain as PRC source gain under the treaty for U.S. foreign tax credit purposes. A U.S. Holder will be eligible for U.S.-PRC Tax Treaty benefits if (for purposes of the treaty) such holder is a resident of the United States and satisfies the other requirements specified in the U.S.-PRC Tax Treaty. Because the determination of treaty benefit eligibility is fact-intensive and depends upon a holder's particular circumstances, U.S. Holders should consult their tax advisors regarding U.S.-PRC Tax Treaty benefit eligibility. U.S. Holders are also encouraged to consult their own tax advisors regarding the tax consequences in the event PRC tax were to be imposed on a disposition of ADSs, including the availability of the U.S. foreign tax credit and the ability and whether to treat any gain as PRC source gain for the purposes of the U.S. foreign tax credit in consideration of their particular circumstances.

Passive Foreign Investment Company Considerations

Status as a PFIC

The rules governing PFICs can have adverse tax effects on U.S. Holders. We generally will be classified as a PFIC for U.S. federal income tax purposes if, for any taxable year, either: (1) 75% or more of our gross income consists of certain types of passive income (the Income Test), or (2) the average value (determined on a quarterly basis), of our assets that produce, or are held for the production of, passive income (including cash) is 50% or more of the value of all of our assets (the Asset Test).

Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income.

Whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year and which depends on the composition of our income and the composition and value of our assets for the relevant taxable year. The fair market value of our assets for purposes of the PFIC rules (including goodwill) may be determined in large part by reference to the quarterly market price of our ADSs, which is likely to fluctuate significantly. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash in our business, including any cash that is raised in a financing transaction.

We believe that our Hong Kong subsidiary, Zai Lab (Hong Kong) Limited, was a PFIC for its taxable year ended July 12, 2017 and we do not expect that the Company and its subsidiaries will be treated as PFICs for the current taxable year. However, because we hold a substantial amount of passive assets, including cash, and because the value of our assets (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early stage of our drug candidates, we cannot give any assurance that we will not be a PFIC status for the current or any future taxable year.

If we are a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and (i) the U.S. Holder makes the "deemed sale election" described below, (ii) the U.S. Holder has a valid mark-to-market election in effect as described below, or a PFIC during such U.S. Holder's holding period in which we are a PFIC or makes a purging election to cause a deemed sale of the PFIC shares at their fair market value in connection with a QEF election (as discussed below). If a U.S. Holder makes a deemed sale election, such U.S. Holder will be deemed to have sold the shares held by such U.S. Holder at their fair market value, and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, a U.S. Holder's ADSs subject to such election will not be treated as shares in a PFIC, and the rules described below with respect to any "excess distributions" or any gain from an actual sale or other disposition of the ADSs will not apply. Prospective investors should consult their own tax advisors regarding our PFIC status for the current or any future taxable years.

U.S. Federal Income Tax Treatment of a Shareholder of a PFIC

If we are a PFIC for any taxable year during which a U.S. Holder owns ADSs, the U.S. Holder, absent the elections listed above, generally will be subject to adverse rules (regardless of whether we continue to be a PFIC) with respect to (1) any "excess distributions" (generally, any distributions received by the U.S. Holder on its ADSs in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for its ADSs) and (2) any gain realized on the sale or other disposition, including in certain circumstances a pledge, of its ADSs.

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income and (c) the amount allocated to each other taxable year during the U.S. Holder's holding period in which we were a PFIC (i) will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and (ii) will be subject to an interest charge at a statutory rate with respect to the resulting tax attributable to each such other taxable year. Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we were a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

If we are a PFIC, a U.S. Holder will generally be treated as owning a proportionate amount (by value) of stock or shares owned by us in any direct or indirect subsidiaries that are also PFICs, or Lower-tier PFICs, and will be subject to similar adverse rules with respect to any distributions we receive from, and dispositions we make of, the stock or shares of such subsidiaries. U.S. Holders are urged to consult their tax advisors about the application of the PFIC rules to any of our subsidiaries.

PFIC "Mark-to-Market" Election

In certain circumstances if we are a PFIC for any taxable year, a U.S. Holder can be subject to rules different from those described above by making a mark-to-market election with respect to its ADSs, provided that the ADSs are "marketable." ADSs will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury Regulations. ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter. A "qualified exchange" includes a national securities exchange that is registered with the SEC.

Under current law, the mark-to-market election may be available to U.S. Holders of ADSs if the ADSs are listed on the Nasdaq Global Market (which constitutes a qualified exchange) and such ADSs are "regularly traded" for purposes of the mark-to-market election (for which no assurance can be given).

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the U.S. Holder's ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in its ADSs. Accordingly, such mark-to-market election may accelerate the recognition of income without a corresponding receipt of cash. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in its ADSs over the fair market value of its ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. The adjusted tax basis of a U.S. Holder's ADSs will be adjusted to reflect amounts included in gross income or allowed as a deduction because of such mark-to-market election. If a U.S. Holder makes an effective mark-to-market election, gains from an actual sale or other disposition of ADSs in a year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of ADSs will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If we are a PFIC for any taxable year in which a U.S. Holder owns ADSs but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

A mark-to-market election is not permitted for the shares of any of our subsidiaries that are also classified as PFICs (unless the shares of such subsidiaries are themselves marketable). Prospective investors should consult their own tax advisors regarding the availability of, and the procedure for making, a mark-to-market election, and whether making the election would be advisable, including in light of their particular circumstances.

PFIC "QEF" Election

Alternatively, if we provide the necessary information, a U.S. Holder can be subject to rules different from those described above by electing to treat us (and each Lower-tier PFIC, if any) as a QEF under Section 1295 of the Code in the first taxable year that we (and each Lower-tier PFIC) are treated as a PFIC with respect to the U.S. Holder. A U.S. Holder must make the QEF election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder's timely filed U.S. federal income tax return.

In any year in which we determine that we are a PFIC, we will provide the information necessary for a U.S. Holder to make a QEF election with respect to us upon the request of a U.S. Holder and will endeavor to cause each Lower-tier PFIC that we control to provide such information with respect to such Lower-tier PFIC. However, there can be no assurance that we will be able to cause any Lower-tier PFIC we do not control to provide such information. We may elect to provide the information necessary to make such QEF elections on our website.

If you make a QEF election with respect to a PFIC, you will be taxed currently on your pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC, even if no distributions were received. If a U.S. Holder makes a QEF election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder's income under the QEF election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its ADSs by an amount equal to any income included under the QEF election and will decrease its tax basis by any amount distributed on the ADSs that is not included in the U.S. Holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of ADSs in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ADSs, as determined in U.S. dollars. Once made, a QEF election remains in effect unless invalidated or terminated by the IRS or revoked by the U.S. Holder. A QEF election can be revoked only with the consent of the IRS. A U.S. Holder will not be currently taxed on the ordinary income and net capital gain of a PFIC with respect to which a QEF election was made for any taxable year of the non-U.S. corporation for which such corporation does not satisfy the PFIC Income Test or Asset Test.

U.S. Holders should note that if they make QEF elections with respect to us and any Lower-tier PFIC, they may be required to pay U.S. federal income tax with respect to their ADSs for any taxable year significantly in excess of any cash distributions received on the ADSs for such taxable year. U.S. Holders should consult their tax advisers regarding the advisability of, and procedure for, making QEF elections in their particular circumstances.

PFIC Information Reporting Requirements

If we are a PFIC in any year with respect to a U.S. Holder, such U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ADSs, and certain U.S. Holders will be required to file an annual information return (also on IRS Form 8621) relating to their ownership of our ADSs.

THE U.S. FEDERAL INCOME TAX RULES RELATING TO PFICS ARE COMPLEX. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

U.S. Backup Withholding and Information Reporting

Backup withholding and information reporting requirements may apply to distributions on, and proceeds from the sale or disposition of, ADSs that are held by U.S. Holders. The payor may be required to withhold U.S. backup withholding tax on payments made with respect to the ADSs to a U.S. Holder, other than an exempt recipient, if the U.S. Holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding requirements. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability (if any) or refunded provided the required information is furnished to the IRS in a timely manner.

Certain U.S. Holders of specified foreign financial assets with an aggregate value in excess of the applicable dollar threshold are required to report information relating to their holding of ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by certain financial institutions) with their tax return for each year in which they hold ADSs. U.S. Holders should consult their own tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of ADSs.

THE ABOVE DISCUSSION DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. PROSPECTIVE INVESTORS ARE STRONGLY URGED TO CONSULT THEIR OWN TAX ADVISORS ABOUT THE TAX CONSEQUENCES OF AN INVESTMENT IN THE ADSs.

F. Dividends and Payment Agents

Not applicable.

G. Statement by experts

Not applicable.

H. Documents on display

We are subject to the informational requirements of the Exchange Act and are required to file reports and other information with the SEC. The SEC maintains a website at *www.sec.gov* that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system.

We are a "foreign private issuer" as such term is defined in Rule 405 under the Securities Act, and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, we do not file the same reports that a U.S. domestic issuer would file with the SEC.

We also make available on our website's investor relations page, free of charge, our annual report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. The address for our investor relations page is "ir.zailaboratory.com" The information contained on our website is not incorporated by reference in this annual report.

I. Subsidiary information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk including foreign exchange risk, credit risk, cash flow interest rate risk and liquidity risk.

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of our company included aggregated amounts of RMB47.2 million and RMB26.9 million, which were denominated in RMB, as of December 31, 2019 and 2018, respectively, representing 9% and 6% of the cash and cash equivalents as of December 31, 2019 and 2018, respectively.

Our business mainly operates in China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the RMB because the value of our business is effectively denominated in RMB, while the ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. On July 21, 2005, China government changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that China government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the RMB by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day's value, respectively.

To the extent that we need to convert U.S. dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amounts available to us.

Credit Risk

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents, short-term investment and prepayment to suppliers. The carrying amounts of cash and cash equivalents and short-term investment represent the maximum amount of loss due to credit risk. As of December 31, 2019 and 2018, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in China and international financial institutions outside of China which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions. With respect to the prepayments to suppliers, we perform on-going credit evaluations of the financial condition of these suppliers.

Inflation

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. According to the National Bureau of Statistics of China, the Consumer Price Index in China increased by 2.9%, 2.1% and 1.6% in 2019, 2018 and 2017, respectively. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Oher Securities

Not applicable

D. American Depositary Shares

Fees and Charges our ADS Holders May Have to Pay

An ADS holder will be required to pay the following service fees to Citibank, N.A., the depositary of our ADS program, and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of the ADSs):

Service	Fees
• Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares **,** upon a change in the ADS(s)-to-share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S.$0.05 per ADS issued
• Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to-share ratio, or for any other reason)	Up to U.S. $0.05 per ADS cancelled
• Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. $0.05 per ADS held
• Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. $0.05 per ADS held
• Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. $0.05 per ADS held
• ADS Services	Up to U.S. $0.05 per ADS held on the applicable record date(s) established by the depositary bank

ADS holders will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary bank in the conversion of foreign currency;
- the fees and expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and American depositary receipts, or ADRs; and
- the fees and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to the ADS holder. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

The depositary has agreed to pay certain amounts to us in exchange for its appointment as depositary. We may use these funds towards our expenses relating to the establishment and maintenance of the ADR program, including investor relations expenses, or otherwise as we see fit. The depositary has reimbursed us for expenses related to the administration and maintenance of the facility in the amount of $0.3 million and $0.3 million, after deduction of applicable U.S. taxes, for the year ended December 31, 2019 and 2018, respectively.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Material Modifications to the Rights of Security Holders

None.

Use of Proceeds

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File No. 333-219980), in relation to our initial public offering, which was declared effective by the SEC on September 20, 2017. In September 2017, we completed our initial public offering in which we issued and sold an aggregate of 9,583,333 ADSs (reflecting the full exercise of the over-allotment option by the underwriters to purchase an additional 1,250,000 ADSs), resulting in net proceeds to us of approximately $157.7 million. J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Leerink Partners LLC were the representatives of the underwriters for our initial public offering.

The net proceeds from our initial public offering have been used as follows:

- approximately $62.5 million for for research development costs driven primarily by ZEJULA, omadacycline and brivanib;
- approximately $11.3 million to support the commercialization efforts for ZEJULA in China, Hong Kong and Macau;
- approximately $34.6 million for licensing and developing new drug candidates;
- approximately $11.3 million for the construction of our large molecule drug product facility in Suzhou; and
- approximately $38.0 million for staff cost, working capital and other general corporate purpose.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report, as required by Rule 13a-15(b) under the Exchange Act.

Based upon that evaluation, our management has concluded that, as of December 31, 2019, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file and furnish under the Exchange Act was recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, to allow timely decisions regarding required disclosure.

B. Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP in and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of our company's assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As required by Section 404 of the Sarbanes-Oxley Act of 2002 and related rules as promulgated by the Securities and Exchange Commission, our management including our Chief Executive Officer and Chief Financial Officer assessed the effectiveness of internal control over financial reporting as of December 31, 2019 using the criteria set forth in the report "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of internal control over financial reporting as of December 31, 2019 has been audited by Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent registered public accounting firm, who has also audited our consolidated financial statements for the year ended December 31, 2019.

C. Attestation Report of the Registered Public Accounting Firm

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated April 29, 2020, expressed an unqualified opinion on those financial statements and included an explanatory paragraph related to the Company's change in method of accounting for leases on January 1, 2019 due to the adoption of FASB Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842) and related ASUs.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China

April 29, 2020

D. Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that William Lis, an independent director (under the standards set forth in Nasdaq Stock Market Rule 5605(a)(2) and Rule 10A-3 under the Exchange Act) and member of our audit committee, is an audit committee financial expert.

ITEM 16B. CODE OF ETHICS

Our board of directors has adopted a code of ethics applicable to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. This code is intended to qualify as a "code of ethics" within the meaning of the applicable rules of the SEC. Our code of ethics is available on our website at http://ir.zailaboratory.com/phoenix.zhtml?c=254615&p=irol-govhighlights. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this annual report. See "Item 6.C. Directors, Senior Management and Employees—Code of Ethics" for more information.

ITEM 16C. PRINCIPAL ACCOU NTANT FEES AND SERVICES

Principal Accountant Fees and Services

The following table sets forth the aggregate fees by the categories specified below in connection with certain professional services rendered by Deloitte Touche Tohmatsu Certified Public Accountants LLP, our independent registered public accounting firm, for the periods indicated. We did not pay any other fees to our auditors during the periods indicated below.

	Year ended December 31,	
	2019	2018
	(in thousands)	
Audit Fees(1)	$ 650	$ 550
Audit-related fees(2)	376	103
Tax fees(3)	36	10

(1) “Audit fees” means the aggregate fees in each of the fiscal years listed for professional services rendered by our independent registered public accounting firm for the audit of our financial statements or services that are normally provided by the auditors in connection with and regulatory filling or engagements.
(2) "Audit-related fees" represents aggregate fees billed for professional services rendered for assurance and related services that are not reported under audit fees.
(3) "Tax fees" represents aggregate fees for professional services performed in connection with tax planning and tax compliance.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by Deloitte Touche Tohmatsu Certified Public Accountants LLP, including audit services, audit-related services, tax services and other services as described above, other than those for de minimis services which are approved by the Audit Committee prior to the completion of the audit.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPOR ATE GOVERNANCE

The Nasdaq Stock Market listing rules include certain accommodations in the corporate governance requirements that allow foreign private issuers, such as us, to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. We currently follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following:

- the majority independent director requirement under Section 5605(b)(1) of the Nasdaq Stock Market listing rules;
- the requirement under Section 5605(d) of the Nasdaq Stock Market listing rules that a compensation committee comprised solely of independent directors governed by a compensation committee charter oversee executive compensation;
- the requirement under Section 5605(e) of the Nasdaq Stock Market listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors; and
- the requirement under Section 5605(b)(2) of the Nasdaq Stock Market listing rules that the independent directors have regularly scheduled meetings with only the independent directors present.

Cayman Islands law does not impose a requirement that the board consist of a majority of independent directors or that such independent directors meet regularly without other members present. Nor does Cayman Islands law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS.

See "Item 18. Financial Statements."

ITEM 18. FINANCIAL STATEMENTS.

The consolidated financial statements of Zai Lab Limited and its subsidiaries are included at the end of this Annual Report on Form 20-F.

ITEM 19. EXHIBITS

EXHIBIT INDEX

Exhibit Number	Exhibit Title
1.1	Fourth Amended and Restated Memorandum and Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.3	Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.4	Third Amended and Restated Shareholders Agreement between Zai Lab Limited and other parties named therein dated June 26, 2017 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
4.5*	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act
10.1 #	Zai Lab Limited 2015 Omnibus Equity Incentive Plan as amended on February 3, 2016 and April 10, 2016 (incorporated by reference to Exhibit 10.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.2 #	Zai Lab Limited 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.3 #	Form Restricted Share Unit Award Agreement (incorporated by reference to Exhibit 10.23 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.4 #	Form Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.24 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.5 #	Form of Non-Statutory Stock Option Award Agreement (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.6 *	Non-Employee Director Compensation Policy
10.7 #	Zai Lab Limited 2017 Cash Bonus Plan (incorporated by reference to Exhibit 10.11 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.8 +	Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd. dated September 28, 2016 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
10.9	Amendment to Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd., dated February 26, 2018 (incorporated by reference to Exhibit 4.3 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 30, 2018)

10.10 +	License Agreement by and between Bristol-Myers Squibb Company and Zai Lab (Hong Kong) Limited dated March 9, 2015 (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
10.11 +	License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd. dated April 21, 2017 (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
10.12 +	License Agreement by and between Sanofi and Zai Lab (Hong Kong) Limited dated July 22, 2015 (incorporated by reference to Exhibit 10.8 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
10.13 +	License Agreement by and between Five Prime Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated December 19, 2017 (incorporated by reference to Exhibit 4.11 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 30, 2018)
10.14 +	License and Collaboration Agreement by and between Entasis Therapeutics Holdings Inc. and Zai Lab (Shanghai) Co., Ltd. dated as of April 25, 2018 (incorporated by reference to Exhibit 10.12 to our Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-227159) filed with the SEC on September 5, 2018)
10.15 +	License and Collaboration Agreement by and between Novocure Limited and Zai Lab (Shanghai) Co., Ltd. dated September 10, 2018 (incorporated by reference to Exhibit 10.15 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
10.16 +	Collaboration Agreement by and between MacroGenics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated November 29, 2018 (incorporated by reference to Exhibit 10.16 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
10.17* ^	License Agreement between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. dated June 10, 2019
10.18* ^	Amendment to License Agreement between Deciphera Pharmaceuticals, LLC and Zai Lab (Shanghai) Co., Ltd. dated January 17, 2020
10.19* ^	Collaboration and License Agreement between Incyte Corporation and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2019
10.20	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
10.21 #	Fourth Amended and Restated Founder Employment Agreement between Samantha (Ying) Du and Zai Lab Limited dated December 1, 2018 (incorporated by reference to Exhibit 10.18 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
10.22 #	Amended and Restated Employment Agreement between William Ki Chul Cho and Zai Lab (Hong Kong) Limited dated March 22, 2019 (incorporated by reference to Exhibit 10.19 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
10.23 #	Second Amended and Restated Employment Agreement between Harald Reinhart and Zai Lab (Hong Kong) Limited dated December 28, 2018 (incorporated by reference to Exhibit 10.22 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
10.24 #	Employment Agreement between Samantha (Ying) Du and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2017 (English translation) (incorporated by reference to Exhibit 10.18 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.25 #	Amended and Restated Employment Agreement between Tao Fu and Zai Lab (US) LLC dated December 3, 2018 (incorporated by reference to Exhibit 10.26 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)

10.26 #	Amended and Restated Employment Agreement between Yongjiang Hei and Zai Lab (US) LLC dated March 22, 2019 (incorporated by reference to Exhibit 10.27 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on March 29, 2019)
10.27 #	Letter Agreement between Samantha (Ying) Du and Zai Lab (US) LLC dated December 11, 2017 (incorporated by reference to Exhibit 4.16 to our Annual Report on Form 20-F (File No. 001-38205) filed with the SEC on April 30, 2018)
10.28* #	Employment Agreement between Valeria Fantin, Ph.D. and Zai Lab (US) LLC dated June 3, 2019
10.29	Jinchuang Building House Leasing Contract by and between Zai Lab (Shanghai) Co., Ltd. and Shanghai Jinchuang Property Co., Ltd. dated September 1, 2016 (English translation) (incorporated by reference to Exhibit 10.26 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
12.1*	Certification of Chief Executive Officer Required by Rule 13a-14(a)
12.2*	Certification of Chief Financial Officer Required by Rule 13a-14(a)
13.1**	Certification of Chief Executive Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code
13.2**	Certification of Chief Financial Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code
21.1	Subsidiaries of the registrant (incorporated by reference to Exhibit 21.1 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
23.1*	Consent of Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent accounting firm, regarding the consolidated financial statements of Zai Lab Limited
23.2*	Consent of Zhong Lun Law Firm
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definitions Linkbase Document

* Filed herewith
** Furnished herewith
# Management contract or compensatory plan
+ Confidential treatment has been granted as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.
^ Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on annual report on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

ZAI LAB LIMITED

By: /s/ Samantha Du
Name Samantha Du
Title: Chief Executive Officer

Date: April 29, 2020

Zai Lab Limited

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Report of independent registered public accounting firm

To the Shareholders and Board of Directors of Zai Lab Limited

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity (deficit) , and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes and schedule (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated April 29, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases on January 1, 2019 due to the adoption of FASB Accounting Standards Update (ASU) 2016-02, Leases (Topic 842) and related ASUs and related ASUs using a modified-retrospective approach.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Research and development expenses- Cut-off — Refer to Notes 2(t) to the financial statements

Critical Audit Matter Description

As disclosed in the consolidated statements of operations, for the year ended December 31, 2019, the Company incurred significant research and development ("R&D") expenses, which amounted to approximately USD142 million. A large amount of the Company's R&D expenses are service fees paid to contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") (collectively referred as "Outsourced Service Providers").

The R&D activities with these Outsourced Service Providers are documented in detailed agreements and are typically performed over an extended period. There are typically several milestones of the services in one agreement, therefore allocation of the service expenses to the appropriate financial reporting period based on the progress of the R&D projects involved judgement and estimation.

We identified cut-off of R&D expenses as a critical audit matter due to the potential significance of misstatements to the financial statements that could arise from not accruing R&D expenses incurred for services provided by the Outsourced Service Providers in the appropriate reporting period.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the cut-off of research and development expenses included the following, among others:

- We tested the effectiveness of key controls over the accrual of the R&D expenses payable to the Outsourced Service Providers.
- We obtained and read the key terms set out in research agreements with Outsourced Service Providers and evaluated the completion status with reference to the progress reported by the representatives of the Outsourced Service Providers, on a sample basis, to determine whether the service fees were recorded based on respective contract sums, progress and/or milestones achieved.
- We sent audit confirmations to Outsourced Service Providers, on a sample basis, to confirm the amount of the R&D service fees incurred for the year ended December 31, 2019 and the amounts payable under the contracts as of December 31, 2019.
- We selected projects from the open contract list as of December 31, 2019 on a sample basis, made inquiries of responsible personnel regarding the project status and inspected invoices and other communications from the Outsourced Service Providers to identify any additional Outsourced Service Providers and related unrecorded R&D expenditures.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China

April 29, 2020

We have served as the Company's auditor since 2017.

Report of independent registered public accounting firm

To the Shareholders and Board of Directors of Zai Lab Limited

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated April 29, 2020, expressed an unqualified opinion on those financial statements and included an explanatory paragraph related to the Company's change in method of accounting for leases on January 1, 2019 due to the adoption of FASB Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842) and related ASUs.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China

April 29, 2020

Z ai Lab Limited

Consolidated balance sheets

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Note	As of December 31, 2018 $	As of December 31, 2019 $
Assets			
Current assets:			
Cash and cash equivalents	3	62,952	75,932
Short-term investments	5	200,350	200,000
Accounts receivable		90	3,791
Inventories	6	4	6,005
Prepayments and other current assets		5,749	6,736
Total current assets		269,145	292,464
Restricted cash, non-current	4	—	510
Investments in equity investees	7	3,150	2,398
Prepayments for equipment		276	440
Property and equipment, net	8	20,494	21,353
Operating lease right-of-use assets	9	—	15,071
Land use rights, net		—	7,655
Intangible assets, net		321	1,148
Long term deposits		557	377
Value added tax recoverable		8,044	13,737
Total assets		**301,987**	**355,153**
Liabilities and shareholders' equity			
Current liabilities:			
Short-term borrowings	11	3,643	6,450
Accounts payable		37,432	22,660
Current operating lease liabilities	9	—	4,351
Other current liabilities	12	7,767	13,174
Total current liabilities		48,842	46,635
Deferred income		2,064	2,881
Non-current operating lease liabilities	9	—	10,977
Total liabilities		**50,906**	**60,493**
Commitments and contingencies (Note 21)			
Shareholders' equity			
Ordinary shares (par value of US$0.00006 per share; 83,333,333 shares authorized, 58,006,967 and 68,237,247 shares issued and outstanding as of December 31,2018 and 2019, respectively)		3	4
Additional paid-in capital		498,043	734,734
Accumulated deficit		(249,627)	(444,698)
Accumulated other comprehensive income	17	2,662	4,620
Total shareholders' equity		**251,081**	**294,660**
Total liabilities and shareholders' equity		**301,987**	**355,153**

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of operations

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Note	Year ended December 31, 2017 $	2018 $	2019 $
Revenue		—	129	12,985
Expenses:				
Cost of sales		—	(43)	(3,749)
Research and development		(39,342)	(120,278)	(142,221)
Selling, general and administrative		(12,049)	(21,576)	(70,211)
Loss from operations		(51,391)	(141,768)	(203,196)
Interest income		527	3,261	8,232
Interest expenses		—	(40)	(293)
Changes in fair value of warrants		200	—	—
Other income, net		530	59	938
Loss before income tax and share of loss from equity method investment		(50,134)	(138,488)	(194,319)
Income tax expense	10	—	—	—
Share of loss from equity method investment		(250)	(587)	(752)
Net loss		(50,384)	(139,075)	(195,071)
Net loss attributable to ordinary shareholders		(50,384)	(139,075)	(195,071)
Loss per share - basic and diluted	14	(2.32)	(2.64)	(3.03)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		21,752,757	52,609,810	64,369,490

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of comprehensive loss

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year ended December 31,		
	2017	2018	2019
	$	$	$
Net loss	(50,384)	(139,075)	(195,071)
Other comprehensive income, net of tax of nil:			
Foreign currency translation adjustments	1,148	2,212	1,958
Comprehensive loss	**(49,236)**	**(136,863)**	**(193,113)**

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of shareholders' (deficit) equity

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Ordinary shares		Additional paid in capital	Subscription receivable	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
	Number of Shares	Amount					
		$	$	$	$	$	$
Balance at January 1, 2017	9,657,175	1	9,314	0	(60,168)	(698)	(51,551)
Issuance of ordinary shares upon vesting of restricted shares	1,666,145	0	0	0	—	—	—
Exercise of shares option	100,834	0	65	—	—	—	65
Exercise of warrant	461,808	0	4,700	—	—	—	4,700
Conversion of convertible preferred shares to ordinary shares	28,443,275	2	163,605	—	—	—	163,607
Issuance of ordinary shares upon initial public offering, net of issuance cost of $2,770	9,583,333	0	157,655	—	—	—	157,655
Share-based compensation	—	—	9,931	—	—	—	9,931
Net loss	—	—	—	—	(50,384)	—	(50,384)
Foreign currency translation	—	—	—	—	—	1,148	1,148
Balance at December 31, 2017	49,912,570	3	345,270	0	(110,552)	450	235,171
Issuance of ordinary shares upon vesting of restricted shares	338,332	0	0	0	—	—	—
Exercise of shares option	256,065	0	196	—	—	—	196
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $652	7,500,000	0	140,348	—	—	—	140,348
Share-based compensation	—	—	12,229	—	—	—	12,229
Net loss	—	—	—	—	(139,075)	—	(139,075)
Foreign currency translation	—	—	—	—	—	2,212	2,212
Balance at December 31, 2018	58,006,967	3	498,043	—	(249,627)	2,662	251,081
Issuance of ordinary shares upon vesting of restricted shares	539,733	0	0	—	—	—	—
Exercise of shares option	670,939	0	1,055	—	—	—	1,055
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $854	9,019,608	1	215,345	—	—	—	215,346
Share-based compensation	—	—	20,291	—	—	—	20,291
Net loss	—	—	—	—	(195,071)	—	(195,071)
Foreign currency translation	—	—	—	—	—	1,958	1,958
Balance at December 31, 2019	68,237,247	4	734,734	—	(444,698)	4,620	294,660

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of cash flows

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year ended December 31,		
	2017	2018	2019
	$	$	$
Operating activities			
Net loss	(50,384)	(139,075)	(195,071)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expenses	548	1,650	3,766
Amortization of deferred income	(78)	(312)	(312)
Share-based compensation	9,931	12,229	20,291
Share of loss from equity method investment	250	587	752
Loss on disposal of property and equipment	13	1	15
Noncash lease expenses	—	—	2,831
Change in fair value of warrants	(200)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	—	(90)	(3,701)
Inventories	—	(4)	(6,001)
Prepayments and other current assets	(811)	(4,794)	(1,125)
Long term deposits	(39)	(250)	180
Value added tax recoverable	(3,685)	(2,982)	(5,693)
Accounts payable	8,444	28,464	(14,772)
Other current liabilities	1,950	7,056	9,136
Operating lease liabilities	—	—	(2,436)
Deferred income	1,694	(18)	1,129
Net cash used in operating activities	(32,367)	(97,538)	(191,011)
Cash flows from investing activities:			
Purchases of short-term investments	—	(200,350)	(277,640)
Proceeds from maturity of short-term investments	—	—	277,990
Disposal of long-term investment	500	—	—
Purchase of equity method investment	(1,900)	(2,086)	—
Purchase of property and equipment	(9,102)	(10,015)	(6,035)
Disposal of property and equipment	83	—	—
Purchase of land use rights	—	—	(7,836)
Purchase of intangible assets	(15)	(103)	(1,371)
Net cash used in investing activities	(10,434)	(212,554)	(14,892)
Cash flows from financing activities:			
Proceed from short-term borrowings	—	3,643	7,252
Repayment of short-term borrowings	—	—	(4,351)
Proceed from issuance of convertible preferred shares, net of issuance cost	29,100	—	—
Proceeds from exercise of warrants	1,000	—	—
Proceeds from exercises of stock options	65	196	1,055
Proceeds from issuance of ordinary shares upon public offerings	160,425	141,000	216,200
Payment of public offering costs	(2,730)	(692)	(854)
Net cash provided by financing activities	187,860	144,147	219,302
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	652	(763)	91
Net increase (decrease) in cash, cash equivalents and restricted cash	145,711	(166,708)	13,490
Cash, cash equivalents and restricted cash - beginning of the year	83,949	229,660	62,952
Cash, cash equivalents and restricted cash - end of the year	229,660	62,952	76,442
Supplemental disclosure on non-cash investing and financing activities:			
Payables for purchase of property and equipment	414	1,709	416
Payables for intangible assets	—	225	—
Payables for public offering costs	40	—	—
Conversion of convertible preferred shares	163,607	—	—
Exercise of warrants	3,700	—	—
Supplemental disclosure of cash flow information:			
Cash and cash equivalents	229,660	62,952	75,932
Restricted cash, non-current	—	—	510
Interest paid	—	36	288

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and principal activities

Zai Lab Limited (the "Company") was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands. The Company and its subsidiaries (collectively referred to as the "Group") are principally engaged in discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical needs in the China market and the global markets, including in the fields of oncology, infectious and autoimmune diseases.

As of December 31, 2019, the Group's significant operating subsidiaries are as follows:

Name of company	Place of incorporation	Date of incorporation	Percentage of ownership	Principal activities
Zai Lab (Hong Kong) Limited	Hong Kong	April 29, 2013	100%	Operating company for business development and R&D activities and commercialisation of innovative medicines and device
Zai Lab (Shanghai) Co., Ltd.	The People's Republic of China ("PRC" or "China")	January 6, 2014	100%	Development and commercialisation of innovative medicines and devices
Zai Lab (AUST) Pty., Ltd.	Australia	December 10, 2014	100%	Clinical trial activities
Zai Lab (Suzhou) Co., Ltd.	PRC	November 30, 2015	100%	Development and commercialisation of innovative medicines
Zai Biopharmaceutical (Suzhou) Co., Ltd.	PRC	June 15, 2017	100%	Development and commercialisation of innovative medicines
Zai Lab (US) LLC	U.S.	April 21, 2017	100%	Operating company for business development and R&D activities
Zai Lab International Trading (Shanghai) Co., Ltd.	PRC	November 6, 2019	100%	Commercialisation of innovative medicines and devices

2. Summary of significant accounting policies

(a) Basis of presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

(b) Principles of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries. All intercompany transactions and balances among the Group and its subsidiaries are eliminated upon consolidation.

(c) Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, assessing the impairment of long-lived assets, discount rate of operating lease liabilities, revenue recognition, allocation of the R&D service expenses to the appropriate financial reporting period based on the progress of the R&D projects, valuation of ordinary shares, share-based compensation expenses, recoverability of deferred tax assets and the fair value of the financial instruments. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

(d) Foreign currency translation

The functional currency of Zai Lab Limited and Zai Lab (Hong Kong) Limited are the United States dollar ("$"). The Company's PRC subsidiaries determined their functional currency to be Chinese Renminbi ("RMB"). The Company's Australia subsidiary determined its functional currency to be Australia dollar ("A$"). The determination of the respective functional currency is based on the criteria of Accounting Standard Codification ("ASC") 830, *Foreign Currency Matters* . The Group uses the United States dollar as its reporting currency.

Assets and liabilities are translated from each entity's functional currency to the reporting currency at the exchange rate on the balance sheet date. Equity amounts are translated at historical exchange rates, and expenses, gains and losses are translated using the average rate for the year. Translation adjustments are reported as cumulative translation adjustments and are shown as a separate component of other comprehensive loss in the consolidated statements of changes in shareholders' deficits and comprehensive loss.

Monetary assets and liabilities denominated in currencies other than the applicable functional currencies are translated into the functional currencies at the prevailing rates of exchange at the balance sheet date. Nonmonetary assets and liabilities are remeasured into the applicable functional currencies at historical exchange rates. Transactions in currencies other than the applicable functional currencies during the year are converted into the functional currencies at the applicable rates of exchange prevailing at the transaction dates. Transaction gains and losses are recognized in the consolidated statements of operations.

(e) Cash, cash equivalents and restricted cash

Cash and cash equivalents

The Group considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash on hand, demand deposits and highly liquid investments with maturity of less than three months and are stated at cost plus interests earned, which approximates fair value.

Restricted cash

Restricted cash mainly consists of the bank deposits held as collateral for issuance of letters of credit.

(f) Short-term investments

Short-term investments are time deposits with original maturities more than three months. Short-term investments are stated at cost, which approximates fair value. Interest earned is included in interest income.

(g) Accounts receivable

Accounts receivable are recorded at the amounts due from customers and net of allowances for doubtful accounts. An allowance for doubtful accounts is recorded when the collection of the full amount is no longer probable. In evaluating the collectability of accounts receivable, the Group considers many factors including aging of the receivable due, the customer's payment history, creditworthiness, financial conditions, and current economic trends. Credit losses of accounts receivable, which may be for all or part of a particular accounts

receivable, shall be deducted from the allowance. The related accounts receivable balance shall be charged off in the period in which the accounts receivable are deemed uncollectible. Recoveries of accounts receivable previously charged written off shall be recorded when received. The Group regularly reviews the adequacy and appropriateness of any allowance for doubtful accounts. No allowance for doubtful accounts was recorded as of December 31, 2018 and 2019 .

(h) Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a weighted average basis. The Group periodically reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. The Group will record a write-down to its net realizable value in cost of sales in the period that the decline in value is first identified. No inventory write-down was recorded as of December 31, 2018 and 2019.

(i) Investments in equity investees

The Group uses the equity method to account for an equity investment over which it has significant influence but does not own a majority equity interest or otherwise control. The Group records equity method adjustments in share of earnings and losses. Equity method adjustments include the Group's proportionate share of investee income or loss, adjustments to recognize certain differences between the Group's carrying value and its equity in net assets of the investee at the date of investment, impairments, and other adjustments required by the equity method. Dividends received are recorded as a reduction of carrying amount of the investment. Cumulative distributions that do not exceed the Group's cumulative equity in earnings of the investee are considered as a return on investment and classified as cash inflows from operating activities. Cumulative distributions in excess of the Group's cumulative equity in the investee's earnings are considered as a return of investment and classified as cash inflows from investing activities.

Prior to adopting ASC Topic 321, Investments—Equity Securities ("ASC 321") on January 1, 2018, for the investments without readily determinable fair value and the Group does not have significant influence or control, the Group carries the investment at cost and recognizes income to the extent of dividends received from the distribution of the equity investee's post-acquisition profits in accordance with ASC 325-20, Cost Method Investments. The Group disposed the cost method investment prior to the adoption ASC 321, see Note 7.

The Group is required to perform an impairment assessment of its investments whenever events or changes in business circumstances indicate that the carrying value of the investment may not be fully recoverable. An impairment loss is recorded when there has been a loss in value of the investment that is other than temporary. No impairment was recorded for the years ended December 31, 2017, 2018 and 2019.

(j) Prepayments for equipment

The prepayments for equipment purchase are recorded in long term prepayments considering the prepayments are all related to property and equipment.

(k) Property and equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	Useful life
Office equipment	3 years
Electronic equipment	3 years
Vehicle	4 years
Laboratory equipment	5 years
Manufacturing equipment	10 years
Leasehold improvements	lesser of useful life or lease term

Construction in progress represents property and equipment under construction and pending installation and is stated at cost less impairment losses if any.

(l) Lease

Before January 1, 2019, the Group adopted the ASC Topic 840, Leases, each lease is classified at the inception date as either a capital lease or an operating lease. All the Group's leases were classified as operating lease under ASC Topic 840.The Group's reporting for periods prior to January 1, 2019 continued to be reported in accordance with *Leases* (Topic 840).

After January 1, 2019, the Group adopted the ASC Topic 842, Leases ("ASC 842"). The Group determines if an arrangement is a lease at inception. The Group classifies the lease as a finance lease if it meets certain criteria or as an operating lease when it does not. The Group has lease agreements with lease and non-lease components, which the Group has elected to account for the components as a single lease component. The Group leases facilities for office, research and development center, and manufacturing facilities in PRC, Hong Kong and U.S, which are all classified as operating leases with fixed lease payments, or minimum payments, as contractually stated in the lease agreement. The Group's leases do not contain any material residual value guarantees or material restrictive covenants.

At the commencement date of a lease, the Group recognizes a lease liability for future fixed lease payments and a right-of-use ("ROU") asset representing the right to use the underlying asset during the lease term. The lease liability is initially measured as the present value of the future fixed lease payments that will be made over the lease term. The lease term includes lessee options to extend the lease and periods occurring after a lessee early termination option, only to the extent it is reasonably certain that the Group will exercise such extension options and not exercise such early termination options, respectively. The future fixed lease payments are discounted using the rate implicit in the lease, if available, or the incremental borrowing rate ("IBR"). Upon adoption of ASU 2016-02, the Group elected to use the remaining lease term as of January 1, 2019 in the Group's estimation of the applicable discount rate for leases that were in place at adoption. For the initial measurement of the lease liability for leases commencing after January 1, 2019, the Group uses the discount rate as of the commencement date of the lease, incorporating the entire lease term. Additionally, the Group elected not to recognize leases with lease terms of 12 months or less at the commencement date in the consolidated balance sheets.

The ROU asset is measured at the amount of the lease liability with adjustments, if applicable, for lease prepayments made prior to or at lease commencement, initial direct costs incurred by the Group and lease incentives. Under ASC 842, land use rights agreements are also considered to be operating lease contracts. The Group will evaluate the carrying value of ROU assets if there are indicators of impairment and review the recoverability of the related asset group. If the carrying value of the asset group is determined to not be recoverable and is in excess of the estimated fair value, the Group will record an impairment loss in other expenses in the consolidated statements of operations. ROU assets for operating leases are included in operating lease right-of-use assets in the consolidated balance sheets.

Operating leases are included in operating lease right-of-use assets and operating lease liabilities in the consolidated balance sheet. Operating lease liabilities that become due within one year of the balance sheet date are classified as current operating lease liabilities.

For operating leases, lease expense relating to fixed payments is recognized on a straight-line basis over the lease term.

(m) Land use rights

All land in the PRC is owned by the PRC government. The PRC government may sell land use rights for a specified period of time. The purchase price of land use rights represents the operating lease prepayments for the rights to use the land in the PRC under ASC 842 and is recorded as land use rights on the balance sheet, which is amortized over the remaining lease term.

In 2019, the Group acquired land use rights from the local Bureau of Land and Resources in Suzhou for the purpose of constructing and operating the research center and biologics manufacturing facility in Suzhou. The land use rights are being amortized over the respective lease terms, which are 30 years.

(n) Long term deposits

Long term deposits represent amounts paid in connection with the Group's long-term lease agreements.

(o) Value added tax recoverable

Value added tax recoverable represent amounts paid by the Group for purchases. The amounts were recorded as long-term assets considering they are expected to be deducted from future value added tax payables arising on the Group's revenues which it expects to generate in the future.

(p) Intangible assets

Intangible assets mainly consist of externally purchased software which are amortized over one to five years on a straight-line basis. Amortization expenses for the years ended December 31, 2017, 2018 and 2019 were $2, $15 and $305, respectively. Amortization expenses of the Group's intangible assets are expected to be approximately $255, $255, $252, $240 and $146 for the years ended December 31, 2020, 2021, 2022, 2023, and 2024 and thereafter, respectively.

(q) Impairment of long-lived assets

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2017, 2018 and 2019, there was no impairment of the value of the Group's long-lived assets.

(r) Fair value measurements

The Group applies ASC Topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures* , in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 - Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Group primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities. As of December 31, 2018 and 2019, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximates its fair value based on the nature of the assessment of the ability to recover these amounts.

(s) Revenue recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued a comprehensive new standard which amends revenue recognition principles. In 2018, the Group adopted of ASC Topic 606 ("ASC 606"), *Revenue from Contracts with Customers,* in recognition of revenue . Under ASC 606, the Group recogn izes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Group determines are within the scope of ASC 606, the Group performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price , including variable consideration, if any ; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Group satisfies a performance obligation. The Group only applies the five-step model to contracts when it is probable that the Group will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Group reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Group recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

The Group's revenue is all from product sales. The Group recognizes revenue from product sales when the Group has satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the consumers. Cost of sales mainly consists of the purchase price of products and royalty fee.

The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Therefore the Group does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between the transfer of the promised good to the customer and receipt of payment will be one year or less.

The Group started to generate product sales revenue since year 2018. For the year ended December 31, 2019, the Group's product revenues were generated from the sale of ZEJULA (niraparib) and OPTUNE (Tumor Treating Fields) to customers, which are typically healthcare providers such as oncology centers. For the year ended December 31, 2018, the Group's product revenues were generated from the sale of ZEJULA (niraparib) to customers, which are typically healthcare providers such as oncology centers. The Group utilizes a distributor in Hong Kong for warehousing services. Based on the nature of the arrangement, the Group has determined that it is a principal in the transaction since the Group is primarily responsible for fulfilling the promise to provide the products to the customers, maintains inventory risk until delivery to the customers and has latitude in establishing the price. Revenue was recognized at the amount to which the Group expected to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the distributor is recognized in operating expenses.

(t) Research and development expenses

Elements of research and development expenses primarily include (1) payroll and other related costs of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to the Group, (3) costs related to pre-clinical testing of the Group’s technologies under development and clinical trials such as payments to contract research organizations (“CROs”) and contract manufacturing organizations ("CMOs"), investigators and clinical trial sites that conduct our clinical studies; (4) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group’s research and development services and have no alternative future uses.

The Group has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under US GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval which meet the capitalization criteria would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. The conditions enabling capitalization of development costs as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred .

(u) Deferred income

Deferred income consists of deferred income from government grants and American Depositary Receipts (the "ADR") Program Agreement with ADR depositary bank (the "DB") in July 2017.

Government grants consist of cash subsidies received by the Group's subsidiaries in the PRC from local governments. Grants received as incentives for conducting business in certain local districts with no performance obligation or other restriction as to the use are recognized when cash is received. Cash grants of $855, $1,332 and $2,151 were included in other income for the years ended December 31, 2017, 2018 and 2019, respectively. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Group may be required to refund the subsidy. Cash grants of $894 and $2,023 were recorded in deferred income as of December 31, 2018 and 2019 respectively, which will be recognized when the government specified performance obligation is satisfied.

According to the ADR program agreement, the Group has the right to receive reimbursements for using DB's services, subject to the compliance by the Group with the terms of the Agreement. The Group performed a detailed assessment of the requirements and recognizes the reimbursements it is expected to be entitled to over the five-year contract term as other income. For the years ended December 31, 2017, 2018 and 2019, $78, $312 and $312 were recorded in other income, respectively, and $1,170 and $858 were recorded in deferred income as of December 31, 2018 and 2019, respectively.

(v) Comprehensive loss

Comprehensive loss is defined as the changes in equity of the Group during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income* , requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Group's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

(w) Stock-based compensation

Awards Granted to Employees

The Group grants share options to eligible employees, management and directors and accounts for these share based awards in accordance with ASC 718, *Compensation-Stock Compensation.*

Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed.

The Group determined the fair value of the stock options granted to employees. Before 2018, the Group applied binomial option pricing model in determining the estimated fair value of the options granted to employees. In 2018, the Group changed to use the Black-Scholes option valuation model since the Group expected the Black-Scholes option valuation model provide a better estimate of fair value. A change in the valuation technique is a change in accounting estimate for the purposes of applying ASC 250, and shall be applied prospectively to new awards.

Awards Granted to Non-Employees

Prior to the adoption of Accounting Standard Update 2018-07 Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019,

The Group has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 505, Equity-Based Payments to Non-Employees. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if the Group had paid cash for the services provided by the non-employees in accordance with ASC 505.

After the adoption of Accounting Standard Update 2018-07 Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019,

The Group grants share options to eligible Non-Employees and accounts for these share based awards in accordance with ASC 718, *Compensation-Stock Compensation.* Non-Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. The Group determined the fair value of the stock options granted to Non-Employees using the Black-Scholes option valuation model.

(x) Income taxes

Income tax expense includes (a) deferred tax expense, which generally represents the net change in the deferred tax asset or liability balance during the year plus any change in valuation allowances; (b) current tax expense, which represents the amount of tax currently payable to or receivable from a taxing authority; and (c) non-current tax expense, which represents the increases and decreases in amounts related to uncertain tax positions from prior periods and not settled with cash or other tax attributes.

The Group recognizes deferred tax assets and liabilities for temporary differences between the financial statement and income tax bases of assets and liabilities, which are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Group evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes* , which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. It is the Group's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

(y) Earnings (loss) per share

Basic earnings (loss) per ordinary share is computed by dividing net income (loss) attributable to ordinary shareholders by weighted average number of ordinary shares outstanding during the period.

The Group's convertible preferred shares are participating securities as the preferred shares participate in undistributed earnings on an as-if-converted basis. Accordingly, the Group uses the two-class method whereby undistributed net income is allocated on a pro rata basis to each participating share to the extent that each class may share income for the period. Undistributed net loss is not allocated to preferred shares because they are not contractually obligated to participate in the loss allocated to the ordinary shares.

Diluted earnings (loss) per ordinary share reflects the potential dilution that could occur if securities were exercised or converted into ordinary shares. The Group had convertible preferred shares, warrants, stock options and non-vested restricted shares, which could potentially dilute basic earnings (loss) per share in the future. To calculate the number of shares for diluted earnings (loss) per share, the effect of the convertible redeemable preferred shares and warrants is computed using the as-if-converted method; the effect of the stock options and non-vested restricted shares is computed using the treasury stock method. The computation of diluted earnings (loss) per share does not assume exercise or conversion of securities that would have an anti-dilutive effect.

(z) Segment information

In accordance with ASC 280, *Segment Reportin* g, the Group's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment. The Group does not distinguish between markets or segments for the purpose of internal reporting. As the Group's long-lived assets are substantially located in and derived from China, no geographical segments are presented.

(aa) Concentration of risks

Concentration of customers

For the year ended December 31, 2019, around 80% of the Group's revenue was from one customer in Hong Kong. 100% of the accounts receivables of December 31, 2019 were from the distributor in Hong Kong.

Concentration of suppliers

The following suppliers accounted for 10% or more of research and development expenses and the inventory purchases for the years ended December 31, 2017, 2018 and 2019:

	Year ended December 31,		
	2017	2018	2019
	$	$	$
A	7,652	*	*
B	7,104	*	*
C	*	25,515	*
D	*	14,664	*
E	*	*	27,966
F	*	*	18,362

* Represents less than 10% of research and development expenses for the years ended December 31, 2017, 2018 and 2019.

Concentration of credit risk

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, short-term investments, and prepayments to suppliers. The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2018 and 2019, all of the Group's cash and cash equivalents and short-term investments were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which management believes are of high credit quality and continually monitors the credit worthiness of these financial institutions. With respect to the prepayments to suppliers, the Group performs on-going credit evaluations of the financial condition of these suppliers.

Foreign currency risk

Renminbi ("RMB") is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Group included aggregated amounts of RMB26,878 and RMB47,168, which were denominated in RMB, as of December 31, 2018 and 2019, respectively, representing 6% and 9% of the cash and cash equivalents as of December 31, 2018 and 2019, respectively.

(ab) Share consolidation ("reverse stock split")

On August 30, 2017, the Company effected a six-to-one share consolidation of all the ordinary shares and preferred shares. All number of shares, par value and per share amounts for all periods presented in these consolidated financial statements and accompanying notes have been adjusted retrospectively, where applicable, to reflect this share consolidation.

(ac) Recent accounting pronouncements

Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASC 842 which supersedes the lease recognition requirements in ASC 840, Leases, ("ASC 840"). The most prominent of the changes in ASC 842 is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases. Consistent with ASC 840, leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. In July 2018, the FASB issued an accounting standard update which amended ASC 842 and offered an additional (and optional) transition method by which entities could elect not to recast the comparative periods presented in financial statements in the period of adoption.

The Group adopted the new standard on January 1, 2019, using the optional adoption method whereby the Group did not adjust comparative period financial statements. Consequently, prior period balances and disclosures have not been restated. The Group elected the package of transition provisions available for expired or existing contracts, which allowed the Group to carry forward its historical assessments of (i) whether contracts are or contain leases, (ii) lease classification and (iii) initial direct costs. For leases in place upon adoption, the Group used the remaining lease term as of January 1, 2019 in determining the incremental borrowing rate ("IBR"). For the initial measurement of the lease liabilities for leases commencing on or after January 1, 2019, the IBR at the lease commencement date was applied.

The Group's lease portfolio consists entirely of operating leases, the adoption of ASU 2016-02 resulted in the initial recognition of ROU assets of $7,093 and related lease liabilities of $6,955 on the consolidated balance sheet at January 1, 2019. Upon adoption, the Group reclassified $138 prepaid rent to operating ROU assets. The Group's leases do not contain any material residual value guarantees or material restrictive covenants. Additionally, the adoption of ASU 2016-02 did not materially affect the consolidated statements of income or the consolidated statements of cash flows.

The impact on the consolidated balance sheet upon adoption of ASU 2016-02 was as follows:

	As of December 31, 2018	Effect of the option of ASU 2016-02	As of January 1, 2019
	As reported		As adjusted
	$	$	$
Assets:			
Prepayments and other current assets	5,749	(138)	5,611
Operating lease right-of-use assets	—	7,093	7,093
Liabilities:			
Current operating lease liabilities	—	(2,287)	(2,287)
Non-current operating lease liabilities	—	(4,668)	(4,668)

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The ASU expands the scope of Topic 718, Compensation—Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The Group adopted this ASU on January 1, 2019 using the modified retrospective method. The adoption of this new standard generally requires the accounting for equity-based payments to nonemployees to be consistent with the accounting for employees. As a result, the Group recognized the cost of services received from a nonemployee in exchange for an equity instrument based on the award's grant-date fair value. Unvested equity-based payments to nonemployees have been remeasured at fair value as of the adoption date. The adoption did not have a material effect on the consolidated financial statements.

Future Adoption of Accounting Standards

In June 2016, the FASB released ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)* : Measurement of Credit Losses on Financial Instruments. ASU 2016-13 replaces the existing impairment model for most financial assets from an incurred loss impairment model to a current expected credit loss model, which requires an entity to recognize an impairment allowance equal to its current estimate of all contractual cash flows the entity does not expect to collect. ASU 2016-13 also requires credit losses relating to AFS debt securities to be recognized through an allowance for credit losses. In April 2019, the FASB issued ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments Credit Losses, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825 Financial Instruments, the amendments of which clarify the modification of accounting for available for sale debt securities excluding applicable accrued interest, which must be individually assessed for credit losses when fair value is less than the amortized cost basis. In May 2019, the FASB issued ASU 2019-05, Financial Instruments— *Credit Losses* (Topic 326)— *Targeted Transition Relief* , which is the final version of Proposed Accounting Standards Update 2019-10— *Targeted Transition Relief* for Topic 326, Financial Instruments—Credit Losses, which has been deleted. This update provides entities with an option to irrevocably elect the fair value option applied on an instrument-by-instrument basis for certain financial assets upon the adoption of Topic 326. The fair value option election does not apply to held-to-maturity debt securities. An entity that elects the fair value option should subsequently apply the guidance in Subtopics 820-10, Fair Value Measurement-Overall, and 825-10. In December 2019, FASB issued ASU No. 2019-11, Codification Improvements to Topic 326, *Financial Instruments—Credit Losses* . This update introduced an expected credit loss model for the impairment of financial assets measured at amortized cost basis. In March 2020, the FASB issued ASU No. 2020-03, Codification Improvements to Financial Instruments. This update clarifies that the contractual term of a net investment in a lease determined in accordance with Topic 842 should be the contractual term used to measure expected credit losses under Topic 326. The standards are to be applied using a modified retrospective approach and are effective for interim periods and fiscal years beginning after December 15, 2019, with early adoption permitted. The Group does not anticipate the adoption of this ASU to have a material impact to its financial statements for its existing business.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)* : Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance must be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for interim periods and fiscal years beginning after December 15, 2019, with early adoption permitted. The Group does not expect the requirements of ASU 2018-13 will have a material impact on the consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)* : Clarifying the Interaction between Topic 808 and Topic 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The update is effective in fiscal years beginning after December 15, 2019, and interim periods therein, and early adoption is permitted for entities that have adopted ASC 606. This guidance should be applied retrospectively to the date of initial application of Topic 606. The Group is currently evaluating the impact on its financial statements of adopting this guidance

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, Income taxes, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group is currently evaluating the impact on its financial statements of adopting this guidance.

3. Cash and cash equivalents

	As of December 31,	
	2018	2019
	$	$
Cash at bank and in hand	36,778	75,111
Cash equivalents	26,174	821
	62,952	75,932
Denominated in:		
US$	58,254	62,478
RMB (note (i))	3,916	6,761
Hong Kong dollar (”HK$"□	20	5,948
Australia dollar ("A$")	762	745
	62,952	75,932

Note:

(i) Certain cash and bank balances denominated in RMB were deposited with banks in the PRC. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

4. Restricted cash, non-current

The Group's restricted cash balance of $510 as of December 31, 2019 was long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Group.

5. Short-term investments

Short-term investments primarily comprise of the time deposits with original maturities between three months and one year. For the years ended December 31, 2017, 2018 and 2019, the Group recorded the interest income of nil, $2,359 and $7,778 from the short-term investments in the consolidated statements of operations, respectively.

6. Inventories

The Group's inventory balance of $4 and $6,005 as of December 31, 2018 and 2019, respectively, consisted of finished goods purchased from Tesaro Inc. ("Tesaro") and Novocure Limited ("Novocure") for distribution in Hong Kong and Macau, and raw materials purchased for ZEJULA commercialization in PRC.

7. Investments in equity investees

In June 2017, the Group entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Group was RMB26,250 in cash, representing 20% of the equity interest of JING, which was fully paid by the Group in 2017 and 2018. The Group accounts for this investment using the equity method of accounting because the Group does not control the investee but has the ability to exercise significant influence over the operating and financial policies of the investee. The Group recorded its share of loss in this investee of $250, $587 and $752 for the years ended December 31, 2017, 2018 and 2019, respectively.

In October 2016, the Group invested $500 in a private company over which the Group does not have significant influence or control and accounted for the investment using cost method of accounting. In April 2017, the Group disposed its investment to Quan Venture Fund I, L.P. for cash consideration of approximately $500 and no gain/loss was recognized upon disposal (Note 15).

8. Property and equipment, net

Property and equipment consist of the following:

	As of December 31,	
	2018	2019
	$	$
Office equipment	384	397
Electronic equipment	599	1,482
Vehicle	77	76
Laboratory equipment	3,917	5,854
Manufacturing equipment	9,369	11,049
Leasehold improvements	4,608	7,528
Construction in progress	3,748	428
	22,702	26,814
Less: accumulated depreciation	(2,208)	(5,461)
Property and equipment, net	20,494	21,353

Depreciation expenses for the years ended December 31, 2017, 2018 and 2019 were $546, $1,634 and $3,372, respectively.

9. Lease

The Group leases facilities for office, research and development center, and manufacturing facilities in PRC, Hong Kong and U.S. Lease terms vary based on the nature of operations and the market dynamics, however, all leased facilities are classified as operating leases with remaining lease terms between one and six years.

The total lease expenses under operating leases which included the short-term lease expenses for the years ended December 31, 2017 and 2018 were $917 and $ 1,494 , respectively. Total lease expense related to short-term leases was insignificant for the year ended December 31, 2019.

Supplemental information related to leases was as follows:

	Year ended December 31, 2019
	$
Operating fixed lease cost	3,245

Supplemental cash flow information related to leases was as follows:

	Year ended December 31, 2019
	$
Cash paid for amounts included in measurement of lease liabilities	2,778
Noncash operating lease liabilities arising from obtaining operating right-of-use assets	10,876

The maturities of lease liabilities in accordance with *Leases (Topic 842)* in each of the next five years and thereafter as of December 31, 2019 were as follows:

	Year ended December 31
	$
2020	4,595
2021	3,910
2022	3,039
2023	1,333
2024	1,379
Thereafter	1,787
Total lease payments	16,043
Less: imputed interest	(715)
Present value of minimum operating lease payments	15,328

Weighted-average remaining lease terms and discount rates are as follows:

	Year ended December 31, 2019
Weighted-average remaining lease term	4.4 years
Weighted-average discount rate	3.1%

The undiscounted future minimum payments under non-cancelable operating leases as of December 31, 2018, prior to the adoption of the Lease ASUs was as follows:

	Year ended December 31 $
2019	2,169
2020	1,007
2021	164
2022 and thereafter	—
Total lease commitment	3,340

10. Income Tax

Cayman Islands ("Cayman")

Zai Lab Limited and ZLIP Holding Limited are incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, Zai Lab Limited and ZLIP Holding Limited are not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

British Virgin Islands Taxation ("BVI")

ZL Capital Limited is incorporated in the British Virgin Islands. Under the current laws of the British Virgin Islands, ZL Capital Limited is not subject to income tax.

Australia ("AUST")

Zai Lab (AUST) Pty., Ltd. is incorporated in Australia and is subject to corporate income tax at a rate of 30%. Zai Lab (AUST) Pty., Ltd. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

U.S. ("US")

Zai Lab (US) LLC. is incorporated in U.S. and is subject to U.S. federal corporate income tax at a rate of 21%. Zai Lab (US) LLC. is also subject to state income tax in Delaware. Zai Lab (US) LLC. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

Hong Kong ("HK")

Zai Lab (Hong Kong) Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with relevant Hong Kong tax laws. The applicable tax rate is 16.5% in Hong Kong. For the years ended December 31, 2017, 2018 and 2019, Zai Lab (Hong Kong) Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented. Under the Hong Kong tax law, Zai Lab (Hong Kong) Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

PRC

Under PRC's Enterprise Income Tax Law ("EIT Law"), the statutory income tax rate is 25%, and the EIT rate shall be reduced to 15% for state-encouraged High and New Technology Enterprises ("HNTE"). Zai Lab (Shanghai) Co., Ltd., first obtained a HNTE certificate in 2018 and began to enjoy the preferential tax rate of 15% from 2018 to 2020. Zai Lab International Trading (Shanghai) Co., Ltd., Zai Lab (Suzhou) Co., Ltd., and Zai Biopharmaceutical (Suzhou) Co., Ltd. are subject to the statutory rate of 25%.

No provision for income taxes has been required to be accrued because the Company and all of its subsidiaries are in cumulative loss positions for all the periods presented.

Loss before income taxes consists of:

	Year ended December 31,		
	2017	2018	2019
	$	$	$
Cayman	3,887	1,218	(3,241)
BVI	8	2	2
PRC	40,972	127,711	185,239
HK	6,240	7,778	3,271
US	—	2,351	9,786
AUST	(723)	15	14
	50,384	139,075	195,071

Reconciliations of the differences between the PRC statutory income tax rate and the Group's effective income tax rate for the years ended December 31, 2017, 2018 and 2019 are as follows:

	Year ended December 31,		
	2017	2018	2019
Statutory income tax rate	25%	25%	25%
Share-based compensations	(3.27%)	(1.93%)	(1.51%)
Non-deductible expenses	(0.79%)	(0.38%)	(0.39%)
Prior year tax filing adjustment	—	1.55%	1.93%
Effect of different tax rate of subsidiary operation in other jurisdictions	(3.06%)	(0.76%)	0.07%
Preferential tax rate	—	—	(9.14%)
Effect of change in tax rate	—	—	(9.15%)
Changes in valuation allowance	(17.88%)	(23.48%)	(6.81%)
Effective income tax rate	—	—	—

The principal components of the deferred tax assets and liabilities are as follows:

	Year ended December 31,		
	2017	2018	2019
	$	$	$
Deferred tax assets:			
Depreciation of property and equipment, net	6	15	57
Government grants	188	187	325
Net operating loss forwards	17,075	49,726	62,833
Less: valuation allowance	(17,269)	(49,928)	(63,215)
Deferred tax assets, net	—	—	—

The Group considers positive and negative evidence to determine whether some portion or all of the deferred tax assets will be more likely than not realized. This assessment considers, among other matters, the nature, frequency and severity of recent losses and forecasts of future profitability. These assumptions require significant judgment and the forecasts of future taxable income are consistent with the plans and estimates the Group is using to manage the underlying businesses. Valuation allowances are established for deferred tax assets based on a more likely than not threshold. The Group's ability to realize deferred tax assets depends on its ability to generate sufficient taxable income within the carry forward periods provided for in the tax law. In 2018 and 2019, the Group has determined that the deferred tax assets on temporary differences and net operating loss carry forwards are related to certain subsidiaries, for which the Group is not able to conclude that the future realization of those net operating loss carry forwards and other deferred tax assets are more likely than

not. As such, it has fully provided valuation allowance for the deferred tax assets as of December 31, 2018 and 2019. Amounts of operating loss carry forwards were $ 72,137 , $ 204,693 and $ 403,460 for the years ended December 31, 2017, 2018 and 2019, respectively, which are expected to expire from 20 20 to 2029 .

Movement of the valuation allowance is as follows:

	2018	2019
	$	$
Balance as of January 1,	(17,269)	(49,928)
Additions	(32,659)	(13,287)
Balance as of December 31,	(49,928)	(63,215)

Uncertainties exist with respect to how the current income tax law in the PRC applies to the Group's overall operations, and more specifically, with regard to tax residency status. The EIT Law includes a provision specifying that legal entities organized outside of the PRC will be considered residents for Chinese income tax purposes if the place of effective management or control is within the PRC. The implementation rules to the EIT Law provide that non-resident legal entities will be considered PRC residents if substantial and overall management and control over the manufacturing and business operations, personnel, accounting and properties, occurs within the PRC. Despite the present uncertainties resulting from the limited PRC tax guidance on the issue, the Group does not believe that the legal entities organized outside of the PRC within the Group should be treated as residents for EIT Law purposes. If the PRC tax authorities subsequently determine that the Company and its subsidiaries registered outside the PRC should be deemed resident enterprises, the Company and its subsidiaries registered outside the PRC will be subject to the PRC income taxes, at a rate of 25%. The Group is not subject to any other uncertain tax position.

11. Short-term borrowings

On June 25, 2018, Zai Lab (Suzhou) Co. Ltd. entered into a three-year facility agreement for RMB25,000 with a local commercial bank, and the outstanding borrowing under this agreement was RMB25,000 as of December 31, 2019, which will be due in 2020. The borrowing is guaranteed by Zai Lab (Shanghai) Co. Ltd., with an average interest rate of 4.785%. The agreement does not contain any financial covenants or restrictions. For the year ended December 31, 2019, Zai Lab (Suzhou) Co. Ltd. drawn down RMB30,000 of this loan and repaid the outstanding principal of RMB 25,000. For the year ended December 31, 2018, Zai Lab (Suzhou) Co. Ltd. drawn down RMB20,000 of this loan.

On December 12, 2018, Zai Biopharmaceutical (Suzhou) Co. Ltd. entered into a three-year facility agreement for RMB40,000 with a local commercial bank, the outstanding borrowing under this agreement was RMB20,000 as of December 31, 2019, which will be due in 2020. The borrowing is guaranteed by Zai Lab (Shanghai) Co., Ltd., with average interest rate of 4.785%. The agreement does not contain any financial covenants or restrictions. For the year ended December 31, 2019, Zai Biopharmaceutical (Suzhou) Co. Ltd. drawn down RMB20,000 of this loan and repaid the outstanding principal of RMB5,000. For the year ended December 31, 2018, Zai Biopharmaceutical (Suzhou) Co. Ltd. drawn down RMB5,000 of this loan.

12. Other current liabilities

Other current liabilities consist of followings:

	As of December 31,	
	2018	2019
	$	$
Payroll	3,699	9,590
Professional service fee	1,564	774
Payables for purchase of property and equipment	1,709	416
Payables for purchase of intangible assets	225	—
Others	570	2,394
Total	7,767	13,174

13. Convertible preferred shares and warrants

Upon the completion of the Company's IPO on September 20, 2017, all of the outstanding Series A1, A2, B1, B2 and C convertible preferred shares were converted into 28,905,083 ordinary shares. The history of the issuance of the preferred shares is as following:

In August 2014 and April 2015, the Company issued 6,244,443 Series A1 convertible preferred shares ("Series A1 Preferred Shares") and 8,442,221 Series A2 convertible preferred shares ("Series A2 Preferred Shares") with a par value $0.00006 per share to a group of investors for a cash consideration of $8,029 or $1.2857 per share and $18,279 or $2.1651 per share, respectively. In August 2014, $2,000 in convertible loans issued in March and April of 2014 to certain investors who purchased Series A1 Preferred Shares were converted into 2,222,222 Series A1 Preferred Shares in connection with the offering at a per share price of $0.90.

On December 31, 2015, as an inducement to participate in the contemplated issuance of Series B1 Preferred Shares and Series B2 Preferred Shares, the Company entered into an agreement with one investor to issue warrants to purchase up to 461,808 Series A2 Preferred Shares at $2.1651 per share, as adjusted from time to time pursuant to the agreement. The fair value of the warrants of $1,980 was expensed on the date of issuance (as opposed to being treated as a cost of equity issuance because the warrants would have become exercisable after the passage of time in the absence of an equity offering).

In January and April 2016, the Company issued 5,562,335 Series B1 convertible preferred shares ("Series B1 Preferred Shares") and 3,973,096 Series B2 convertible preferred shares ("Series B2 Preferred Shares") with a par value of $0.00006 per share to a group of investors including existing preferred share investors for a cash consideration of $53,100 or $9.5464 per share and $53,100 or $13.3649 per share, respectively.

In June 2017, the Company issued 1,998,958 Series C convertible redeemable preferred shares ("Series C Preferred Shares") with a par value of $ 0.00006 per share to a group of investors including existing preferred share investors for a cash consideration of $30,000 or $15.0078 per share.

On July 19, 2017, the investor holding the warrants exercised the warrants to purchase 461,808 Series A2 Preferred Shares at $2.1651 per share.

The key terms of the warrants were as follows:

Vesting date

The warrants were vested on April 1, 2016.

Exercise period

If not previously exercised, the warrants shall expire on the earlier of (1) the sixth (6th) anniversary of the issue date or (2) ninety (90) days prior to the date on which the Company consummates a QIPO.

The Company has classified the Series A1, A2, B1 , B2 and C Preferred Shares as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event outside of the Company's control (i.e. a liquidation event or failure to complete the QIPO within required period). The holders of the Series A1, A2, B1 , B2 and C Preferred Shares have a liquidation preference and will not receive the same form of consideration upon the occurrence of the conditional event as the ordinary shareholders would. The holders of the Series A1, A2, B1 , B2 and C Preferred Shares have the ability to convert the instrument into the Company's ordinary shares. The conversion option of the convertible preferred shares did not qualify for bifurcation accounting because the conversion option was clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily convertible into cash.

The Company has determined that there was no beneficial conversion feature ("BCF") attributable to the Series A1, A2, B1, B2 and C Preferred Shares, as the effective conversion price was greater than the fair value of the ordinary shares on the respective commitment date.

The Company concluded that redemption of that the Series A1, A2, B1, B2 and C Preferred Shares was not probable due to the remote likelihood of a liquidation event and the expected successful QIPO within five years. Therefore, no adjustment was made to the initial carrying amount of the Series A1, A2, B1, B2 and C Preferred Shares.

The warrants are freestanding instruments and are recorded as liabilities in accordance with ASC480. The Series A1, A2, B1, B2 and C Preferred Shares were initially recorded as mezzanine equity equal to the proceeds received. The warrants are initially recognized at fair value, with subsequent changes in fair value recorded in gain or loss. For the year ended December 31, 2017, the Company recognized a gain from the decrease in fair value of the warrants of $200.

14. Loss per share

Basic and diluted net loss per share for each of the years presented are calculated as follow:

	For the years ended December 31,		
	2017	2018	2019
Numerator:			
Net loss attributable to ordinary shareholders	(50,384)	(139,075)	(195,071)
Denominator:			
Weighted average number of ordinary shares-basic and diluted	21,752,757	52,609,810	64,369,490
Net loss per share-basic and diluted	(2.32)	(2.64)	(3.03)

The Group has determined that its convertible preferred shares are participating securities as the preferred shares participate in undistributed earnings on an as-if-converted basis. The holders of the preferred shares are entitled to receive dividends on a pro rata basis, as if their shares had been converted into ordinary shares. Accordingly, the Group used the two-class method of computing earnings per share, for ordinary and preferred shares according to participation rights in undistributed earnings, However, undistributed net loss is only allocated to ordinary shareholders because holders of preferred shares were not contractually obligated to share losses.

As a result of the Group's net loss for the three years ended December 31, 2017, 2018 and 2019, preferred shares, share options, non-vested restricted shares and warrants outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	As of December 31,		
	2017	2018	2019
Share options	6,548,377	8,761,735	9,122,980
Non-vested restricted shares	693,333	1,112,001	743,268

15. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of December 31, 2019:

Company Name	Relationship with the Group
Quan Venture Fund I, L.P.	Significantly influenced by Samantha Du, founder, chairman and CEO of the Company
MEDx (Suzhou) Translational Medicine Co., Ltd. (Formerly known as Qiagen (Suzhou) Translational Medicine Co., Ltd)	Significant influence held by Samantha Du's immediate family

In 2018 and 2019, the Group incurred $126 and $234 research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for drug research and development services.

On April 30, 2017, the Group disposed its investment in a cost method investee to Quan Venture Fund I, L.P. for a cash consideration of $500 and no gain/loss was recognized upon disposal.

16. Share-based compensation

Share options

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan") which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group ("Option Pool").

In May 2017, the Group granted 158,313 share options to certain management and employees of the Group at an exercise price of $3.0 per share under the 2015 Plan. These options granted have a contractual term of 10 years and generally vest over a four or five year period, with 25% or 20% of the awards vesting on each annual anniversary after the grant date.

In May 2017, the Group granted 4,583 share options to certain individual advisors of the Group at an exercise price of $3.0 per share. These options granted have a contractual term of 10 years and generally vest over a three year period, with 33.33% of the awards vesting anniversary year after the grant date.

In connection with the completion of the IPO, the Board of Directors has approved the 2017 Equity Incentive Plan (the "2017 Plan") and all equity-based awards subsequent to the IPO would be granted under the 2017 Plan.

In September 2017, the Group granted 101,584 share options to certain management and employees of the Group at an exercise price of $18.0 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

In 2018, the Group granted 2,759,750 share options to certain management and employees of the Group at the exercise price ranging from $17.60 to $24.58 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

In 2019, the Group granted 1,067,385 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from $27.23 to $41.59 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

Before 2018, the binomial option-pricing model was applied in determining the estimated fair value of the options granted. The model requires the input of highly subjective assumptions including the estimated expected stock price volatility and, the exercise multiple for which employees are likely to exercise share options. For expected volatilities, the Group has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Group. For the exercise multiple, prior to the IPO, the Group had no historical exercise patterns as a reference, thus the exercise multiple was based on management's estimation, which the Group believes is representative of the future exercise pattern of the options. The risk-free rate for periods within the contractual life of the option is based on the U.S. treasury bonds with maturity similar to the maturity of the options as of valuation dates plus a China country risk premium. Prior to the completion of the Company's IPO, the estimated fair value of the ordinary shares, at the option grant dates, was determined with assistance from an independent third-party valuation firm. The Group's management is ultimately responsible for the determination of the estimated fair value of its ordinary shares. With the completion of the Company's IPO, a public trading market for the ADSs has been established, the Company uses the current share price as the fair value of underlying ordinary shares.

From 2018, the Group changed to use the Black-Scholes option valuation model going forward in determining the estimated fair value of the options granted, because the new technique or model is expected to produce a better estimate of fair value. The change in valuation technique is accounted for as a change in accounting estimate under ASC 250 and applied prospectively to new awards.

The following table presents the assumptions used to estimate the fair values of the share options granted in the years presented:

	May 2017	September 2017	2018	2019
Risk-free rate of return	3.2%	3.5%	2.7%-3.2%	1.6%-2.5%
Contractual life of option	10 years	10 years	10 years	10 years
Expected term	n/a	n/a	6.5 years	6 or 6.5 years
Estimated volatility rate	70%	70%	70%	70%
Expected dividend yield	0%	0%	0%	0%
Fair value of underlying ordinary shares	9.60	27.93	17.60-24.58	27.23-41.59

A summary of option activity under the Plan during the years ended December 31, 2017, 2018 and 2019 is presented below:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
		$	Years	$
Outstanding at January 1, 2017	7,228,141	0.97	9.00	53,677,170
Granted	264,480	8.76	—	—
Exercised	(100,834)	0.65	—	—
Forfeited	(843,410)	1.11	—	—
Outstanding at December 31, 2017	6,548,377	1.28	8.06	130,668,851
Granted	2,759,750	21.15	—	—
Exercised	(256,065)	0.76	—	—
Forfeited	(290,327)	3.73	—	—
Outstanding at December 31, 2018	8,761,735	7.47	7.80	138,009,758
Granted	1,067,385	32.22	—	—
Exercised	(670,939)	1.57	—	—
Forfeited	(35,201)	25.99	—	—
Outstanding at December 31, 2019	9,122,980	10.73	7.16	281,562,301
Vested and Exercisable as of December 31, 2019	4,379,511	3.51	6.25	166,772,005
Vested or expected to vest as of December 31, 2019	9,122,980	10.73	7.16	281,562,301

The weighted-average grant-date fair value of the options granted in 2017, 2018 and 2019 were $13.92, $14.03 and $20.98 per share, respectively. The Group recorded compensation expense related to the options of $4,752, $9,403 and $14,925 for the years ended December 31, 2017, 2018 and 2019, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	Year ended December 31,		
	2017	2018	2019
	$	$	$
Selling, general and administrative	2,215	4,428	6,931
Research and development	2,537	4,975	7,994
Total	4,752	9,403	14,925

As of December 31, 2019, there was $52,921 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 2.13 years.

Ordinary shares issued to Red Kingdom Investment Limited ("Red Kingdom")

Red Kingdom is a company incorporated in the British Virgin Islands in August 2013 and owned by a group of senior management including the Chief Executive Officer (the "CEO") of the Company and advisors of the Group and third-party investors. Red Kingdom has no activities and does not have employees. All the shareholders of the Red Kingdom have delegated their voting rights to the CEO of the Company.

On April 3, 2014, the Company issued 8,083,333 shares to Red Kingdom which are corresponding to the total outstanding shares of Red Kingdom for total consideration of $142. One share of Red Kingdom is entitled to indirectly all of the economic rights associated with the underlying ordinary shares of the Company. Of these shares, 7,847,500 shares were held by members of senior management and certain advisors of the Group, who paid par value.

In April and May 2014, Red Kingdom entered into restricted share arrangements with the members of senior management and one of the advisors of the Group to secure their services, pursuant to which all of their 6,459,167 and 350,000 ordinary shares of the Red Kingdom respectively became subject to transfer restrictions (the "Restricted Shares" and the "Advisor Restricted Shares"). The 1,038,333 shares the Company issued to Red Kingdom corresponded to the shares of Red Kingdom held by advisors of the Group, purchased for par value in 2014 are not subject to the transfer restrictions or other repurchase rights, and so were considered vested immediately at the date of grant and expensed.

On December 15, 2015, 1,921,000 unvested Restricted Shares granted to the CEO were deemed vested by the Company and the unrecognized share-based compensation of $1,152 as of the modification date was immediately recognized as compensation expense in the consolidated statements of operations.

On June 15, 2017, pursuant to the Board's resolution, Red Kingdom distributed all of the ordinary shares that it held in the Group to all Red Kingdom shareholders, in accordance with the Articles of Association of Red Kingdom. All the prior restricted share arrangements in force as of the distribution date between Red Kingdom and members of senior management and advisors were amended to assign the rights and obligations of Red Kingdom thereunder to the Group (the "Transfer"). Before the Transfer, 811,667 restricted shares of Red Kingdom had been vested and 1,329,999 non-vested restricted shares of Red Kingdom have been repurchased by Red Kingdom due to the termination of employment by certain members of senior management and allocated to the founders of Red Kingdom at par value in 2017.

Non-vested restricted shares

In March and May 2017, pursuant to the board resolution of the Company, the Repurchase Right to all the remaining 2,100,000 non-vested restricted shares of the CEO which were subject to the restricted share arrangement dated April 3, 2014 was removed and the unrecognized share-based compensation of $840 as of the modification date was immediately recognized as an expense in the consolidated statements of operations.

In September 2017, pursuant to the successful IPO of the Company, the Repurchase Right to all the remaining 134,516 non-vested restricted shares of the individual advisor which were subject to the restricted share arrangement dated August 10, 2015, July 15, 2016 and August 25, 2016 was terminated and the unrecognized share-based compensation of $2,421 as of the modification date was immediately recognized as an expense in the consolidated statements of operations.

On September 20, 2017, 50,000 ordinary shares were authorized for grant to the independent directors. One third of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2018, 62,500 ordinary shares were authorized for grant to the independent directors, respectively. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2018, 694,500 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2019, 50,000 ordinary shares were authorized for grant to the independent directors, respectively. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited.

In 2019, 121,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited .

The Group measured the fair value of the non-vested restricted shares as of respective grant dates, and recognized the amount as compensation expense over the deemed service period using a graded vesting attribution model on a straight-line basis.

The following table summarized the Group's non-vested restricted share activity in 2019:

	Numbers of non-vested restricted shares	Weighted average grant date fair value
		$
Non-vested as of January 1, 2018	693,333	2.57
Granted	757,000	20.73
Vested	(338,332)	1.95
Non-vested as of December 31, 2018	1,112,001	15.13
Granted	171,000	27.55
Vested	(539,733)	8.97
Non-vested as of December 31, 2019	743,268	22.45

As of December 31, 2019, there was $13,730 of total unrecognized compensation expense related to non-vested restricted shares. The Group recorded compensation expense related to the restricted shares of $5,179, $2,826 and $5,366 for the years ended December 31, 2017, 2018 and 2019, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	Year ended December 31,		
	2017	2018	2019
	$	$	$
Selling, general and administrative	3,848	2,206	3,643
Research and development	1,331	620	1,723
Total	5,179	2,826	5,366

17. Accumulated other comprehensive (loss) income

The movement of accumulated other comprehensive (loss) income is as follows:

	Foreign currency translation adjustments
	$
Balance as of January 1, 2017	(698)
Other comprehensive income	1,148
Balance as of December 31, 2017	450
Other comprehensive income	2,212
Balance as of December 31, 2018	2,662
Other comprehensive income	1,958
Balance as of December 31, 2019	4,620

18. Licenses and collaborative arrangement

The following is a description of the Group's significant collaboration agreements for the years ended December 31, 2017, 2018 and 2019.

License and collaboration agreement with Tesaro

In September 2016, the Group entered into a collaboration, development and license agreement with Tesaro, under which the Group obtained an exclusive license for certain patents and know-how that Tesaro licensed from Merck, Sharp & Dohme Corp. (a subsidiary of Merck & Co. Inc.), or Merck Corp., and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize Tesaro's proprietary PARP inhibitor, niraparib, in mainland China, Hong Kong and Macau, or the licensed territory, in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). Tesaro has the option to elect to co-promote the licensed products in the Group's licensed territory.

Under the terms of the agreement, the Group made an upfront payment of $15,000 to Tesaro which was recorded as a research and development expense in 2016. If the Group successfully develops and commercializes the licensed products, the Group will make a milestone payment to Tesaro for the achievement of a certain development milestone event. In addition, if Tesaro does not exercise its co-promotion option, the Group will pay Tesaro milestone payments for the achievement of certain sales milestone events, and also tiered royalties at certain percentages of net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

On December 27, 2019, the China National Medical Products Administration (NMPA) approved the New Drug Application (NDA) for ZEJULA (niraparib). The Group achieved the milestone related to its collaboration agreement with Tesaro for regulatory approval for the first indication by NMPA and a milestone payment was payable to Tesaro according to the agreement.

License and collaboration agreement with Paratek Bermuda Ltd. ("Paratek")

In April 2017, the Group entered into a collaboration, development and license agreement with Paratek, under which the Group obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, use, sell, import and commercialize omadacycline in mainland China, Hong Kong, Macau and Taiwan, or licensed territory, in the field of all human therapeutic and preventative uses other than biodefense, or the licensed field. Paratek retains the right to manufacture the licensed product in the licensed territory for use outside the licensed territory. The Group also granted to Paratek a non-exclusive license to certain of intellectual property for Paratek Bermuda Ltd.

Under the terms of the agreement, the Group made an upfront payment of $7,500 to Paratek which was recorded as a research and development expense in 2017. The Group made a milestone payment to Paratek for the achievement of milestone upon receipt of the first regulatory approval for the Product in the U.S. in 2018 according to the agreement. The Group will make further milestone payments to Paratek for the achievement of certain development milestone and sales milestone event. In addition, the Group will pay to Paratek tiered royalties at certain percentage rates on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group has the right to terminate this agreement for any or no reason by providing Paratek with prior written notice with no penalty.

License and collaboration agreement with Five Prime Therapeutics, Inc. ("Five Prime")

On December 19, 2017, the Group and Five Prime entered into an exclusive license agreement for FPA144 in China, Hong Kong, Macau and Taiwan and global strategic development collaboration.

Under the terms of the agreement, Five Prime has granted the Group an exclusive license to develop and commercialize FPA144 in the China, Hong Kong, Macau and Taiwan territory: China, Hong Kong, Macau, and Taiwan. The Group will be responsible for conducting the Phase III FIGHT trial in China, Hong Kong, Macau and Taiwan, including screening, enrolment and treatment of patients, and for commercialization of FPA144 in the China, Hong Kong, Macau and Taiwan territory. Five Prime will manufacture and supply FPA144 for the study. A Joint Steering Committee will be formed between the companies to oversee development, regulatory and commercialization activities in China, Hong Kong, Macau and Taiwan.

The Group made an upfront payment of $5,000 in January 2018, and made a milestone payment to Five Prime for the achievement of a milestone by enrolling the first patient in Phase III FIGHT trail of the Product in China in October 2018 according to the agreement. The Group will make further milestone payments for the achievement of certain development and regulatory milestones to Five Prime. In addition, the Group will pay to Five Prime a royalty percentage on net sales of FPA144 in China, Hong Kong, Macau and Taiwan. And the Group is also eligible to receive a royalty from Five Prime on net sales of FPA144 outside of China, Hong Kong, Macau and Taiwan.

License and collaboration agreement with Entasis Therapeutics Holdings Inc.("Entasis")

On April 25, 2018, the Group entered into an exclusive license agreement with Entasis, under which the Group obtained an exclusive right to develop and commercialize Entasis's broad-spectrum intravenous inhibitor of β-lactamases or ETX2514 in the Asia-Pacific region for the treatment of a variety of serious multidrug-resistant infections caused by Acinetobacter baumannii.

The Group paid $5,000 upfront fees to Entasis upon entering the agreement in 2018, and paid two milestone payments to Entasis in November 2019 for the achievements of first patient dosed in pivotal study and first patient dosed in a registration study for the lead product in China according to the agreement. The Group will make future milestone payments upon the achievement of contractually specified development, regulatory and sales milestones, plus royalties.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Entasis.

License and collaboration agreement with Crescendo Biologics Ltd. ("Crescendo")

On May 25, 2018, the Group and Crescendo entered into an exclusive, worldwide licensing agreement, under which the Group will develop, commercialize, and manufacture a topical, innovative antibody VH domain therapeutic for potential application in inflammatory indications.

Under the terms of the agreement, Crescendo granted to the group a worldwide exclusive license to develop and commercialize its drug candidate for all indications. The Group will be responsible for conducting all regulatory filings, clinical studies, and commercialization activities, with both companies participating in a Joint Development Committee.

The Group paid $2,000 upfront fees to Crescendo in 2018. And the Group will provide development, regulatory, and commercial milestones for multiple indications. Crescendo will also be eligible to receive tiered royalties on global sales.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Crescendo.

License and collaboration agreement with Novocure Limited ("Novocure")

On September 10, 2018, the Group entered into an exclusive license agreement with Novocure for Tumor Treating Fields, including the brand name Optune in China, Hong Kong, Macau and Taiwan and a global strategic development collaboration.

Under the terms of agreement, Novocure granted the Group an exclusive license to commercialize Tumor Treating Fields in China, Hong Kong, Macau and Taiwan. The Group will be responsible for regulatory submissions in Greater China and will work to establish Tumor Treating Fields as an oncology treatment in this territory.

The Group paid $15,000 upfront fees to Novocure in 2018 and will make future milestone payments upon the achievement of contractually certain development, regulatory and commercial milestones. Novocure will also be eligible to receive a royalty on net sales of the licensed products in China, Hong Kong, Macau and Taiwan.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Novocure.

License and collaboration agreement with MacroGenics Inc. ("MacroGenics")

On November 29, 2018, the Group entered into an exclusive collaboration and license agreement with MarcroGenics to develop and commercialize Margetuximab, MGD013 and TRIDENT™ Molecule in Greater China.

Under the terms of agreement, MacroGenics granted the Group regional development and commercialization rights for these programs in mainland China, Hong Kong, Macau and Taiwan. The Group will lead clinical development in its territory by leveraging its regulatory and clinical development expertise and broad regional network of investigators. As part of the collaborative clinical development effort, the Group and MacroGenics intend to initiate a global study using combination regimens containing margetuximab in order to maximize potential clinical benefit in gastric cancer, the fifth most common cancer in the world and the second most common in China.

The Group paid upfront fee of $25,000 to MacroGenics in January 2019, and will make future milestone payments upon the achievement of potential development and regulatory-based milestones. In addition, the Group would pay MacroGenics royalties on annual net sales of the assets, which may be subject to adjustment in specified circumstances.

The Group has the right to terminate this agreement at any time by providing written notice of termination to MacroGenics.

License and collaboration agreement with Deciphera Pharmaceuticals, LLC ("Deciphera")

On June 10, 2019, the Group entered into an exclusive collaboration and license agreement with Deciphera to advance the development and commercialization of ripretinib in China, Hong Kong, Macau and Taiwan. Discovered and developed by Deciphera, ripretinib is an investigational, oral, kinase switch control inhibitor in clinical development for the treatment of GIST and other solid tumors driven by KIT or PDGFRα.

Under the terms of the agreement, Deciphera granted the Group exclusive regional development and commercialization rights for ripretinib in China, Hong Kong, Macau and Taiwan.

The Group paid upfront fee of $20,000 to Deciphera in July 2019, and paid a milestone payment to Deciphera in September 2019 for the achievements of the completion of enrollment and dosing with the licensed product of thirty patients in the INTRIGUE Study according to the agreement. The Group will make future milestone upon the achievement in potential development and commercial milestones. In addition, the Group would pay Deciphera royalties on annual net sales of ripretinib in China, Hong Kong, Macau and Taiwan.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Deciphera.

License and collaboration agreement with Incyte Corporation ("Incyte")

On July 1, 2019, the Group entered into an exclusive collaboration and license agreement with Incyte for the development and commercialization of INCMGA0012, an investigational anti-PD-1 monoclonal antibody, in China, Hong Kong, Macau and Taiwan.

Under the terms of agreement, Incyte granted the Group the rights to develop and exclusively commercialize INCMGA0012 in hematology and oncology in mainland China, Hong Kong, Macau and Taiwan. Incyte will retain an option to assist in the promotion of INCMGA0012 in the Group's licensed territories.

The Group paid upfront fee of $17,500 to Incyte in September 2019, and will make future milestone payments upon achievement of potential development, regulatory and commercial milestones, as well as tiered royalties, with Incyte responsible for all royalties and pass-through payments to its licensing partner, MacroGenics.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Incyte.

As noted above, the Group has entered into various license and collaboration agreements with third party licensors to develop and commercialize drug candidates. Based on the terms of these agreements the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management's evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Group up to an aggregate of approximately $1,394,547 in future milestone payments upon the achievement of contractually specified development milestones, such as regulatory approval for the drug candidates, which may be before the Group has commercialized the drug or received any revenue from sales of such drug candidate, which may never occur.

19. Restricted net assets

The Group's ability to pay dividends may depend on the Group receiving distributions of funds from its PRC subsidiary. Relevant PRC statutory laws and regulations permit payments of dividends by the Group's PRC subsidiary only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Group's PRC subsidiary.

In accordance with the Company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group's PRC subsidiary was established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2017, 2018 and 2019, no appropriation to statutory reserves was made because the PRC subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Group's PRC subsidiary is restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulation in the PRC may further restrict the Group's PRC subsidiary from transferring funds to the Group in the form of dividends, loans and advances. As of December 31, 2018 and 2019, amounts restricted are the paid-in capital of the Group's PRC subsidiaries, which amounted to $90,952 and $155,858, respectively.

20. Employee defined contribution plan

Full time employees of the Group in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that the Group's PRC subsidiary make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Group has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were $579, $1,425 and $5,406 for the years ended December 31, 2017, 2018 and 2019, respectively.

21. Commitments and Contingencies

(a) Purchase commitments

As of December 31, 2019, the Group's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statement was $692 which is expected to be incurred within one year.

(b) Contingencies

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 18).

22 . Subsequent events

In January 2020, the Company closed an underwritten public offering of 5,500,000 American depositary shares ("ADSs") at a price of $47.50 per ADS. In addition, the underwriters fully exercised their option to purchase an additional 800,000 ADSs at the public offering price. Total proceeds, net of underwriting fees and offering expenses, were $280,568.

From January to April 2019, the Company granted 842,500 share options to certain management and employees of the Group at the exercise price from $44.94 to $51.48 per share under the 2017 Plan with a vesting period of 20% of the awards vesting on the anniversary date one year after the grant date.

From January to April 2019, 50,000 ordinary shares were authorized for grant to independent directors of the Group. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement. 12,000 ordinary shares were authorized for grant to certain management and employees of the Company. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary of the date of the agreement.

In March 2020, the Group entered into an Exclusive Promotion Agreement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd, or Hanhui. Under the terms of the agreement, the Company will leverage Hanhui's existing infrastructure to optimize an anticipated future commercial launch of omadacycline in China given that omadacycline is a broad spectrum antibiotic in both the hospital and community setting. In consideration for the exclusive partner grant to the Hanhui for the territory, Hanhui paid the Group a non-creditable, up-front payment of RMB90,000 in April 2020.

In April 2020, the Group entered into a Collaboration Agreement with a wholly-owned subsidiary of Regeneron Pharmaceuticals, Inc., or Regeneron. Under the terms of the agreement, Regeneron will receive a $30,000 upfront payment and is eligible to receive up to $160,000 in additional regulatory and sales milestones. The Group will contribute to the global development costs for REGN1979 for certain trials and will receive the rights to develop and exclusively commercialize REGN1979 in oncology in mainland China, Hong Kong, Taiwan and Macau. Additionally, the Group will make payments to Regeneron based on net sales, such that Regeneron shares in a significant portion of any potential profits. Regeneron will be responsible for the manufacture and supply of REGN1979 for development and commercialization in the region.

Beginning in January 2020, the outbreak of COVID-19 created business interruptions for companies in China including the Group. For example in the biopharma sector, patients were having difficulties accessing hospitals resulting in fewer opportunities for patients to receive health care services and treatment. The COVID-19 outbreak has been largely contained in China as of April 2020 and the Group do es not appear to have been materially impacted; however, outbreaks may occur again which could cause business disruptions in the future.

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed balance sheets

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	As of December 31,	
	2018	2019
	$	$
Assets		
Current assets:		
Cash and cash equivalents	746	55,442
Short-term investment	200,350	200,000
Prepayments and other current assets	2,912	4,179
Total current assets	204,008	259,621
Investment in subsidiaries	48,748	36,504
Total assets	**252,756**	**296,125**
Liabilities and shareholders' deficits		
Liabilities		
Current liabilities:		
Other current liabilities	505	607
Total current liabilities	505	607
Deferred income	1,170	858
Total liabilities	**1,675**	**1,465**
Shareholders' equity		
Ordinary shares (par value of US $0.00006 per share; 83,333,333 shares authorized, 58,006,967 and 68,237,247 shares outstanding as of December 31, 2018 and 2019, respectively)	3	4
Additional paid-in capital	498,043	734,734
Accumulated deficit	(249,627)	(444,698)
Additional other comprehensive income	2,662	4,620
Total shareholders' equity	**251,081**	**294,660**
Total liabilities and shareholders' equity	**252,756**	**296,125**

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed statements of operations and comprehensive loss

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year Ended December 31,		
	2017	2018	2019
	$	$	$
Operating Expenses:			
Research and development	—	(234)	(101)
General and administrative	(4,114)	(4,251)	(4,864)
Loss from operations	**(4,114)**	**(4,485)**	**(4,965)**
Interest income	50	3,042	7,987
Changes in fair value of warrants	200	—	—
Other income, net	78	312	311
Loss before income tax and equity in loss of subsidiaries	**(3,786)**	**(1,131)**	**3,333**
Equity in loss of subsidiaries	(46,598)	(137,944)	(198,404)
Income tax expense	—	—	—
Net loss attributable to ordinary shareholders	**(50,384)**	**(139,075)**	**(195,071)**
Net loss	(50,384)	(139,075)	(195,071)
Other comprehensive income, net of tax of nil:			
Foreign currency translation adjustment	1,148	2,212	1,958
Comprehensive loss	**(49,236)**	**(136,863)**	**(193,113)**

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed statements of cash flows

(In thousands of U.S. dollars ("$") except for number of shares and per share data)

	Year Ended December 31,		
	2017	2018	2019
	$	$	$
Cash flows from Operating activities:			
Net loss	(50,384)	(139,075)	(195,071)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Amortization of deferred income	(78)	(312)	(312)
Share based compensation	3,346	1,408	2,013
Change of fair value of warrants	(200)	—	—
Equity in loss of subsidiaries	46,598	137,944	198,404
Changes in operating assets and liabilities:			
Prepayments and other current assets	(450)	(2,462)	(1,267)
Other current liabilities	553	(49)	102
Deferred income	1,560	—	—
Net cash provided by (used in) operating activities	945	(2,546)	3,869
Cash flows from investing activities:			
Purchases of short-term investments	—	(200,350)	(277,640)
Proceeds from maturity of short-term investments	—	—	277,990
Investment in subsidiaries	(31,708)	(118,773)	(165,924)
Net cash used in investing activities	(31,708)	(319,123)	(165,574)
Cash flows from financing activities:			
Proceed from issuance of convertible preferred shares, net of issuance cost	29,100	—	—
Proceeds from exercise of warrants	1,000	—	—
Proceeds from exercises of stock options	66	196	1,055
Proceeds from issuance of ordinary shares upon public offerings	160,425	141,000	216,200
Payment of public offering costs	(2,730)	(692)	(854)
Net cash provided by financing activities	187,861	140,504	216,401
Effect of foreign exchange rate changes on cash and cash equivalent	—	—	—
Net increase (decrease) in cash and cash equivalents	157,098	(181,165)	54,696
Cash and cash equivalents-beginning of the year	24,813	181,911	746
Cash and cash equivalents-end of the year	181,911	746	55,442

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Notes to schedule I

(In U.S. dollars ("$") except for number of shares)

1. Schedule I has been provided pursuant to the requirements of Rule 12-04(a) and 5-04(c) of Regulation S-X, which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.

2. The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements except that the equity method has been used to account for investments in its subsidiaries. For the parent company, the Company records its investments in subsidiaries under the equity method of accounting as prescribed in ASC 323, *Investments-Equity Method and Joint Ventures* . Such investments are presented on the Condensed Balance Sheets as ‘‘Investment in subsidiaries’’. Ordinarily under the equity, an investor in an equity method investee would cease to recognize its share of the losses of an investee once the carrying value of the investment has been reduced to nil absent an undertaking by the investor to provide continuing support and fund losses. For the purpose of this Schedule I, the parent company has continued to reflect its share, based on its proportionate interest, of the losses of subsidiaries regardless of the carrying value of the investment even though the parent company is not obligated to provide continuing support or fund losses.

3. As of December 31, 2018 and 2019, there were no material contingencies, significant provisions of long term obligations, mandatory dividend or redemption requirements of redeemable stocks or guarantees of the Company.

Exhibit 4.5

DESCRIPTION OF SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, the registrant had the following series of securities registered pursuant to Section 12 of the U.S. Securities Exchange Act of 1934, as amended:

Title of each class:	Name of each exchange on which registered:
Ordinary Shares	**Nasdaq Global Market***
American depositary shares, each representing one ordinary share, par value $0.00006 per share	**Nasdaq Global Market**

* Listed, not for trading, but only in connection with the registration of American Depositary Shares, pursuant to the requirements of the Securities and Exchange Commission (the "SEC")

Citibank, N.A. acts as the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, 23rd Floor, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A.—Hong Kong, located at 9/F., Citi Tower, One Bay East, 83 Hoi Bun Road, Kwun Tong, Kowloon, Hong Kong.

As of March 31, 2020, our authorized share capital consists of $5,000.00 divided into 83,333,333 ordinary shares, with a par value of $0.00006 each.

Each American depositary share ("ADS") repr esents the right to receive, and to exercise the beneficial ownership interests in, one ordinary share that is on deposit with the depositary bank and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary bank may agree to change the ADS-to-share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

An ADS holder will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents such ADSs. The deposit agreement and the ADR specify our rights and obligations as well as ADS holders' rights and obligations as owner of ADSs and those of the depositary bank. ADS holders appoint the depositary bank to act on their behalf in certain circumstances. The deposit agreement and the

ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require ADS holders to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. ADS holders are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary bank, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on ADS holders' behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

We will not treat ADS holders as our shareholders and ADS holders will not have direct shareholder rights. The depositary bank will hold on ADS holders' behalf the shareholder rights attached to the ordinary shares underlying the ADSs. ADS holders will be able to exercise the shareholders rights for the ordinary shares represented by the ADSs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement, an ADS holder will, as an ADS owner, need to arrange for the cancellation of such ADSs and become a direct shareholder.

The manner in which ADS holders owns the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect the holders' rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to the holders. An ADS holder may hold the ADSs either by means of an ADR registered in such holder's name, through a brokerage or safekeeping account, or through an account established by the depositary bank in such holder's name reflecting the registration of uncertificated ADSs directly on the books of the depositary bank (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary bank to the holders of the ADSs. The direct registration system includes automated transfers between the depositary bank and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If an ADS holder decides to hold the ADSs through such holder's brokerage or safekeeping account, the holder must rely on the procedures of his/her broker or bank to assert his/her rights as an ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit an ADS holder's ability to exercise such holder's rights as an owner of ADSs. ADS holders should consult with their broker or bank if they have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes ADS holders have opted to own the ADSs directly by means of ADSs registered in such holders' name and, as such, we will refer to ADS holders as the "holders."

The registration of the ordinary shares in the name of the depositary bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary bank or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and distributions

Holders of ADSs generally have the right to receive the distributions we make on the securities deposited with the custodian. ADS holders' receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to Cayman Islands laws and regulations.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary share ratio, in which case each ADS holders hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary share ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). Holders may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of such rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary bank will not distribute the rights to holders if:

- We do not timely request that the rights be distributed to holders or we request that the rights not be distributed to holders ; or
- We fail to deliver satisfactory documents to the depositary bank; or
- It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

Elective distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to holders . In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to holders only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable holders to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to holders, holders will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

Other distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to holders. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to holders and if we provide to the depositary bank all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will not distribute the property to holders and will sell the property if:

- We do not request that the property be distributed to holders or if we request that the property not be distributed to holders; or
- We do not deliver satisfactory documents to the depositary bank; or
- The depositary bank determines that all or a portion of the distribution to holders is not reasonably practicable; or
- The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. Holders may have to pay fees, expenses, taxes and other governmental charges upon the redemption of the ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a pro rata basis, as the depositary bank may determine.

Changes affecting ordinary shares

The ordinary shares held on deposit for the ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, the ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to holders, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of holders' existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary bank may not lawfully distribute such property to holders, the depositary bank may sell such property and distribute the net proceeds to holders as in the case of a cash distribution.

Issuance of ADSs upon deposit of ordinary shares

Our ordinary shares have been and will be deposited with the custodian. The depositary bank may create ADSs on a holder's behalf if such holder or such holder's broker deposits ordinary shares with the custodian. The depositary bank will deliver these ADSs to the person such holder indicates only after such holder pays any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Holders' ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Cayman Islands legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When a holder makes a deposit of ordinary shares, such holder will be responsible for transferring good and valid title to the depositary bank. As such, the holder will be deemed to represent and warrant that:

- The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- The holder is duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at holders' cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, combination and split up of ADRs

Holders will be entitled to transfer, combine or split up their ADRs and the ADSs evidenced thereby. For transfers of ADRs, a holder will have to surrender the ADRs to be transferred to the depositary bank and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have the ADRs either combined or split up, a holder must surrender his/her ADRs in question to the depositary bank with such holder's request to have them combined or split up, and such holder must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of ordinary shares upon cancellation of ADSs

Holders will be entitled to present their ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Holders' ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Cayman Islands considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by the ADSs, holders will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. Holders assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If a holder holds ADSs registered in his/her name, the depositary bank may ask such holder to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel the ADSs. The withdrawal of the ordinary shares represented by the ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

Holders will have the right to withdraw the securities represented by the ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.
- Obligations to pay fees, taxes and similar charges.
- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.
- The deposit agreement may not be modified to impair holders' right to withdraw the securities represented by the ADSs except to comply with mandatory provisions of law.

Voting rights

Holders generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by ADSs.

At our request, the depositary bank will distribute to holders any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs.

If the depositary bank timely receives voting instructions from a holder, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with such voting instructions as follows:

- *In the event of voting by show of hands* , the depositary bank will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders who provide timely voting instructions.
- *In the event of voting by poll, the depositary bank will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders.*

In the event of voting by poll, holders in respect of which no timely voting instructions have been received shall be deemed to have instructed the depositary bank to give a discretionary proxy to a person designated by us to vote the ordinary shares represented by such holders' ADSs; provided, that no such instructions shall be deemed given and

no such discretionary proxy shall be given with respect to any matter as to which we inform the depositary bank that we do not wish such proxy to be given; provided, further, that no such discretionary proxy shall be given (x) with respect to any matter as to which we inform the depositary that (i) there exists substantial opposition, or (ii) the rights of holders or the shareholders of our company will be materially adversely affected, and (y) in the event that the vote is on a show of hands.

Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure that holders will receive voting materials in time to enable them to return voting instructions to the depositary bank in a timely manner.

Fees and charges

Holders will be required to pay the following fees under the terms of the deposit agreement:

Service	Fees
• Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S. 5¢ per ADS issued
• Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to-share ratio, or for any other reason)	Up to U.S. 5¢ per ADS cancelled
• Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. 5¢ per ADS held
• Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
• Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. 5¢ per ADS held
• ADS Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary bank

Holders will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary bank in the conversion of foreign currency;
- the fees and expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in

the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to holders. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of an ADS offering. Note that the fees and charges holders may be required to pay may vary over time and may be changed by us and by the depositary bank. Holders will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Amendments and termination

We may agree with the depositary bank to modify the deposit agreement at any time without holders' consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to holders' substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges holders are required to pay. In addition, we may not be able to provide holders with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

Holders will be bound by the modifications to the deposit agreement if they continue to hold their ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent holders from withdrawing the ordinary shares represented by the ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to holders at least 30 days before termination. Until termination, holders' rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until holders request the cancellation of their ADSs) and may sell the securities held on deposit.

After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

Books of depositary

The depositary bank will maintain ADS holder records at its depositary office. Holders may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on obligations and liabilities

The deposit agreement limits our obligations and the depositary bank's obligations to holders. Please note the following:

- we and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- the depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- the depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to holders on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- we and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- we and the depositary bank disclaim any liability if we or the depositary bank, or our respective controlling persons or agents are prevented or forbidden from, or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our articles of association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- we and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our articles of association or in any provisions of or governing the securities on deposit.
- we and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- we and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to holders.
- we and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- we and the depositary bank also disclaim liability for any consequential, indirect or punitive damages for any breach of the terms of the deposit agreement, or otherwise.
- no disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.
- nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and holders.

- nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those
transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

Pre-release transactions

Subject to the terms and conditions of the deposit agreement, the depositary bank may issue to broker/dealers ADSs before receiving a deposit of ordinary shares or release ordinary shares to broker/dealers before receiving ADSs for cancellation. These transactions are commonly referred to as "pre-release transactions," and are entered into between the depositary bank and the applicable broker/dealer. The deposit agreement limits the aggregate size of pre-release transactions (not to exceed 30% of the ordinary shares on deposit in the aggregate) and imposes a number of conditions on such transactions (e.g., the need to receive collateral, the type of collateral required, the representations required from brokers, etc.). The depositary bank may retain the compensation received from the pre-release transactions.

Taxes

Holders will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. Holders will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on holders' behalf. However, holders may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. Holders are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes arising out of any refund of taxes, reduced rate of withholding or of the tax benefit obtained for or by the holders.

Foreign currency conversion

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. Holder may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing law/waiver of jury trial

The deposit agreement and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) is governed by the laws of the Cayman Islands.

By holding an ADS or an interest therein, ADS holders irrevocably agree that any legal suit, action or proceeding against or involving us or the Depositary, arising out of or based upon the deposit agreement, ADSs or ADRs, may only be instituted in a state or federal court in New York, New York, and ADS holders irrevocably waive any objection to the laying of venue and irrevocably submit to the exclusive jurisdiction of such courts with respect to any such suit, action or proceeding.

AS A PARTY TO THE DEPOSIT AGREEMENT, ADS HOLDERS IRREVOCABLY WAIVE THE RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT, THE ADRs AND ANY TRANSACTIONS CONTEMPLATED THEREIN (WHETHER BASED ON CONTRACT, TORT, COMMON LAW OR OTHERWISE) AGAINST US AND/OR THE DEPOSITARY BANK.

Exhibit 10.6

ZAI LAB LIMITED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Effective as of the consummation of the initial public offering (the "IPO") of the American depository shares ("ADS") of Zai Lab Limited (the "Company"), each individual who provides services to the Company as a director, other than a director who is employed by the Company or an affiliate, (a "Non-Employee Director") shall be entitled to receive the following amounts of compensation:

Type of Compensation	Amount and Form of Payment
Annual cash retainer	$50,000 (payable in cash on a quarterly basis)
Equity retainer	In calendar years 2018 and 2019, non-employee directors received an annual grant of 12,500 restricted shares under our 2017 Equity Plan, which vested in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date. Commencing in calendar year 2020, non-employee directors will receive an annual grant of 10,000 restricted shares under our 2017 Equity Plan, which vest in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date. In connection with the IPO, grant of restricted stock in respect of 25,000 ordinary shares to be made to each Non-Employee Director, other the Compensation Committee Chair, who was appointed to the board of directors of the Company following the adoption of this policy by the board of directors of the Company and whose appointment is effective prior to the IPO; which vests ratably on each of the first three anniversaries of the date of grant, subject to continued service as a member of our board of directors through such date.
Additional annual cash retainer for Audit Committee chair	$20,000 (payable in cash on a quarterly basis)
Additional annual cash retainer for Audit Committee member	$10,000 (payable in cash on a quarterly basis)
Additional annual cash retainer for Compensation Committee chair	$15,000 (payable in cash on a quarterly basis)
Additional annual cash retainer for Compensation Committee member	$7,500 (payable in cash on a quarterly basis)
Additional annual cash retainer for Nominating Committee chair	$10,000 (payable in cash on a quarterly basis)
Additional annual cash retainer for Nominating Committee member	$5,000 (payable in cash on a quarterly basis)

Additional annual cash retainer for Compliance Committee chair	$10,000 (payable in cash on a quarterly basis)
Additional annual cash retainer for Compliance Committee member	$5,000 (payable in cash on a quarterly basis)

In addition, Non-Employee Directors will be reimbursed by the Company for reasonable and customary expenses incurred in connection with attendance at board of director and committee meetings, in accordance with the Company's policies as in effect from time to time.

For the avoidance of doubt, directors who are (i) employees of the Company, (ii) employees of one of its affiliates or (iii) (a) are affiliated with a shareholder holding more than one percent (1%) of the ordinary shares or ordinary share equivalents of the Company or (b) individually (or through any trust or estate planning entity) hold more than one percent (1%) of the ordinary shares or ordinary share equivalents) of the Company will not receive compensation for their service as a director, other than reimbursement for reasonable and customary expenses incurred in connection with attendance at board of director and committee meetings, in accordance with the Company's policies as in effect from time to time.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.17

LICENSE AGREEMENT

This **License Agreement** (this " **Agreement** ") is made as of June 10th , 2019 (the " **Effective Date** "), by and between **Deciphera Pharmaceuticals, LLC** a limited liability company organized and existing under the laws of Delaware, U.S.A., located at 500 Totten Pond Rd, Waltham, MA 02451, U.S.A., (" **Deciphera** "), and **Zai Lab (Shanghai) Co., Ltd.** , an exempted company organized and existing under the laws of P.R. of China, located at 4F, Bldg 1 , Jinchuang Plaza , 4560 Jinke Rd, Shanghai, China, 201210 (" **Zai** "). Deciphera and Zai are referred to in this Agreement individually as a " **Party** " and collectively as the " **Parties** ."

RECITALS

WHEREAS , Deciphera is a biopharmaceutical company specializing in the field of developing novel drug candidates to treat cancer, and Deciphera and its Affiliates own or control rights to the Compounds and Licensed Products (as defined herein);

WHEREAS , Zai is a pharmaceutical company having experience in the development and commercialization of pharmaceutical products in the Territory;

WHEREAS , Zai wishes to research, develop and commercialize the Licensed Products in the Territory; and

WHEREAS , Deciphera wishes to grant to Zai, and Zai wishes to be granted, the right to Develop and Commercialize (each as defined herein) Licensed Products in the Field in the Territory (each as defined herein) in accordance with the terms and conditions set forth below.

AGREEMENT

NOW, THEREFORE , in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1. " [***] **GIST** " means, with respect to patients diagnosed with GIST, [***] .

1.2. " [***] **GIST Regional Study** " shall have the meaning set forth in Section 5.4(b).

1.3. " [***] **GIST** " means, with respect to patients diagnosed with GIST, [***] .

1.4. " **Acquirer** " shall have the meaning set forth in Section 2.6(b)(i).

1.5. " **Abandoned Development** " shall have the meaning set forth in Section 5.3.

1.6. **"Active Development Activities"** shall have the meaning set forth in Section 5.3.

1.7. " **Adverse Event** " means any unwanted or harmful medical occurrence in a patient or subject who is administered a Licensed Product, whether or not considered related to such Licensed Product, including any undesirable sign (including abnormal laboratory findings of clinical concern).

1.8. " **Affiliate** " means, with respect to a specified Person, any entity that directly or indirectly controls , is controlled by or is under common control with such Person . As used in this Section 1.7 , "Control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means, in the case of a corporation, the ownership of fifty percent (50%) or more of the outstanding voting securities thereof or, in the case of any other type of entity, an interest that results in the ability to direct or cause the direction of the management and policies of such party or the power to appoint fifty percent (50%) or more of the members of the governing body of the party or, where ownership of fifty percent (50%) or more of such securities or interest is prohibited by law, ownership of the maximum amount legally permitted. Notwithstanding the foregoing, Affiliates of a Party shall exclude Persons who are financial investors in such Person or under common control of such investors other than such Person and its parent and subsidiary entities.

1.9. " **Agreement** " shall have the meaning set forth in the introduction to this agreement.

1.10. " **Alliance Manager** " shall have the meaning set forth in Section 3.1 .

1.11. " **Anti-Corruption Laws** " shall have the meaning set forth in Section 12.5(a)(i).

1.12. " **Applicable Laws** " means all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the relevant activities contemplated by this Agreement.

1.13. " **Business Day** " means a day other than Saturday, Sunday or any day on which banks located in the United States or the PRC are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

1.14. " **Calendar Quarter** " means the respective periods of three consecutive calendar months ending on March 31st, June 30th, September 30th and December 31st.

1.15. " **Calendar Year** " means each twelve (12) month period commencing on January 1st .

1.16. " **cGMP** " means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S . Current Good Manufacturing Practices, 21 C.F.R. Parts 4 , 210 , 211 , 601 , 610 and 820 , (b) European Directive 2003 /94/EC and Eudralex 4 , (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Applicable Laws in any relevant country or region, each as may be amended and applicable from time to time.

1.17. " **Clinical Trial** " means any clinical testing of a Licensed Product in human subjects.

1.18. " **CMOs** " means Third Party contractor manufacture organizations .

1.19. " **Change of Control** " means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which would result in shareholders or equity holders of such Party immediately prior to such transaction, no longer owning at least 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

1.20. " **Combination Product** " means [***] .

1.21. " **Commercialization** " or " **Commercialize** " means all activities directed to marketing, distribution, promoting or selling of pharmaceutical products (including importing and exporting activities in connection therewith **)** .

1.22. " **Commercialization Plan** " means the written plan for the Commercialization of the Licensed Product in the Territory.

1.23. " **Commercially Reasonable Efforts** " means with respect to a Party, the use of diligent, good faith efforts and resources, in an active and ongoing program, as normally used by such Party for a product discovered or identified internally or in-licensed from a Third Party that is important to such Party's overall strategy or objectives, which product is at a similar stage in its development or product life and is of similar market potential and intellectual property protection but in the event such Party is Zai, not considering the obligations (including financial) to Deciphera or the rights of Deciphera hereunder; provided, *however* , that in no event shall such efforts and resources be less than those a similarly situated biopharmaceutical company would

apply to the development , manufacture, or commercialization of a similarly situated product . Commercially Reasonable Efforts requires that a Party, at a minimum, (i) assign responsibility for such obligations to qualified employees, (ii) set annual goals and objectives for carrying out such obligations, and (iii) allocate adequate resources designed to meet such goals and objectives, in each case, in order to Develop and Commercialize the Licensed Product as an active and ongoing program, and obtain Regulatory Approval for the Licensed Product in the Territory in an expeditious manner and then exercise such efforts towards Commercialization.

1.24. " **Competing Activities** " shall have the meaning set forth in Section 2.6(b)(i).

1.25. " **Competing Product** " shall have the meaning set forth in Section 2.6(a).

1.26. " **Compound** " means (a) ripretinib (also known as DCC - 2618), or (b) any Follow-on Compound, in each case, (a) and (b), includes any salt, metabolite, prodrugs, free-base, hydrate, solvate, polymorph, racemate, isotope, stereoisomer enantiomer thereof.

1.27. " **Confidential Information** " means all confidential information of the Disclosing Party or its Affiliates, regardless of its form or medium as provided to the Receiving Party or its Affiliates in connection with this Agreement; provided that, Confidential Information shall not include any information that the Receiving Party can show by competent written evidence: (a) was already known to the Receiving Party at the time it was disclosed to the Receiving Party by the Disclosing Party without an obligation of confidentiality and not through a prior disclosure by the Disclosing Party, (b) was or becomes generally known to the public through no act or omission of the Receiving Party in violation of the terms of this Agreement, (c) was lawfully received by the Receiving Party from a Third Party without restriction on its disclosure and without, to the reasonable knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party, or (d) was independently developed by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party. The terms of this Agreement that are not publicly disclosed through a press release or by filings to financial regulatory authorities shall be the Confidential Information of both Parties.

1.28. " **Control** " or " **Controlled** " means, with respect to any Know-How, Patents or other intellectual property rights, that a party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, access or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.29. " **Deciphera** " shall have the meaning set forth in the preamble of this Agreement.

1.30. " **Deciphera Acquired Party** " shall have the meaning set forth in Section 2.6(b)(ii).

1.31. " **Deciphera Background Know-How** " means any and all Know-How Controlled by Deciphera or its Affiliates as of the Effective Date or during the Term of this Agreement that [***] . Schedule 1.31 contains a list of Deciphera Background Know-How as of the Effective Date . Deciphera Background Know-How shall include Deciphera's interest in any improvements to any Deciphera Background Know-How [***] . Notwithstanding the foregoing, in the event after the Effective Date, a Third Party becomes an Affiliate of Deciphera or becomes Deciphera's successor in interest with respect to this Agreement in each case through a Change of Control of Deciphera, no Know-How Controlled by such Third Party entity or its Affiliates immediately prior to such Change of Control transaction or during the Term shall be considered to be Deciphera Background Know-How for the purposes of this Agreement unless [***] .

1.32. " **Deciphera Indemnitee(s)** " shall have the meaning set forth in Section 13.1 .

1.33. " **Deciphera IP** " means Deciphera Background Know-How and Deciphera Program IP.

1.34. " **Deciphera Know-How** " means Deciphera Background Know-How and Deciphera Program Know-How.

1.35. **"Deciphera Product Marks"** shall have the meaning set forth in Section 9.4.

1.36. " **Deciphera Program IP** " means the Deciphera Program Know-How and Deciphera Program Patents.

1.37. " **Deciphera Program Know-How** " means any and all Know-How Controlled by Deciphera or its Affiliates as of the Effective Date or during the Term of this Agreement that [***] . Schedule 1.37 contains a list of Deciphera Program Know-How as of the Effective Date. Deciphera Program Know-How (i) shall include Deciphera's interest in any improvements to any Deciphera Program Know-How [***] and (ii) all Know-How within the New Program IP. Notwithstanding the foregoing, in the event after the Effective Date, a Third Party becomes an Affiliate of Deciphera or becomes Deciphera's successor in interest with respect to this Agreement in each case through a Change of Control of Deciphera, no Know-How Controlled by such Third Party entity or its Affiliates immediately prior to such Change of Control transaction or during the Term shall be considered to be Deciphera Program Know-How for the purposes of this Agreement unless [***] .

1.38. " **Deciphera Program Patents** " means the Patents in the Territory Controlled by Deciphera or its Affiliates as of the Effective Date or during the Term of the Agreement that (a) claim the Compound or the Licensed Product (including the composition of matter, formulation, or method of making or using thereof) and (b) are otherwise necessary for the Development, packaging or Commercialization of the Licensed Product. Schedule 1.38 contains a list of Deciphera Program Patents as of the Effective Date. Deciphera Program Patents shall include (i) Deciphera's interest in any improvements to any Deciphera Program Patents developed by (1) either Party or its Affiliates alone or (2) both Parties jointly when performing its or their

obligations hereunder and (ii) all Patents in the Territory claiming New Program IP. Notwithstanding the foregoing, in the event after the Effective Date, a Third Party becomes an Affiliate of Deciphera or becomes Deciphera's successor in interest with respect to this Agreement in each case through a Change of Control of Deciphera, no Patent Controlled by such Third Party entity or its Affiliates immediately prior to such Change of Control transaction or during the Term shall be considered to be a Deciphera Program Patent for the purposes of this Agreement unless such Patent (A) is also Controlled by Deciphera or its Affiliate prior to such transaction or (B) claims any Invention generated or used by Deciphera or such Third Party entity or their Affiliates in the Development , packaging or Commercialization of the Licensed Product.

1.39. " **Deficient Site** " shall have the meaning set forth in Section 5.7(c).

1.40. " **Develop** " or " **Development** " or " **Developing** " means research, discovery, and preclinical and clinical drug or biological development activities, including test method development and stability testing, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, approval and registration.

1.41. " **Development Milestone Event** " shall have the meaning set forth in Section 10.2(a).

1.42. " **Development Milestone Payment** " shall have the meaning set forth in Section 10.2(a).

1.43. " **Development Plan** " shall have the meaning set forth in Section 5.2.

1.44. " **Development Technology Transfer** " shall have the meaning set forth in Section 4.1 .

1.45. " **Disclosing Party** " shall have the meaning set forth in Section 11.1(a).

1.46. " **Dispute** " shall have the meaning set forth in Section 16.1 .

1.47. " **DPI** " shall have the meaning set forth in Section 7.4.

1.48. " **Effective Date** " shall have the meaning set forth in the preamble in this Agreement.

1.49. " **Executive Officers** " shall have the meaning set forth in Section 3.2(f).

1.50. " **Expenses** " shall have the meaning set forth in Section 5.4(b).

1.51. " **Expiration Date** " shall have the meaning set forth in Section 15.1(a).

1.52. " **Field** " means the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans .

1.53. " **First Commercial Sale** " means, with respect to any Licensed Product, the first arm's length sale of such Licensed Product to a Third Party in a region of the Territory by Zai, its Affiliate(s) or Sublicensee(s) for use or consumption in such region following Regulatory Approval. Sales prior to receipt of marketing and pricing approvals, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales" and any sales to any government, foreign or domestic, including purchases for immediate sale or stockpiling purposes, are not a First Commercial Sale in that region.

1.54. " **Follow-on Compound** " means a Compound other than ripretinib [***].

1.55. " **FTE** " means the equivalent of the work of a full-time individual for a twelve (12) month period.

1.56. " **FTE Rate** " means a rate of US$ [***] per FTE per year, to be pro-rated on an hourly basis of US$ [***] per FTE per hour, based on [***] hours per year for an FTE and is subject to adjustments on an annual basis as of January 1 of each year, beginning in [***] , by factors which reflect (a) the increase in Deciphera's (or its Affiliate's) costs or (b) any change in the Consumer Price Index for All Urban Consumers (CPI-U) All Items (U.S. city average), as reported by the U.S. Bureau of Labor Statistics, for January 1 of such year when compared to the comparable statistics for January 1 of the preceding year.

1.57. " **Fully Burdened Manufacturing Costs** " means the cost of Manufacturing the Licensed Product. Fully Burdened Manufacturing Costs shall be a "standard cost" per unit (calculated annually), comprised of the following elements calculated in accordance with GAAP: [***] . To the extent that Licensed Products are sourced from one or more CMOs by Deciphera, Fully Burdened Manufacturing Costs shall be the actual invoiced price paid by Deciphera to such CMO(s) for the manufacture and supply of a Licensed Product.

1.58. " **GAAP** " means the United States generally accepted accounting principles, consistently applied.

1.59. " **GCP** " means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials , including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21 , Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.60. " **Generic Product** " shall have the meaning set forth in Section 10.4(c)(ii) .

1.61. " **GIST** " means Gastrointestinal Stromal Tumors as defined in the International Classification of Diseases, 10 th Revision (ICD10) as code C49.A0-9.

1.62. " **Global Study** " means a clinical study designed to obtain Regulatory Approvals for the Licensed Products in multiple regions and countries through the conduct of a Clinical Trial in multiple medical institutions, countries, regions, territories and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

1.63. " **GLP** " means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.64. " **Governmental Authority** " means any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, region, state or local authority or any political subdivision thereof, or any association of countries.

1.65. " **GSP** " means all applicable Good Supply Practice standards, including, as applicable, as set forth in the then current good supply practice standards promulgated or endorsed by the FDA as defined in Good Supply Practice for Pharmaceutical Products or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.66. " **ICC Rules** " shall have the meaning set forth in Section 16.4(a).

1.67. " **IND** " means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence Clinical Trials in the applicable country.

1.68. " **Indemnifying Party** " shall have the meaning set forth in Section 13.3 .

1.69. " **Indemnitee** " shall have the meaning set forth in Section 13.3 .

1.70. " **Indication** " means a separate and distinct disease or condition, or sign or symptom of a disease or medical condition. For clarity, different lines of treatment or the treatment of separate stages or forms of the same diseases or medical condition shall not constitute separate Indications.

1.71. " **Initial Development Plan** " shall have the meaning set forth in Section 5.2.

1.72. **" Initiation "** means, with respect to a Clinical Trial, the administration of the first dose of the Licensed Product or comparator to the first patient or subject in such Clinical Trial.

1.73. " **INTRIGUE Study** " shall have the meaning set forth in Section 5.4(a).

1.74. " **Invention** " means any process, method, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented as a result of a Party (or the Parties jointly) exercising its (their) rights or carrying out its obligations under this Agreement, including all rights, title and interest in and to the intellectual property rights therein.

1.75. " **IRB** " shall have the meaning set forth in Section 5.3.

1.76. " **Joint Steering Committee** " or " **JSC** " shall have the meaning set forth in Section 3.2(a).

1.77. " **Know-How** " means any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge , know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

1.78. " **Knowledge** " means, with respect to [***] .

1.79. " **Licensed Product** " means any pharmaceutical preparation containing the Compound.

1.80. " **Losses** " shall have the meaning set forth in Section 13.1 .

1.81. " **Manufacture** " or " **Manufacturing** " or " **Manufactured** " means all operations involved in the manufacturing, filling and finishing, quality control testing (including in-process, release and stability testing, if applicable), storage, releasing and packaging.

1.82. " **Major Market** " shall have the meaning set forth in Section 15.1(c)

1.83. " **Medical Affairs** " means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), publications, congress presentations and posters, published manuscripts, activities performed in connection with patient registries and post-approval trials, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Licensed Product and are not conducted by a Party's medical affairs (or equivalent) departments, all of which shall be conducted in accordance with Applicable Law.

1.84. " **Medical Affairs Plan** " means an overall plan for the Medical Affairs activities for the Licensed Product to be conducted in the Territory prepared and updated by Zai as provided in Section 8.1 , however Medical Affairs activities conducted outside the Territory with healthcare professionals resident in the Territory (e.g., meetings at congresses outside the Territory) may be included in this Medical Affairs Plan.

1.85. " **Milestone Events** " means Development Milestone Events and Net Sales Milestone Events.

1.86. " **Milestone Payments** " means Development Milestone Payments and Net Sales Milestone Payments.

1.87. " **Net Sales** " means the gross price billed or invoiced on sales of the Licensed Product by Zai, its Affiliates, or Sublicensees to a Third Party in the Territory, less (without duplication) usual and customary:

(a) [***] discounts actually granted and deducted solely on account of sales of the Licensed Product, but excluding early payment discounts;

(b) rebates actually paid [***] solely on account of the purchase of such Licensed Product;

(c) credits issued for the Licensed Product [***] actually granted and related to the Licensed Product;

(d) (i) freight expense (actual), including insurance, to the extent it is not charged to or reimbursed by the customer, (ii) [***] , (iii) bad debt written off under GAAP, with reasonable collection efforts and added back if collected, [***] ; and

(e) Taxes (including, but not limited to sales, value added, consumption and similar taxes ; but excluding income taxes) actually incurred, paid or collected and remitted to the relevant tax authority for the sale of the Licensed Product; provided that any amount of such taxes refunded, recovered or credited back by the relevant tax authority shall be included in Net Sales.

Each of the amounts set forth above shall be determined from the books and records of Zai, its Affiliate or Sublicensee, maintained in accordance with GAAP or in the case of Sublicensees, such similar accounting principles, consistently applied, and any amounts that are deducted from Net Sales pursuant to one subsection may not be deducted pursuant to another subsection (i.e., a deduction may only be taken once).

The transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party (w) in connection with the Development or testing of a Licensed Product (including the conduct of clinical studies), (x) for purposes of distribution as promotional samples, (y) for indigent or similar public support or compassionate use programs, or (z) by and between Zai and its Affiliates or Sublicensees shall not, in any case, be considered a Net Sale of a Licensed Product under this Agreement. Subject to the foregoing, any sales income received by Zai, its Affiliates or Sublicensees for Licensed Products prior to Regulatory Approval shall be Net Sales and subject to the Royalty Payments under Section 10.4.

Net Sales shall also include and be deemed to have been made with respect to any Licensed Products used by Zai or any Affiliate, for its own commercial purposes, or transferred to any Third Party for less than the transferee is then charging in normal arms-length sales transactions; and Net Sales in all such cases shall be deemed to have been made at the prices therefor at which such Licensed Products are then being sold to the customers of such user or transferor (or of Zai, if an Affiliate is a user but not a seller) in arms-length sales transactions. For clarity, in the event the License d Product is sold in an arms-length transaction to a governmental agency, a group purchase entity or any other entity having the bargaining power to negotiate the purchase price below normal retail price in transactions of lesser volume, Net Sales shall be calculated based on the actual price negotiated and agreed to for such agency or entity and not be based on the price charged in other arms-length sales transactions.

To the extent that Zai or any of its Affiliates, or Sublicensees, provides to the purchasing Third Party discounts or allowances that are applicable to purchases of the Licensed Product and one or more other products (such as in a "bundled sale" arrangement), such discounts and allowances shall be allocated between the Licensed Product (for purposes of the deductions used in calculating Net Sales as above) and such other products in an equitable and commercially reasonable manner that does not unfairly or inappropriately bias the level of discounting against the Licensed Product (as compared to the other products).

If Zai or any of its Affiliates, or Sublicensees, sells a Licensed Product as a Licensed Component of a Combination Product in the Territory in any Calendar Quarter, then Net Sales shall be calculated by multiplying the Net Sales of the Combination Product during such Calendar Quarter by the fraction A/(A+B), where A is the average Net Sales per unit sold of the Licensed Component when sold separately in the Territory during such Calendar Year (calculated by determining the Net Sales of the Licensed Component during such Calendar Quarter in accordance with the definition of Net Sales set forth herein and dividing such Net Sales by the number of units of the Licensed Component during such Calendar Quarter) and B is the average Net Sales per unit sold of the Other Component(s) included in the Combination Product when sold separately during such Calendar Quarter (calculated by determining the Net Sales of such Other Component(s) sold during such Calendar Quarter by applying the definition of Net Sales set forth herein as if it applied to sales of such Other Component(s) and dividing such Net Sales by the number of units of such Other Component(s) sold during such Calendar Quarter).

For purposes of calculating the average Net Sales per unit sold of a Licensed Component and Other Component(s) of a Combination Product, any of the deductions described herein that apply to such Combination Product shall be allocated among sales of the Licensed Component and sales of the Other Component(s) included in such Combination Product as follows: (1) deductions that are attributable solely to the Licensed Component or one of the Other Component(s) shall be allocated solely to Net Sales of the Licensed Component or such Other Component, as applicable, and (2) all other deductions shall be allocated among sales of the Licensed Component and sales of the Other Component(s) in proportion to Zai's and Deciphera's mutual agreement of the fair market value of the Licensed Component and the Other Component(s).

In the event that no separate sales of the Licensed Component or any Other Component(s) included in a Combination Product are made by Zai or its Affiliates, or Sublicensees, during a Calendar Quarter in which such Combination Product is sold, the average Net Sales per unit sold in the above described equation shall be replaced with Zai's and Deciphera's mutual agreement of the fair market value of the Licensed Component and each of the Other Component(s) included in such Combination Product.

1.88. " **Net Sales Milestone Event** " shall have the meaning set forth in Section 10.3(a).

1.89. " **Net Sales Milestone Payment** " shall have the meaning set forth in Section 10.3(a).

1.90. " **New IP** " shall have the meaning set forth in Section 14.1(a).

1.91. " **New Program IP** " shall have the meaning set forth in Section 14.1(a).

1.92. " **NMPA** " means the National Medical Product Administration , formerly known as the China Food and Drug Administration, and local or provincial counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

1.93. **"Party"** or **"Parties"** shall have the meaning set forth in the preamble to this Agreement.

1.94. " **Patent Prosecution** " means the responsibility and authority for (a) preparing, filing and prosecuting applications (of all types) for any Patent, (b) managing any interference, opposition, re-issue, reexamination, invalidation proceedings, revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding to abandon Patent(s), (d) listing in regulatory publications (as applicable), (e) patent term extension, and (f) settling any interference, opposition, revocation, nullification or cancellation proceeding.

1.95. " **Patents** " means (a) all national, regional and international patents and patent applications, including any provisional patent application, (b) any patent application claiming priority from such patent application or provisional patent applications, including divisions, continuations, continuations-in-part, additions, (c) any patent that has issued or in the future issues from any of the foregoing patent applications, including any utility or design patent or certificate of invention , and (d) re-issues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates and equivalents to any of the foregoing.

1.96. " **Person** " means any individual, sole proprietorship, corporation, joint venture, limited liability company, partnership, limited partnership, limited liability partnership, trust or any other private, public or governmental entity.

1.97. " **Pharmacovigilance Agreement** " shall have the meaning set forth in Section 6.4(a).

1.98. " **Phase I Clinical Study** " means any Clinical Trial(s), the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy the requirement of 21 C.F.R. § 312.21(a), or its foreign equivalent , as may be amended from time to time, or any analogous Clinical Trial described or defined in Applicable Laws .

1.99. " **Phase III Clinical Study** " means any Clinical Trial(s), which Clinical Trial(s) is (are) designed to (a) establish that the Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; and (c) be a pivotal study for submission of an Regulatory Approval Application to obtain Regulatory Approval for such Licensed Product in any region or regulatory jurisdiction, as defined in 21 C.F.R . § 312.21(c), or its foreign equivalent, as may be amended from time to time, or any analogous Clinical Trial described or defined in Applicable Laws.

1.100. " **PRC** " means the People's Republic of China, which for the purposes of this Agreement shall exclude Hong Kong, Macau, and Taiwan.

1.101. " **Prime Rate** " means for any day a per annum rate of interest equal to the "prime rate," as published in the "Money Rates" column of The Wall Street Journal, from time to time, or if for any reason such rate is no longer available, a rate equivalent to the base rate on corporate loans posted by at least percent (70%) of the ten largest U.S. banks.

1.102. " **Product Infringement** " shall have the meaning set forth in Section 14.4(a).

1.103. " **Product Marks** " shall have the meaning set forth in Section 9.4 .

1.104. " **Product Specifications** " means the acceptance criteria agreed by the Parties, including numerical limits, ranges or other criteria for the Licensed Product.

1.105. " **Public Official** " shall have the meaning set forth in Section 12.5(d).

1.106. " **Quality Agreement** " shall have the meaning set forth in Section 7.2.

1.107. " **Receiving Party** " shall have the meaning set forth in Section 11.1(a).

1.108. " **Reduced Taxes** " shall have the meaning set forth in Section 10.8.

1.109. **"Regional Studies"** shall have the meaning set forth in Section 5.2(b).

1.110. " **Regulatory Approval** " means, with respect to a Licensed Product in a region or a country, the approvals from the necessary Governmental Authority or Regulatory Authority to import, market and sell such Licensed Product in such region, including pricing approvals (but excluding reimbursement approvals **)** .

1.111. " **Regulatory Approval Application** " mean s a New Drug Approval Application or Biologics License Application (each, a s defined in the U.S . Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time) in the U.S., or any corresponding application for approval to market or sell a product in any country, region or jurisdiction in the Territory outside the U.S.

1.112. " **Regulatory Authority** " means any applicable Governmental Authority responsible for granting Regulatory Approvals for Licensed Products, including the NMPA, and any corresponding national or regional regulatory authorities.

1.113. " **Regulatory Submissions** " means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to a Licensed Product.

1.114. " **Remedial Action** " shall have the meaning set forth in Section 6.8 .

1.115. " **Replacement Site** " shall have the meaning set forth in Section 5.7(c).

1.116. " **Retained Rights** " shall have the meaning set forth in Section 2.2 .

1.117. " **Royalty Payment** " shall have the meaning set forth in Section 10.4(a).

1.118. " **Royalty Term** " shall have the meaning set forth in Section 10.4(b).

1.119. [***]

1.120. **"Sublicensee"** means a Third Party, or Zai's Affiliates who was granted a sublicense by Zai under the licenses granted in Section 2.1 . For clarity, a Third Party who was granted a sublicensee by a Sublicensee shall also be deemed a Sublicensee.

1.121. " **Supply Agreement** " shall have the meaning set forth in Section 7.2.

1.122. " **Supply Notice** " shall have the meaning set forth in Section 15.1(c).

1.123. " **Support Studies** " shall have the meaning set forth in Section 5.2(b).

1.124. [***]

1.125. [***]

1.126. " **Tax** " or " **Taxes** " means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon **)** . For the avoidance of doubt, Taxes includes VAT.

1.127. " **Term** " shall have the meaning set forth in Section 15.1 .

1.128. " **Territory** " means the PRC, Hong Kong, Macau, and Taiwan (which for purposes of this Agreement shall each be deemed a region **)** .

1.129. [***]

1.130. " **Third Party** " means an entity other than (a) Zai and its Affiliates or (b) Deciphera and its Affiliates.

1.131. " **Transition Period** " shall have the meaning set forth in Section 15.8(b)(iv).

1.132. " **U.S. Dollars** " or " **$** " means United States dollars, the lawful currency of the United States.

1.133. " **Upfront Payment** " shall have the meaning set forth in Section 10.1 .

1.134. " **Valid Claim** " means (a) a claim of an issued and unexpired Patent included within the Deciphera Program Patents that (i) covers the practice of the Licensed Product in the Territory that (ii) has not been permanently revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) a claim of a pending patent application included within the Deciphera Program Patents in the Territory that (1) would cover the practice of the Licensed Product in the Territory if such claim was to issue, (2) has not been pending for more than [***] from its earliest priority date, and (3) (A) has not been cancelled, withdrawn or abandoned or (B) finally rejected by an administrative agency action from which no appeal can be taken or that has not been appealed within the time allowed for appeal.

1.135. " **VAT** " means value-added taxes or other similar taxes.

1.136. [***]

1.137. " **Zai** " shall have the meaning set forth in the preamble of this Agreement.

1.138. " **Zai Acquired Party** " shall have the meaning set forth in Section 2.6(b)(iii).

1.139. " **Zai Indemnitee(s)** " shall have the meaning set forth in Section 13.2 .

1.140. " **Zai IP** " means any and all Know-How and Patents Controlled by Zai or its Affiliates as of the Effective Date or during the Term that are generated or used by Zai in the Development, packaging, having packaged, or Commercialization of a Licensed Product; provided that if any such Know-How or Patent is in-licensed by Zai from a Third Party, then such Know-How or Patent shall not be included in Zai IP unless Deciphera agrees in writing to comply (and does in fact comply) with the applicable terms and conditions of such Third Party license and to pay (and does in fact pay) any amount that Zai is obligated to pay such Third Party on account of Zai's grant and/or Deciphera's exercise of a sublicense under such Know-How or Patent .

ARTICLE 2

LICENSES; NON-COMPETE

2.1. License Grant to Zai .

(a) Subject to the terms and conditions of this Agreement, Deciphera hereby grants to Zai, during the Term, (i) an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.3, under the Deciphera Program IP to Develop, package or have packaged, distribute, use, sell, offer for sale, import and otherwise Commercialize the Licensed Products in the Field in the Territory; (ii) a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.3, under the Deciphera Background Know-How to Develop, package or have packaged, distribute, use, sell, offer for sale, import and otherwise Commercialize the Licensed Products in the Field in the Territory; and (iii) a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.3, under the Deciphera Program IP and Deciphera Background Know-How to package or have packaged the Licensed Product in [***] for Development, distribution, use, sale and Commercialization in the Field in the Territory.

(b) For clarity, the licenses granted under this Section 2.1 (i) do not include the right to primary or secondary Manufacture or to have Manufactured the Compound, Licensed Products or drug substance of the Licensed Products in the Field in the Territory but (ii) include the right for Zai to package the Licensed Product in the Territory solely pursuant to Section 7.1.

2.2. Deciphera Retained Rights . Notwithstanding anything to the contrary in this Agreement, Deciphera hereby expressly retains, on behalf of itself (and its Affiliates, licensees, and sublicensees) (a) all rights under the Deciphera IP to fulfill, either itself, its Affiliates or through subcontractors, Deciphera's obligations under this Agreement, (b) subject to Section 2.6 and subject to Zai's non-exclusive right to package or have packaged the Licensed Product in [***] in accordance with Section 2.1(a) , the exclusive rights with respect to Deciphera IP to the extent relating to the Development, Manufacture and Commercialization of the Compound or Licensed Product outside the Territory, and (c) (i) the non-exclusive rights under the Deciphera IP to Develop or have Developed, and (ii) the exclusive the rights to Manufacture or have Manufactured, in each case of (i) and (ii) the Compound or Licensed Product in the Territory solely to support (1)

the Development and Commercialization of the Licensed Product by Deciphera outside of the Territory or (2) the Development and Commercialization of the Licensed Product by Zai in the Territory (including through the conduct of Global Studies by Deciphera pursuant to Section 5.4) (the " **Retained Rights** "). In the event that Deciphera wishes to exercise its Retained Rights to Manufacture or have Manufactured the Licensed Product in the Territory, or to conduct the Global Studies in the Territory during the Term , Deciphera shall notify Zai in writing and the Parties shall discuss and coordinate regulatory activities relating to such Manufacture and Development activities in the Territory ; provided that in no event such discussion and coordination shall diminish Deciphera's sole discretion and final decision-making authority with respect to any Global Study . Zai acknowledges and agrees that the Retained Rights includes the right for Deciphera to grant licenses under clause (a) or clause (c) of the Retained Rights to its Affiliates and Third Parties in the Field in the Territory; provided that, except for sales to Zai, subject to Section 15.1 , during and after the expiration (but not early termination) of the Term, Deciphera shall not, and shall obligate its Affiliates, licensees, and sublicensees to not, sell or offer for sale in the Territory any Licensed Product Manufactured under the Retained Rights. For the avoidance of doubt, subject to Section 15.1 , the Retained Rights shall exclude the right under the Deciphera IP to Commercialize the Compound or Licensed Product in the Field in the Territory during and after the expiration (but not early termination) of the Term, and Deciphera, its Affiliates and licensees shall not undertake such Commercialization in the Field in the Territory without Zai's express prior written consent.

2.3. Right to Sublicense .

(a) **General** . [***] Zai shall have the right to grant sublicenses to any Third Party as proposed in writing by Zai under the licenses granted in Section 2.1 . [***]. Zai shall be liable for (i) its Sublicensee's conduct that is prohibited under this Agreement, and (ii) its Sublicensee's breach of this Agreement which shall be deemed a breach of this Agreement as if Zai had itself conducted the action or inaction attributed to the beach of this Agreement, provided that Zai shall have the right to cure, if curable, such breach on behalf of such Sublicensee within [***] days following the receipt of notice of such breach.

(b) **Restrictions** . Zai shall not grant a sublicense to any Third Party that has been debarred or disqualified by any Governmental Authority or is subject to any proceedings, sanctions or fines under any Anti-Corruption Law. Zai shall ensure that, prior to engaging any Third Party as a Sublicensee that such Third Party is subject to written agreements containing terms and conditions that : (i) require each such Sublicensee to protect and keep confidential any Confidential Information of the Parties, including in accordance with ARTICLE 11; (ii) provide Deciphera with the right to audit (either by itself or through Zai or Zai's designee) the books and records of each such Sublicensee in accordance with this Agreement (including pursuant to Sections 5.7(b), 6.5, 9.6 , 10.6(d) , and 12.5(a)(iv)); (iii) do not impose any payment obligations or liability on Deciphera; and (iv) are otherwise consistent with the terms of this Agreement. Zai shall provide a copy of the complete executed agreement with each Sublicensee to Deciphera; provided that Zai shall be permitted to redact commercially sensitive economic terms of any such agreement which terms are not necessary for Deciphera to confirm its rights hereunder. Zai shall remain primarily responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any Sublicensee.

2.4. License Grant to Deciphera . Zai hereby grants to Deciphera a perpetual, non-exclusive, fully paid-up and royalty free, transferrable, unlimited, sublicenseable (in multiple tiers) license under Zai IP to (a) f ulfill, eithe r itself, its Affiliates or through subcontractors, its obligations under this Agreement, including its manufacturing and supply obligations under ARTICLE 7 , (b) Develop or Manufacture the Compound and Licensed Product in the Territory solely for the purpose of the Development and Commercialization of the Compound and Licensed Product outside the Territory, and (c) Develop, Manufacture and Commercialize the Compound and Licensed Product outside the Territory.

2.5. No Implied Licenses; Negative Covenant . Except as set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Know-How, trademarks, patents or patent applications of the other Party. Each Party shall not, and shall not permit any of its Affiliates or sublicensees to, practice any Patent or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6. Exclusivity .

(a) **Non-Compete** . During the Term, except as provided in Section 2.6(b) below or otherwise expressly contemplated under this Agreement, neither Party shall, and each Party shall cause its Affiliates and Sublicensees to not, engage in (independently or for or with any Third Party) any Development, Manufacture or Commercialization in the Territory of any compound or product that is [***] ; provided that in the event (i) [***] ; and (ii) [***] , then (iii) the Parties shall discuss in good faith whether such pharmaceutical product would not be deemed a Competing Product for the purposes of this Agreement and (iv) [***] , shall such pharmaceutical product not be deemed a Competing Product.

(b) **Change of Control; Acquisition** .

(i) **Change of Control of a Party** . In the event that a Party or any of its Affiliates undergoes a Change of Control with a Third Party (a " **Acquirer** "), the restrictions set forth in Section 2.6(a) shall not apply to (1) any activities that would otherwise constitute a breach of Section 2.6(a), including a Competing Product that is being developed, manufactured or commercialized (collectively, " **Competing Activities** "), [***] .

(ii) **Acquisition of a Third Party by Deciphera** . In the event that Deciphera or any of its Affiliates merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transactions) (a " **Deciphera Acquired Party** "), the restrictions set forth in Section 2.6(a) shall not apply [***] .

(iii) **A cquisition of a Third Party by Zai** . In the event that Zai or any of its Affiliates merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transactions) (a " **Zai Acquired Party** "), that is performing any Competing Activities at the closing of such transaction, then [***] . Notwithstanding the foregoing, in the event [***] , then [***] unless and until [***] .

ARTICLE 3

GOVERNANCE

3.1. Alliance Managers . Within thirty (30) days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications (including a general understanding of pharmaceutical Development and Commercialization issues) to act as its alliance manager under this Agreement (the " **Alliance Manager** "). The Alliance Managers shall serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Alliance Managers shall (a) facilitate the flow of information; (b) otherwise promote communication, coordination and collaboration between the Parties, providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party or cross-functional disputes in a timely manner; and (c) manage the JSC meetings by (i) calling meetings of the JSC; (ii) preparing and issuing minutes of each such meeting within ten (10) Business Days thereafter; and (iii) preparing and circulating an agenda for the upcoming meeting, in each case at the direction of and in consultation with the then current chairperson. Each Party may replace its Alliance Manager by written notice to the other Party.

3.2. Joint Steering Committee .

(a) **Formation** . Within twenty (20) days after the Effective Date, the Parties shall establish a joint steering committee (the " **Joint Steering Committee** " or the " **JSC** ") to cooperate, coordinate, integrate, monitor and oversee the Development and Commercialization of the Licensed Products in the Field in the Territory under this Agreement. Each Party shall appoint three (3) representatives to the JSC, each of whom shall be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. Each Party may replace its JSC representatives upon written notice to the other Party. Upon the JSC's establishment, a representative from Zai shall act as the chairperson of the JSC. Once a year, the role of chairperson shall rotate between representatives of the Parties. The chairperson shall not have any greater authority than any other representative of the JSC.

(b) **Role** . The JSC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement; (ii) review, discuss and approve the overall strategy for the Development and Commercialization of the Licensed Product in the Field in the Territory; (iii) review, discuss and approve the Development Plan and amendments thereto; (iv) review and discuss the Commercialization Plan and amendments thereto; (v) review, discuss and approve the Product Specifications; (vi) establish subcommittees as necessary or advisable to further the purpose of this Agreement; (vii) report safety issues of the Licensed Products to Regulatory Authorities; (viii) manage the supply chain; (ix) through a subcommittee solely consisting of medical affairs personnel, review, discuss, and approve the Medical Affairs Plan and oversee the Medical Affairs activities of the Parties in the Territory; and (x) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

(c) **Limitation of Authority** . The JSC shall only have the powers expressly assigned to it in this ARTICLE 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement; (iv) make any decisions related to, [***] other matters related to [***] ; or (v) impose any other obligations on either Party without the prior written consent of such Party. Notwithstanding anything to the contrary under this Agreement or in the Development Plan, [***] .

(d) **Meetings** . The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every Calendar Quarter until the earlier of (i) one (1) year after the Effective Date, or (ii) Zai first receives a Regulatory Approval Application for the Licensed Product in the PRC. Thereafter, the JSC shall hold meeting no less frequently than once every six (6) months. Each Party may call additional ad hoc JSC meetings as the needs arise with reasonable advance notice to the other Party. Meetings of the JSC may be held in person , by audio or video teleconference; provided that at least one (1) meeting per Calendar Year of the JSC shall be held in person . In-person JSC meetings shall be held at locations selected alternately by the Parties. Each Party shall be responsible for such Party's expenses of participating in the JSC meetings. No action taken at any JSC meeting shall be effective unless at least two (2) representatives of each Party are participating in such JSC meeting.

(e) **Non-Member Attendance** . Each Party may from time to time invite a reasonable number of participants relevant to items on the issued agenda, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party. Such Party shall also ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(f) **Decision-Making** . All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach a decision as to such matter within [***] after such matter was brought to the JSC for resolution, such matter shall be referred by the Parties' Alliance Managers to the Chief Executive Officer of Deciphera (or a senior office designated by the Chief Executive Officer of Deciphera) and the Chief Executive Officer of Zai (or a senior office designated by the Chief Executive Officer of Zai) (the " **Executive Officers** ") for resolution. [***] .

(g) **Exchange of Information** . The Parties shall cooperate to exchange information with respect to Development, Commercialization and Medical Affairs activities conducted by each Party and their Affiliates, licensees and sublicensees. Such exchange shall include summaries of all Clinical Trials and other studies of the Licensed Product as reasonably requested by a Party . For Clinical Trials that may be used to support Regulatory Approval in the other Party's Territory (including Global Studies), such exchange shall also include all data, results and analyses as reasonably requested by a Party, and the other Party shall have the right to use such data and results for the purpose of obtaining and maintaining Regulatory Approval of the Licensed Product in its territory.

ARTICLE 4

DEVELOPMENT TECHNOLOGY TRANSFERS

4.1. Transfer of Deciphera Know-How . Deciphera shall transfer to Zai all Deciphera Know-How listed in Schedule 1.31 and Schedule 1.37 to the extent necessary or reasonably useful for Zai to perform its obligations under this Agreement , which transfer shall occur in a manner and following a reasonable schedule established by the JSC. During the Term, Deciphera shall provide Zai with additional Deciphera Know-How, to the extent such Deciphera Know-How comes to Deciphera's attention (or are reasonably requested by Zai) and have not previously been provided to Zai, to the extent necessary or reasonably useful for Zai to exercise its rights or perform its obligations under this Agreement.

4.2. Assistance by Deciphera . At Zai's reasonable request, Deciphera shall cooperate with Zai to provide such reasonable technical assistance as may be necessary in connection with (a) the transfer to Zai of the Development of Licensed Products in the Territory and (b) the seeking of Regulatory Approval for Licensed Products in the Territory, in each case as is consistent with the capacity and capabilities of Deciphera. Upon Zai's request for any reasonable technical assistance, Deciphera shall provide Zai with such reasonable technical assistance [***] . For clarity, [***] part of technical assistance provided to Zai by Deciphera to the extent [***] .

4.3. No Manufacturing Technology Transfer . For the avoidance of doubt, Deciphera shall not be obligated to transfer any Know-How Controlled by Deciphera or its Affiliates or otherwise relating to the Manufacture of the Licensed Product to Zai.

ARTICLE 5

DEVELOPMENT

5.1. Diligence and Responsibilities .

(a) Zai shall be responsible for, and shall use Commercially Reasonable Efforts to, Develop the Licensed Product in the Field in the Territory in accordance with the Development Plan. For clarity, Zai shall use Commercially Reasonable Efforts to Develop the Licensed Products pursuant to the Development Plan [***] .

(b) Zai shall use Commercially Reasonable Efforts to conduct its tasks pursuant to the Development Plan and to achieve the objectives of the Development Plan. Zai shall perform such obligations under the Development Plan in a professional manner, and in compliance in all respects with the Development Plan and the requirements of Applicable Laws, GCP and cGMP. Changes in the scope or direction of the Development work under this Agreement that would require a material deviation from the Development Plan must be approved by the JSC as set forth in Section 3.2(b) .

(c) Zai shall use Commercially Reasonable Efforts to Develop the Licensed Product through the most expeditious available regulatory pathway in the Territory.

5.2. D evelopment Plan . The Parties shall undertake the Development of the Licensed Product in a collaborative and efficient manner in accordance with this ARTICLE 5. The Development of the Licensed Product relating to the Territory under this Agreement shall be governed by a written Development Plan (the **"Development Plan"**), as such Development Plan may be revised from time to time in accordance with this Section 5.2 . The Development Plan shall also include an outline of the Global Studies ; provided that for clarity, such outline shall be for purposes of reference only [***] . Deciphera shall provide Zai with the protocol of the Global Studies upon request. The Development Plan shall contain in reasonable detail the major Development activities and the timelines for achieving such activities, including activities designed to achieve Regulatory Approvals for the Licensed Product in the Territory [***] . As of the Effective Date, the Parties have agreed to the initial Development Plan , which is attached hereto as Schedule 5.2 (the " **Initial Development Plan** "). From time to time, [***] , Zai shall propose updates or amendments, if any, to the Development Plan in consultation with Deciphera and submit such proposed updated or amended plan to the JSC for review, discussion, and approval. In accordance with Section 3.2(b) , the JSC shall review and approve any updates or amendments to the Development Plan.

(a) The Initial Development Plan shall list those activities that the Parties mutually agree that Zai shall undertake over a [***] period from the Effective Date for the purpose of coordinating and integrating the Development activities for the worldwide Development of the Licensed Products.

(b) The Initial Development Plan shall include (i) a list of any non-clinical studies or Clinical Trials in the Territory or outside the Territory (other than the Global Studies) that the Parties mutually agree would be required to support the regulatory activities in the Territory, such as drug interaction studies or comparability studies in connection with any manufacturing process changes (the " **Support Studies** "), or (ii) any country-specific development plans required to support registration of a Licensed Product in one or more regions in the Territory that are not covered under the Global Studies or Support Studies (the " **Regional Studies** ").

5.3. Abandoned Development . If, prior to the First Commercial Sale of any Licensed Product Developed under the Development Plan, (a) no Active Development Activities (as defined below) have been conducted by Zai, its Affiliates or permitted Sublicensee for [***] , (b) such inactivity was not caused by a Serious Adverse Event or Serious Adverse Drug Reaction reported pursuant to the Pharmacovigilance Agreement, Regulatory Authority or was not due to a force majeure event or Deciphera's failure to supply sufficient quantities of the Licensed Product to Zai, and (c) Deciphera has complied with its obligations under this Agreement and the Supply Agreement during such time period, then Zai shall be deemed to have abandoned the Development under the applicable Development Plan for the Licensed Product therein (" **Abandoned Development** "). [***] . " **Active Development Activities** " exists if Zai has performed or is performing any of the following Development activities: [***] .

5.4. Global Study .

(a) **General** . Deciphera (i) may initiate, suspend, or cease a Global Study for the Licensed Product for any Indication and (ii) shall [***] such Global Study or [***] such Global Study. The Parties acknowledge that Deciphera is currently conducting a Global Study for the Licensed Product for [***] . Notwithstanding anything to the contrary hereunder, (1) Deciphera shall be responsible for all Clinical Trial costs for any Global Study initiated and conducted by Deciphera [***] in the Territory, such costs to exclude all FTE costs and related expenses incurred by Zai in providing such assistance (referred to in the preceding sentence) in the Territory related to a Global Study, (2) [***] , (3) Zai shall provide reasonable assistance [***] to Deciphera for any such Global Study in the Territory upon reasonable request of Deciphera, (4) Deciphera shall keep Zai reasonably informed of any material activities or progress of any such Global Study to the extent related to the Development of the Licensed Products in the Territory, and (5) Zai may provide recommendations or advice on Clinical Trial sites, and other Territory-specific matters in relation to any such Global Study, which Deciphera shall consider in good faith; provided, however, [***] .

(b) [***] .

5.5. Development Reports . The status, progress and results of Zai's Development activities under this Agreement shall be discussed at meetings of the JSC. At least [***] each regularly scheduled JSC meeting, Zai shall provide the JSC with a written report detailing its Development activities and the results thereof, covering subject matter at a level of detail reasonably required by Deciphera and sufficient to enable Deciphera to determine Zai's

compliance with its diligence obligations pursuant to Section 5.1 and Section 5.3 . Through the JSC, Deciphera shall keep Zai reasonably informed on the Development of the Licensed Product conducted by or on behalf of Deciphera, including t he Global Studies and Support Studies . In addition, each Party shall make available to the other Party such additional information about its Development activities as may be reasonably requested by the other Party from time to time. All updates and reports provided by a Party pursuant to this Section 5.5 shall be the Confidential Information of such Party.

5.6. Development Costs . Zai shall be solely responsible for all expenses and costs incurred for all Development, packaging, having-packaged, and Commercialization of the Licensed Products in the Territory and packing and having-packaged in [***] , including those incurred for the Regional Studies in the Territory but expressly excluding the cost of any Global Studies (which cost shall be borne solely by Deciphera unless otherwise agreed by the parties in writing) pursuant to Section 5.4, [***] . Zai shall be responsible for all expenses and costs incurred for the portion of the Support Studies that is conducted in the Territory and Deciphera shall be responsible for all expenses and costs incurred for the portion of such Support Studies that is conducted outside the Territory.

5.7. Clinical Trial Audit Rights .

(a) **Clinical Trials** . Each Party shall conduct all Clinical Trial of the Licensed Products in compliance with all Applicable Laws, including GCP and regulations promulgated by the NMPA and FDA.

(b) **Conduct of Audits** . [***] Deciphera or its representatives may conduct an audit of Zai, its Affiliates, or any Sublicensees, subcontractors, and all Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees, subcontractors to perform Zai's obligations under any Development Plan, in each case, to ensure that the applicable Clinical Trials are conducted in compliance with the Development Plan, GCP , and Applicable Laws; provided that in the event any such audit of Zai's subcontractors or Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees, subcontractor requires Zai's assistance, Zai shall provide Deciphera or its representatives with such assistance, to the extent reasonable, including providing personnel of Zai to be present for such audit and producing any documents or authorizations allowing Deciphera or its representatives to conduct such audit , to the extent reasonable. No later than thirty (30) days after the completion of such audit, Deciphera shall provide Zai with a written summary of Deciphera's findings of any deficiencies or other areas of remediation that Deciphera identifies during any such audit. Zai shall use Commercially Reasonable Efforts to respond or remediate any such deficiencies within thirty (30) days following Deciphera's receipt of such report. Without limiting the foregoing, Zai shall have the right to be present at any such audit conducted by Deciphera pursuant to this Section 5.7 of any Sublicensees, subcontractors, subcontractors or Clinical Trial sites. For the avoidance of doubt, [***] .

(c) **Deficient Sites and Replacement** . With res pect to any Clinical Trial in a Support Study or Regional Study, if the Parties acting reasonably and in good faith agree that any deficiencies with respect to a Clinical Trial site identified pursuant to Section 5.7(b) (each, a " **Deficient Site** ") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from the con duct of any such Clinical Trial at such Deficient Site, then Deciphera shall notify Zai of such Deficient Site and the Parties shall discuss and attempt to agree upon a remediation plan for such Deficient Site. If the Parties cannot agree to such a remediation plan for a Deficient Site, then Zai shall promptly remove such Deficient Site from such Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a " **Replacement Site** ") in the Territory, and Zai shall be solely responsible for the costs of such replacement (unless not permitted by Applicable Law or for ethical reasons). Any such Replacement Site shall be compliant in all respects with Applicable Law.

5.8. Records . Each Party shall maintain appropriate records in either tangible or electronic form of (a) all significant Development, Manufacture, final packaging, and Commercialization events and activities conducted by it or on its behalf related to a Licensed Product; and (b) all significant information generated by it or on its behalf in connection with the Development, Manufacture, packaging, or Commercialization of a Licensed Product, in each case in accordance with its usual documentation and record retention practices. Such records shall be in sufficient detail to properly reflect, in a good scientific manner, all significant work done, and the results of studies and trials undertaken and, further, shall be at a level of detail appropriate for patent and regulatory purposes. Each Party shall document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines. Upon a Party's reasonable request, the other Party shall, and shall cause its Affiliates and Sublicensees, to provide to the first Party copies of such records (including access to relevant databases, if any) of Development, packaging, and Commercialization activities to the extent necessary for the Development, packaging, and Commercialization of the Licensed Product in the other Party's territory , including for regulatory and patent purposes. All such records, reports, information and data provided shall be subject to the confidentiality provisions of ARTICLE 11.

ARTICLE 6

REGULATORY

6.1. Zai's Responsibilities . Zai shall use Commercially Reasonable Efforts to obtain Regulatory Approvals and pricing and reimbursement approvals for Licensed Products in the Territory in accordance with the Development Plan and Zai shall be solely responsible for all costs and expenses incurred in connection with performing such activities in the Territory. Zai shall be responsible for all regulatory activities leading up to and including the obtaining of the Regulatory Approvals for a Licensed Product from the Regulatory Authority on a region-by-region basis, at its sole cost and expense. Zai or its designee shall own, hold and maintain all Regulatory Approvals for a Licensed Product in the Territory; provided however that [***] ; provided that in the event [***] . Zai shall keep Deciphera promptly informed of regulatory developments related to the Licensed Products in the Territory and shall promptly notify Deciphera in writing of any decision by any Regulatory Authority in the Territory regarding a Licensed Product.

(a) **Review of Regulatory Submissions** . Each Party shall provide to Deciphera for review and comment drafts of all Regulatory Submissions in the Territory for the Licensed Products no later than [***] prior to the planned submission. Each Party shall incorporate any comments received from the other Party on such Regulatory Submissions where required under any Applicable Law and shall consider in good faith any other comments received from the other Party on such Regulatory Submissions. In addition, each Party shall notify the other Party of any material Regulatory Submissions for the Licensed Products and any other material documents, comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and shall provide such other Party with copies thereof as soon as reasonably practicable, but in all events within [***] after submission or receipt thereof. If any such Regulatory Submission, comment, or correspondence is not in English, then, at the other Party's request and expense, the Party providing such copies shall also provide the other Party with a written English translation within the corresponding timelines as set forth in this ARTICLE 6 .

(b) **Notice of Meetings** . Each Party shall provide the other Party with notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Licensed Product no later than [***] after receiving notice thereof. The notifying Party shall lead any such meeting or discussion and the other Party or its designee shall have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. At the notifying Party's request, the other Party shall reasonably cooperate with the notifying Party in preparing for any such meeting or discussion. If the notified Party elects not to attend such meeting or discussion, then the notifying Party shall provide to the other Party a written summary thereof in English promptly following such meeting or discussion.

(c) **Notice of Regulatory Action** . If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Zai relating to any Licensed Product, then Zai shall notify Deciphera of such contact, inspection, or notice or action within [***] after receipt of such notice (or, if action is taken without notice, within [***] of Zai becoming aware of such action). Deciphera shall have the right to review and comment on any other responses to Regulatory Authority that pertain to a Licensed Product in the Territory.

6.2. Deciphera's Responsibilities . Deciphera shall reasonably cooperate with Zai in obtaining any Regulatory Approvals for a Licensed Product in the Territory by providing, to the extent reasonably required by Zai, access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for the Licensed Product outside of the Territory pursuant to ARTICLE 4 if such information is required in furtherance of such Regulatory Approvals. In addition, upon Zai's reasonable request, Deciphera shall, and shall cause its Affiliates and sublicensees (to the extent permitted in such sublicensees' agreement with Deciphera), to provide to Zai copies of such records of Development, Manufacturing, and Commercialization activities to the extent necessary or reasonably useful to obtain Regulatory Approval of the Licensed Product in the Territory. [***] .

6.3. Right of Reference . Each Party hereby grants to the other Party the right of reference to all Regulatory Submissions pertaining to the Licensed Product in the Field submitted by or on behalf of such Party. Zai may use such right of reference to Deciphera's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining Regulatory Approval of the Licensed Products in Field in the Territory. Deciphera may use the right of reference to Zai's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining Regulatory Approval of the Licensed Products outside the Territory.

6.4. Adverse Events Reporting .

(a) Promptly following the Effective Date, but in no event later than thirty (30) days thereafter, Zai and Deciphera shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Products, such as safety data sharing and exchange, Adverse Events reporting and prescription events monitoring in a written agreement (the " **Pharmacovigilance Agreement** "). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other safety problem of any significance, and product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The Pharmacovigilance Agreement shall be promptly updated if required by changes in legal requirements. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations. To the extent there is any disagreement between this Section 6.4 , Section 6.5 , or any related definitions and the Pharmacovigilance Agreement, the Pharmacovigilance Agreement shall control with respect to safety matters and this Agreement shall control with respect to all other matters.

(b) Zai shall be responsible for complying with all Applicable Laws governing Adverse Events in the Territory for all Clinical Trials performed by Zai and Deciphera shall be responsible for complying with all Applicable Laws covering Adverse Events (i) in the Territory for all Clinical Trials performed by Deciphera [***] and (ii) outside the Territory for all Clinical Trials.

6.5. Safety and Regulatory Audits . In addition to Deciphera's right to conduct Clinical Trial audits pursuant to Section 5.7 , upon reasonable notification, Deciphera shall be entitled to conduct an audit of safety and regulatory systems, procedures and practices of Zai, including on-site evaluations to the extent permitting such on-site evaluations is in the control of Zai. With respect to any inspection of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to any Licensed Product, Zai shall notify Deciphera of such inspection (a) no later than [***] after Zai receives notice of such inspection or (b) within [***] after the completion of any such inspection of which Zai did not receive prior notice. Zai shall promptly provide Deciphera with all information related to any such inspection. Zai shall also permit Governmental Authorities outside of the Territory to conduct inspections of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product, and shall ensure that all such Affiliates or Sublicensees permit such inspections. Deciphera shall have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority),

to be present at any such inspection. Following any such regulatory inspection related to the Licensed Products, Zai shall provide Deciphera with (i) an unredacted copy of any finding, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Product) within [***] of Zai receiving the same, and (ii) in the event that s uch findings, notice, or report [***] such finding, notice, or report of a Governmental Authority related to such inspection (to the extent related to the Licensed Product) [***] receiving the sam e . Further details including notification, timing, response and scope of such audits shall be included in the Pharmacovigilance Agreement .

6.6. No Harmful Actions . If Deciphera believes that Zai is taking or intends to take any action with respect to a Licensed Product that could have a material adverse impact upon the regulatory status of the Licensed Product outside the Territory, Deciphera shall have the right to bring the matter to the attention of the JSC and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (a) Zai shall not communicate with any Regulatory Authority having jurisdiction outside the Territory, unless so ordered by such Regulatory Authority, in which case Zai shall immediately notify Deciphera of such order; and (b) Zai shall not submit any Regulatory Submissions or seek Regulatory Approvals for the Licensed Product outside the Territory.

6.7. Notification of Threatened Action . Each Party shall [***] the other Party of any information it receives regarding any threatened or pending action, inspection or communication by any Third Party, which would reasonably be expected to affect the safety or efficacy claims of any Licensed Product or the continued marketing of any Licensed Product (as to Deciphera's notification obligation, only to the extent it would reasonably be expected to affect the Territory). Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action with respect to the Territory.

6.8. Remedial Actions . Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (as to Deciphera's notification obligation, only to the extent it would reasonably be expected to affect the Territory) (a " **Remedial Action** "). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action with respect to the Territory. Zai shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action; provided that Deciphera shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory to the extent related to any Global Study. The cost and expenses of any Remedial Action in the Territory shall be borne solely by the Party with sole discretion, provided however that to the extent a Remedial Action in the Territory results primarily from the failure of the Licensed Product supplied by Deciphera to comply with the Product Specifications , product warranties (as set forth in the Supply Agreement) and Applicable Laws, including cGMP requirements, then Deciphera shall reimburse Zai for the reasonable cost and expense of such Remedial Action if this is required and after consultation with Deciphera . Each shall, and shall ensure that its Affiliates and sublicensees shall, maintain adequate records to permit the Parties to trace the distribution and use of the Licensed Product in the Territory.

ARTICLE 7

MANUFACTURING

7.1. **Packaging** . Zai shall (a) be responsible for, and use Commercially Reasonable Efforts to package or have packaged the Licensed Products, sufficient and solely to meet the Development and Commercialization requirements of a Licensed Product in the Territory, at its sole cost and expense, and (b) undertake such activities of the Licensed Products in accordance with the Product Specifications. Zai may not manufacture Licensed Products other than as otherwise specified in this Section 7.1.

7.2. **Supply of Licensed Products** . Customary terms of forecasting and ordering procedures, Product Specifications, and other operational matters relating to the supply of the Licensed Product under this Section 7.2 shall be set forth in a supply agreement to be mutually agreed upon by the Parties consistent with this ARTICLE 7 to be executed by the Parties within [***] following the Effective Date (the " **Supply Agreement** "). In connection with such Supply Agreement, the Parties shall enter into a quality agreement governing the agreed upon specifications and other technical aspects of the Licensed Product (the " **Quality Agreement** "). Subject to the terms of this ARTICLE 7 , the Supply Agreement and Quality Agr eement, Deciphera shall, itself or through one or more CMOs, (a) [***] . Zai or its Affiliates shall (i) obtain and maintain all required import licenses, and shall serve as importer of record for all Licensed Products delivered in or into any region in the Territory pursuant to this Agreement and the Supply Agreement; and (ii) be responsible for all customs' duties, import tariffs, taxes, freight, insurance, inspection costs and the like attributed to or for the transport and importation of the Licensed Product in or into any region in the Territory.

7.3. [***] .

7.4. [***] .

ARTICLE 8

MEDICAL AFFAIRS

8.1. **Medical Affairs Plans** . [***] the Effective Date , Zai shall develop and provide a preliminary draft of the Medical Affairs Plan for the Licensed Product to the JSC's subcommittee represented solely by medical affairs personnel for its review, discussion and approval. Upon approval and thereafter, Zai shall (a) undertake the major Medical Affairs activities for the Licensed Products in the Territory and the estimated timelines for performing such activities pursuant to the Medical Affairs Plan; and (b) from time to time but no less frequent than [***], propose updates or amendments to the Medical Affairs Plan for the JSC subcommittee's review, discussion and approval.

8.2. Medical Affairs Reports . For each Calendar Year following the first Regulatory Approval for a Licensed Product in the Territory, Zai shall provide to Deciphera a report (by means of a slide presentation or otherwise) summarizing the Medical Affairs activities performed by or on behalf of Deciphera and its Affiliates and Sublicensees in the Territory for the Licensed Product in each region in the Territory since the prior report provided by Zai. Such reports shall be Confidential Information of Zai and subject to the terms of ARTICLE 11 . Zai shall provide updates to any such report at each meeting of the subcommittee established by the JSC to oversee the Medical Affairs activities under this Agreement.

8.3. Coordination of Medical Affairs Activities . The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the License Products inside and outside of the Territory. Accordingly, the Parties shall coordinate such activities through the subcommittee established by the JSC to oversee the Medical Affairs activities under this Agreement where appropriate.

ARTICLE 9

COMMERCIALIZATION

9.1. Commercialization Diligence . Zai shall be responsible for, and use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Commercialization Plan, at its sole cost and expense. Upon Zai's reasonable request, Deciphera shall reasonably assist Zai in such Commercialization of the Licensed Product [***] .

9.2. Commercialization Plan . The Commercialization Plan shall contain in reasonable detail the major Commercialization activities and the timelines for achieving such activities, including [***] in the Territories. Zai shall deliver an initial Commercialization Plan to the JSC for review and discussion no later than [***] of the first Regulatory Approval for a Licensed Product in the Territory. Thereafter, from time to time, but at least [***] , Zai shall propose updates or amendments to the Commercialization Plan to reflect changes in such plans, including those in response to changes in the marketplace, relative success of the Licensed Product, and other relevant factors influencing such plan and activities, and submit such proposed updated or amended Commercialization Plan to the JSC. In preparing the initial Commercialization Plan and any updates or amendments thereto, Zai shall provide Deciphera with an opportunity to comment and Zai shall consider any Deciphera's comments in good faith in finalizing the initial Commercialization Plan and any updates or amendments thereto.

9.3. Commercialization Reports . Zai shall update the JSC at each regularly scheduled JSC meeting regarding Zai's Commercialization activities with respect to the Licensed Products in the Territory. Each such update shall be in a form to be agreed by the JSC and shall summarize Zai's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Licensed Products in the Territory, covering subject matter at a level of detail reasonably required by Deciphera and sufficient to enable Deciphera to determine Zai's compliance with its diligence obligations pursuant to Section 9.1 . In addition, Zai shall make available to Deciphera such additional information about its Commercialization activities as may be reasonably requested by Deciphera from time to time. All updates and reports generated pursuant to this Section 9.3 shall be the Confidential Information of Zai.

9.4. Product Trademarks . Zai shall only use (pursuant to this Section 9.4) the trademarks Controlled by Deciphera in the Territory as Deciphera may provide to Zai in writing from time to time (the " **Deciphera Product Marks** ") and shall use the English mark thereof with Chinese phonetic translation below. Deciphera hereby grants to Zai, during the Term and subject to the terms and conditions of this Agreement, a royalty-free, exclusive license under Deciphera's rights to use such Deciphera Product Marks in connection with the Commercialization of the Licensed Products in the Field in the Territory in compliance with Applicable Laws. Zai may also brand the Licensed Products in the Territory using other trademarks, logos, and trade names specific for the Licensed Product; provided, *however* , that (a) prior to such use, Zai shall submit such trademarks, logos and trade names for Deciphera's prior written approval, (b) upon Deciphera's prior written approval, such trademarks, logos and trademarks shall be deemed owned by Zai (the " **Product Marks** "). Zai shall own all rights in the Product Marks in the Territory and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary. Upon Zai's request, Deciphera shall reasonably assist Zai in the selection and design of the Product Marks at Zai's cost. Zai shall comply with Deciphera's brand usage guidelines provided to Zai in its use of the Deciphera Product Marks. For the avoidance of doubt, Deciphera (i) has sole discretion regarding prosecution and maintenance of the Deciphera Product Marks, provided that, after Zai has initiated launch efforts to Commercialize the Licensed Product under any particular Deciphera Product Mark, Deciphera shall notify Zai in writing of any decision to modify or discontinue the application or registration of such Deciphera Product Mark in the Territory, and shall not carry out such modification or discontinuation without Zai's prior written consent (not to be unreasonably withheld), further provided that Deciphera shall not be required to obtain Zai's consent if such modification or discontinuation is required by the applicable Regulatory Authority in the Territory or is necessary to avoid any potential infringement of the rights of any Third Party, and (ii) has no obligation to ensure that, and provides no guarantee that, any applications included in the Deciphera Products Marks issues to a registered trademark in the Territory.

9.5. Commercialization Assistance . [***] provide assistance to Zai at Zai's request for the Commercialization activities, including assistance pursuant to Sections 9.1 and 9.4 as requested by Zai.

9.6. Compliance . Zai shall (a) comply, and shall cause its Affiliates and Sublicensees to comply, with all Applicable Laws and all applicable cGMP, GCP, GLP and GSP (or similar standards) in their conduct of the Development, packaging, and Commercialization activities under this Agreement and (b) ensure that its Affiliates and Sublicensees do not transfer or divert the Compound or Licensed Product to an entity other than Zai, or an entity approved by Zai, in each case in a manner that would cause the sale of such Compound or Licensed Product in the chain of distribution (from Zai or its Affiliates or Sublicensees to the end user) to be excluded (except as an exception provided in the Net Sales definition) in the calculation of Net Sales, provided that for each unit of the Compound or Licensed Product, the inclusion of such sales in the calculation of Net Sales shall occur only once. Upon reasonable notification, Deciphera shall have the right to conduct audits of Zai, and Zai shall procure such right for Deciphera to audit Zai's Affiliates and Sublicensees (either directly or through Zai and its designee), to ensure (i) compliance with applicable cGMP, GCP, GLP, and GSP standards, including on-site evaluations (to the extent permitting such evaluations is under the control of the audited Party), and (ii) compliance with this Section 9.6.

9.7. No Diversion . (a) Each of Deciphera and Zai hereby covenants and agrees that it shall not, and shall ensure that its Affiliates and sublicensees shall not, directly or indirectly, promote, market, distribute, import, sell or have sold the Licensed Products, including via internet or mail order, outside its territory ; (b) With respect to any country or region outside its territory, each Party shall not, and shall ensure that its Affiliates and their respective sublicensees shall not: (i) unless otherwise agreed by the Parties in writing, establish or maintain any branch, warehouse or distribution facility for Licensed Products in such countries (except, in the event such Party is Zai, Zai shall have the right to [***] solely to support the packaging and having-packaged activities of the Licensed Product by Zai or its Affiliates in [***]) , (ii) engage in any advertising or promotional activities relating to Licensed Products that are directed primarily to customers or other purchaser or users of Licensed Products located in such countries, (iii) solicit orders for Licensed Products from any prospective purchaser located in such countries, or (iv) sell or distribute Licensed Products to any person in such Party's territory who intends to sell or has in the past sold Licensed Products in such countries ; (c) if a Party receives any order for any Licensed Product from a prospective purchaser reasonably believed to be located in a region or country outside its territory, such Party shall promptly refer that order to the other Party, and such Party shall not accept any such orders ; (d) neither Party shall deliver or tender (or cause to be delivered or tendered) Licensed Products into a country or region outside its territory ; and (e) each Party shall not, and shall ensure that its Affiliates and their respective sublicensees shall not, knowingly restrict or impede in any manner the other Party's exercise of its exclusive rights to Commercialize the Licensed Products in its territory. For the purpose of this Section 9.7 , Zai's territory shall mean all countries and regions in the Territory and Deciphera's territory shall mean all countries and regions outside the Territory.

ARTICLE 10

PAYMENTS AND MILESTONES

10.1. Upfront Payment . In partial consideration of the rights granted by Deciphera to Zai hereunder, Zai shall pay to Deciphera an irrevocable, non-refundable, non-creditable amount of twenty million U.S. Dollars ($20,000,000) (the " **Upfront Payment** ") within [***] of the Effective Date.

10.2. Development Milestones Payments to Deciphera .

(a) Subject to Section 5.4(b) , in partial consideration of the rights granted herein, when each distinct Licensed Product first achieves the Milestone Events set forth below (each such event, a " **Development Milestone Event** ") Zai shall pay to Deciphera the following irrevocable, non-refundable, non-creditable Development milestone payments (each such payment, a " **Development Milestone Payment** ") within [***] of the achievement of the corresponding Milestone Events.

Development Milestone Event	Development Milestone Payment
The [***] in the INTRIGUE Study	Five Million U.S. Dollars ($5,000,000)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) For the avoidance of doubt , (i) each Development Milestone Payment shall be payable on the first occurrence of the corresponding Development Milestone Event for a distinct Licensed Product, and (ii) none of the Development Milestone Payments shall be payable more than once for each distinct Licensed Product. For the purpose of this Section 10.2, a Licensed Product is distinct if [***] for which the applicable Development Milestone Payment was made. [***]. Notwithstanding the foregoing, in the event that Zai discontinues the Development of a Licensed Product, any Development Milestone Payment made with respect to such discontinued Licensed Product shall be credited against the corresponding Milestone Payments payable on another Licensed Product that achieves such milestones.

(c) If a Development Milestone Event described in the table above in this Section 10.2 is achieved for a Licensed Product before the achievement of a preceding Development Milestone Event listed in such table with respect to the same Indication, then all preceding Development Milestone Event(s) shall be deemed automatically achieved, and the corresponding Development Milestone Payment(s) shall be due and payable together with the payment of the Development Milestone Payment for the subsequent achieved Development Milestone Event. [***] in relation to a Licensed Product is achieved, both Development Milestone Events in relation to such Licensed Product for [***] shall be deemed automatically achieved, and the corresponding Development Milestone Payments for both Development Milestone Events in relation to such Licensed Product for [***] shall be due (if not already achieved and paid) immediately with the corresponding Development Milestone Payment for such Development Milestone Event in relation to a Licensed Product for [***] .

10.3. Sales Milestones .

(a) In partial consideration of the rights granted herein, Zai shall pay to Deciphera the following milestone payments (each such payment, a " **Net Sales Milestone Payment"**) for the achievement of the corresponding Net Sales milestone events set forth below (each such event, a " **Net Sales Milestone Event** ") within [***] after the end of the Calendar Quarter in which the Net Sales Milestone Event occurs.

Net Sales Milestone Event	Net Sales Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) For the avoidance of doubt (i) each Net Sales Milestone Payment shall be payable on the first occurrence of the corresponding Net Sales Milestone Event, and (ii) none of the Net Sales Milestone Payments shall be payable more than once.

10.4. Royalties .

(a) **Royalty Payment** . During the Royalty Term, Zai shall pay to Deciphera tiered royalties as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated Net Sales of all Licensed Product in the Territory in a Calendar Year (a " **Royalty Payment** "). The tiered royalty rates on Net Sales shall be as set forth below:

For that portion of annual Net Sales in a Calendar Year	Royalty %
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) **Royalty Term.** The Royalty Payments payable under this Section 10.4 shall be payable on a region-by-region and Licensed Product-by-Licensed Product basis from the First Commercial Sale of a Licensed Product in such region until the later of: (i) the abandonment, expiry or final determination of invalidity of the last Valid Claim within the Deciphera Program Patent in such region in the Territory; (ii) the expiry of the regulatory exclusivity for such Licensed Product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the First Commercial Sale of such Licensed Product in such region (the " **Royalty Term** ").

(c) **Royalty Reductions.**

(i) D uring the Royalty Term for a Licensed Product in a region in the Territory, subject to Section 10.4(c)(iv), the royalty rate applicable to Net Sales of such Licensed Product in such region shall be reduced by [***] after the expiration of the last Valid Claim that covers such Licensed Product in such region.

(ii) During the Royalty Term for a Licensed Product in a region in the Territory, subject to Section 10.4(c)(iv), the royalty rate applicable to Net Sales of such Licensed Product in such region shall be reduced by [***] after the first commercial sale of a Generic Product of such Licensed Product in such region , pursuant to Regulatory Approval. For the purpose of this Section 10.4, " **Generic Product** " means, with respect to a particular Licensed Product in a particular region, any pharmaceutical product that contains the same active ingredient as such Licensed Product and obtained regulatory approval in such region on an expedited or abbreviated basis in a manner relied on or incorporated data submitted by Deciphera, Zai, their Affiliates, licensees or sublicensees for such Licensed Product.

(iii) If Zai reasonably determines in good faith after advice of counsel that it is necessary for Zai to obtain a license under any Patents owned or controlled by a Third Party in order to Develop or Commercialize the Licensed Product in the Territory, subject to Section 10.4(c)(iv) , Zai shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this Section 10.4, an amount equal to [***] of the royalties paid by Zai to such Third Party pursuant to such license on account of the sale of the Licensed Product in the Territory ; provided that (1) prior to entering into such license, Zai shall [***] ; and (2) in the event [***] , (A) [***] , (B) [***] , and (C) if [***] , then the Parties shall [***] (and, for clarity, [***]); further provided that if [***] for Zai to Develop or Commercialize the Licensed Product in the Territory, the royalty reduction mechanism described in this Section 10.4(c)(iii) shall [***] . Within [***] following the execution of any such Third Party license, Zai shall provide Deciphera with a true and complete copy of such Third Party licens e.

(iv) Notwithstanding the foregoing, in no event shall the operation of Section 10.4(c)(i) through (iii), individually or in combination, reduce the royalties paid to Deciphera with respect to the Net Sales of any Licensed Product in any region in the Territory in any Calendar Quarter to less than [***] of the amount that would otherwise have been due pursuant to Section 10.4(a) with respect to such Net Sales.

(d) **Royalty Estimate and Royalty Reports** . Following the First Commercial Sale of a Licensed Product for which royalties are due pursuant to this Section 10.4 , and continuing for so long as royalties are due hereunder:

(i) Zai shall, within [***] Business Days after the end of each Calendar Quarter, provide Deciphera with a good faith estimate of the royalties due for such Calendar Quarter.

(ii) Zai shall, within [***] days after the end of each Calendar Quarter, provide Deciphera with a royalty report showing, on a region-by-region basis:

(1) the Net Sales of each Licensed Product sold by Zai, its Affiliates and Sublicensees during such Calendar Quarter reporting period;

(2) the Royalty Payments in United States dollars which shall have accrued hereunder with respect to such Net Sales, with supporting calculations showing the applicable royalty rate applied and any royalty reduction taken;

(3) the rate of exchange with supporting calculations, determined in accordance with Section 10.5(b), used by Zai in determining the amount of United States dollars payable hereunder.

(4) attaching a pro forma invoice in a form and with information acceptable to Zai which Deciphera can issue to Zai in relation to such Royalty Payment.

(e) **Royalty Payment** . After the receipt of each royalty report provided by Zai under Section 10.4(d) above, Deciphera shall submit to Zai an invoice for the amount of Royalty Payment set forth therein. Zai shall pay to Deciphera the royalties for each Calendar Quarter within [***] after the receipt of the invoice from Deciphera. If no royalty is due for any Calendar Quarter following commencement of the reporting obligation, Zai shall so report.

10.5. Payment .

(a) **Mode of Payment** . All payments to be made under this Agreement shall be made in U.S. Dollars and shall be paid by electronic transfer in immediately available funds to such bank account in the United States as is designated in writing by Deciphera. All payments shall be free and clear of any transfer fees or charges.

(b) **Currency Exchange Rate** . All payments under this Agreement shall be payable in U.S. Dollars. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars for calculating Net Sales in a Calendar Quarter (for purposes of both the royalty calculation and whether a Net Sales milestone has been achieved) shall be made at the average exchange rate as published by the Wall Street Journal for such Calendar Quarter, or such other source as the Parties may agree in writing.

(c) **Payment Timeline** . Except as otherwise provided in this Agreement, all payments to be made by one Party to the other Party under this Agreement shall be due within [***] following such Party's receipt of an invoice from the other Party.

10.6. Audits .

(a) Zai shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with the GAAP, consistently applied), for a period not less than [***] complete and accurate records in sufficient detail to properly reflect Net Sales and to enable any Milestone Payment payable hereunder to be determined.

(b) Upon the written request of Deciphera, Zai shall permit, and shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Deciphera and reasonably acceptable to Zai, at Deciphera's expense, to have access during normal business hours to such records of Zai or its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any Calendar Year ending not more [***] . These rights with respect to any Calendar Year shall [***] end of any such Calendar Year and shall be limited to once each Calendar Year (provided that the foregoing frequency limit shall not apply if Deciphera has cause). Deciphera shall provide Zai with a copy of the accounting firm's written report [***]. If such accounting firm correctly concludes that an underpayment was made, then Zai shall pay the amount due within [***] of the date Deciphera delivers to Zai such accounting firm's written report so correctly concluding. If such accounting firm concludes that an overpayment was made, then such over payment shall be credited against any future payment due to Deciphera hereunder (if there is no future payment due, then Deciphera shall promptly refund such overpayment to Zai). Deciphera shall bear the full cost of such audit unless such audit correctly discloses that the additional payment payable by Zai for the audited period is more [***] the amount otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

(c) Deciphera shall treat all financial information, subject to review under this Section 10.6 in accordance with the confidentiality provisions of ARTICLE 11 , and, prior to commencing such audit, shall cause its accounting firm to enter into a confidentiality agreement with Zai obligating it to treat all such financial information in confidence pursuant to such confidentiality provisions. Such accounting firm shall not disclose Zai's Confidential Information to Deciphera, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Zai or the amount of payments to or by Zai under this Agreement.

(d) Zai shall include in each relevant sublicense granted by it a provision requiring any Sublicensee to maintain records of sales of Licensed Products made pursuant to such sublicense, and to grant access to such records by an accounting firm to the same extent and under the same obligations as required of Zai under this Agreement. Deciphera shall advise Zai in advance of each audit of any such Sublicensee with respect to Licensed Product sales either by Deciphera or its designated auditor under the terms of such Sublicensee agreement. Deciphera shall provide Zai with a summary of the results received from the audit and, if Zai so requests, a copy of the audit report. Deciphera shall pay the full costs charged by the accounting firm, unless the audit discloses that the additional payments payable to Deciphera for the audited period is more than [***] from the amounts otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

10.7. Interest . Each Party shall pay interest on any amounts overdue under this Agreement [***] from the day payment was initially due; provided, however, that in no case shall such interest rate exceed the highest rate permitted by Applicable Laws. The payment of such interest shall not foreclose a Party from exercising any other rights it may have because any payment is overdue.

10.8. Taxes . Notwithstanding any other provision hereof, for any payment payable by Zai to Deciphera hereunder, [***] . Zai and Deciphera shall cooperate with respect to (i) any and all documentation required by any taxing authority or reasonably requested by Zai to secure a reduction in the rate of applicable Taxes and (ii) claiming refunds, credits or exemptions from such Tax deductions or withholdings under any relevant agreement or treaty, which is in effect. [***] . The Parties shall (1) discuss applicable reasonable mechanisms for minimizing such Taxes to the extent possible in compliance with Applicable Laws; and (2) use reasonable efforts, to the extent permitted by Applicable Laws, to minimize indirect Taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement; provided that in effectuating the foregoing sentences, [***] . In order to ensure all of the Territory Tax liabilities are duly withheld and settled in all regions of the Territory, each Party will, at the request of the other Party, provide such other Party promptly with an original or scanned copy of the relevant Tax filing form(s), Tax payment certificate and any other supporting documentation requested by the other Party, as applicable.

10.9. Blocked Currency . If by Applicable Law in a country or region in the Territory, conversion into Dollars or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Zai shall promptly notify Deciphera and, thereafter, amounts accrued in such country or region under this ARTICLE 10 shall be paid to Deciphera (or its designee) in such country or region in local currency by deposit to an escrow account in a local bank designated by Deciphera and to the credit of Deciphera, unless the Parties otherwise agree.

ARTICLE 11

CONFIDENTIALITY; PUBLICATION

11.1. Nondisclosure Obligation .

(a) For the Term of this Agreement [***] , the Party receiving the Confidential Information of the other Party (such receiving Party, the " **Receiving Party** ") shall keep confidential and not publish, make available or otherwise disclose any Confidential Information to any Third Party, without the express prior written consent of the Party that disclosed such Confidential Information (the " **Disclosing Party** "); provided however, the Receiving Party may disclose the Confidential Information to those of its Affiliates, officers, directors, employees, agents, consultants or independent contractors (including sublicensees) of such Receiving Party who need to know the Confidential Information in connection with this Agreement and are bound by confidentiality obligations with respect to such Confidential Information. The Receiving Party shall exercise at a minimum the same degree of care it would exercise to protect its own Confidential Information (and in no event less than a reasonable standard of care) to keep confidential the Confidential Information. The Receiving Party shall use the Confidential Information solely in connection with the purposes of this Agreement.

(b) It shall not be considered a breach of this Agreement if the Receiving Party discloses Confidential Information in order to comply with a lawfully issued court or governmental order or with a requirement of Applicable Laws or the rules of any internationally recognized stock exchange; provided that: (i) the Receiving Party gives prompt written notice of such disclosure requirement to the Disclosing Party and cooperates with the Disclosing Party's efforts to oppose such disclosure or obtain a protective order for such Confidential Information, and (ii) if such disclosure requirement is not quashed or a protective order is not obtained, the Receiving Party shall only disclose those portions of the Confidential Information that it is legally required to disclose and shall make a reasonable effort to obtain confidential treatment for the disclosed Confidential Information. To the extent there is any conflict between this ARTICLE 11 and any other agreement related to Confidential Information entered into between the Parties, including the Confidentiality Agreement executed by the Parties dated as of [***] , the terms of this ARTICLE 11 shall control to the extent of such conflict.

11.2. Scientific Publication . The JSC shall discuss the publication strategy for the publication of scientific papers, abstracts, meeting presentations and other disclosure of the results of the Clinical Trials (other than the Global Studies and the Support Studies) carried out under this Agreement, taking into consideration the Parties' interest in publishing the results of the Development work in order to obtain recognition within the scientific community and to advance the state of scientific knowledge , and the need to protect Confidential Information, intellectual property rights and other business interests of the Parties; provided that Zai's publication outside the Territory (including in any form or media that may be distributed outside the Territory) shall require Deciphera's prior written consent. Subject to the immediately preceding sentence, Zai shall provide Deciphera with the opportunity to review and comment on any proposed publication that pertains to the Licensed Products at [***] its intended submission for publication which shall only be permitted in the Territory and as to data, results and the like with respect to patients or subjects located in the Territory. Deciphera shall provide Zai with its comments, if any, [***] the receipt of such proposed publication. Zai shall consider in good faith the comments provided by Deciphera and shall comply with Deciphera's request to: (a) remove any and all Confidential Information of Deciphera from such proposed publication; and (b) delay the submission for a period [***] as may be reasonably necessary to seek patent protection for the information disclosed in the proposed publication. Zai agrees to acknowledge the contribution of Deciphera and Deciphera's employees in all publication as scientifically appropriate. Zai shall have no right to publish outside the Territory without Deciphera's prior written consent.

11.3. Publication and Listing of Clinical Trials . With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, each Party shall comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 11.3 shall be considered a publication for purposes of this Agreement and shall be subject to Section 11.2.

11.4. Publicity; Use of Names .

(a) Each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to (i) advisors (including consultants, financial advisors, attorneys and accountants), (ii) bona fide potential and existing investors and acquirers on a need to know basis, in each case under circumstances that reasonably protect the confidentiality thereof, (iii) to the extent necessary to comply with the terms of agreements with Third Parties, or (iv) to the extent required by Applicable Laws, including securities laws and regulations. Notwithstanding the foregoing, the Parties agree upon the initial press release(s) to announce the execution of this Agreement as contained in Schedule 11.4; thereafter, Deciphera and Zai may each disclose to Third Parties the information contained in such press release(s) without the need for further approval by the other.

(b) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding a Licensed Product for use in the Field in the Territory and other activities in connection with this Agreement, beyond what may be strictly required by Applicable Laws and the rules of a recognized stock exchange, and each Party may make such disclosures from time to time with respect to a Licensed Product with the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed. Such disclosures may include achievement of significant events in the Development (including regulatory process) or Commercialization of a Licensed Product for use in the Field in the Territory. Unless otherwise requested by the applicable Party, each Party shall indicate that Deciphera is the licensor of a Licensed Product and Deciphera IP, as applicable, in each public disclosure issued by such Party regarding a Licensed Product. When a Party elects to make any public disclosure under this Section 11.4(b) , it shall give the other Party reasonable notice to review and comment on such statement, it being understood that (i) if the other Party does not notify such Party in writing [***] or such shorter period if required by Applicable Laws of any reasonable objections, as contemplated in this Section 11.4(b) , such disclosure shall be deemed approved, and (ii) if the other Party does notify such Party in writing within the time period set forth in clause (i) above, and reasonably determines that such public disclosure would entail the public disclosure of the other Party's Confidential Information or of patentable Inventions upon which patent applications should be filed prior to such public disclosure, such public disclosure shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of the other Party, or the drafting and filing of a pa tent application covering such Inventions , provided such additional period shall not [***] from the proposed date of the public disclosure, and, in any event, the other Party shall work diligently and reasonably to agree on the text of any proposed disclosure in an expeditious manner. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Laws and regulatory guidance documents, and reasonable sensitivity to potential negative reactions of applicable Regulatory Authorities.

(c) The Parties acknowledge the need to keep investors and others informed regarding such Party's business under this Agreement, including as required by the rules of a recognized stock exchange. To the extent a Party is publicly listed or becomes publicly listed, and subject to Sections 11.4(a) and 11.4(b), such Party may issue press releases or make disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, as reasonably necessary to comply with laws or regulations or for appropriate market disclosure; provided that each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws.

ARTICLE 12

REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1. Representations and Warranties of Each Party . Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement; and

(d) All consents, approvals and authorization from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

12.2. Additional Representations and Warranties of Deciphera . Deciphera represents and warrants to Zai that as the Effective Date:

(a) Deciphera is the sole owner of the Deciphera Program IP and it has the right under the Deciphera Program IP and Deciphera Background Know-How to grant the licenses to Zai as purported to be granted pursuant to this Agreement;

(b) Schedule 1.38 lists all Patents in the Territory Controlled by Deciphera that are necessary for the Development and Commercialization of the Licensed Product in the Territory;

(c) Deciphera has not granted (and shall not grant) any right to any Third Party under the Deciphera Program IP or Deciphera Background Know-How that would conflict with the rights granted to Zai hereunder;

(d) Deciphera and its Affiliates and their employees, consultants and contractors involved in the Development of the Compounds and Licensed Products are not, and have not been, debarred or disqualified by any Regulatory Authority as of the Effective Date, and have complied in all material respects with all Applicable Laws in connection with the Development of the Compounds and Licensed Product;

(e) [***] ;

(f) no claim or action has been brought agains t Deciphera or, to Deciphera's Knowledge , threatened in writing to Deciphera, by any Third Party alleging that (1) the Deciphera Program Patents are invalid or unenforceable, or (2) use of the Compound or Licensed Product infringes the Patents or misappropriates the Know-How of any Th ird Party; and, to Deciphera's Knowledge, no interference, opposition, cancellation or other protest proceeding has been filed against a Deciphera Program Patent owned by Deciphera; and

(g) [***] .

12.3. Additional Representations, Warranties and Covenants of Zai . Zai represents, warrants and covenants to Deciphera that as of the Effective Date with respect to itself and its Affiliates:

(a) there are no legal claims, judgments or settlements against or owed by Zai or its Affiliates, or pending or, to Zai's or its Affiliates' actual knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations, including under any Anti-Corruption Laws;

(b) Zai and its Affiliates is not, and has not been, debarred or disqualified by any Regulatory Authority;

(c) [***] ;

(d) it shall comply with all Applicable Laws in connection with the Development, packaging, having packaging and Commercialization of the Licensed Product in the Territory and packaging and having packaging the Licensed Product in Singapore or the United States; and

(e) [***] .

12.4. Covenants of Each Party . Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, it shall, and shall cause its Affiliates, Sublicensees to, comply with the Development Plan, all agreements referenced herein, all Applicable Laws, including as applicable, cGMP, GCP, GLP, and GSP standards, and shall not employ or engage any party who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

12.5. Compliance with Anti-Corruption Laws .

(a) Notwithstanding anything to the contrary in the Agreement, each Party hereby covenants to each other that:

(i) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (collectively " **Anti-Corruption Laws** ", including the provisions of the U.S. Foreign Corrupt Practices Act, the U.K. Anti-Bribery Law , and the Anti-Corruption Act of the PRC) that may be applicable to either or both Parties to the Agreement;

(ii) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it shall, on request by the other Party, verify in writing that to the best of such Party's knowledge , there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or shall provide details of any exception to the foregoing; and

(iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 12.5, and upon request of the other Party, upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section 12.5. Acceptance of a proposed Third Party auditor may not be unreasonably withheld or delayed by either Party. It is expressly agreed that the costs related to the Third Party auditor shall be fully paid by the Party requesting the audit, and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

(b) To its knowledge as of the Effective Date and during the Term, neither Zai nor any of its subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of Zai or any of its subsidiaries or any of their Affiliates:

(i) has taken or shall take any action in violation of any applicable anticorruption law, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78 dd-1 et seq.); or

(ii) has corruptly, offered, paid, given, promised to pay or give, or authorized or shall corruptly, offer, pay give, promise to pay or give or authorize, the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 12.5(d) below), for the purposes of:

(iii) has influenced or shall influence any act or decision of any Public Official in his official capacity;

(iv) has induced or shall induce such Public Official to do or omit to do any act in violation of his lawful duty;

(v) has secured or shall secure any improper advantage; or

(vi) has induced or shall induce such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever.

(c) As of the Effective Date, no ne of the officers, directors, employees, of Zai or of any of its Affiliates or agents acting on behalf of Zai or any of its Affiliates, in each case that are employed or reside outside the United States, are themselves Public Officials.

(d) For purposes of this Section 12.5 , " **Public Official** " means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union , the International Monetary Fund, the United Nations or the World Bank; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

12.6. NO OTHER REPRESENTATIONS OR WARRANTIES . EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL SUCH REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 13

INDEMNIFICATION

13.1. By Zai . Zai shall indemnify and hold harmless Deciphera, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the " **Deciphera Indemnitee(s)** ") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, " **Losses** ") arising after the Effective Date to the extent arising from (a) the packaging, having packaged, Development, and Commercialization of the Licensed Product in the Territory, including the promotion of a Licensed Product and product liability claims relating to the Licensed Product, or any actions (or omissions) in the performance of its regulatory activities, in each case by Zai or any of its Affiliates or Sublicensees, (b) the packaging and having packaging of the Licensed Product [***] (including any and all activities relating to or support such packaging and having packaging); (c) the gross negligence, illegal conduct or willful misconduct of Zai or any of its Affiliates or Sublicensees, (d) Zai's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement or (e) [***] in accordance with [***], in each case of clauses (a) through (e) above except to the extent such Losses arise from, are based on, or result from any activity or occurrence for which Deciphera is obligated to indemnify the Zai Indemnitees under Section 13.2.

13.2. By Deciphera . Deciphera shall indemnify and hold harmless Zai, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the " **Zai Indemnitee(s)** ") from and against all Losses to the extent arising from (a) Manufacture, Development and Commercialization of the Compounds and Licensed Products outside the Territory or in the Territory with respect to Global Studies or any Manufacturing activities in the Territory, in each such case by Deciphera or any of its Affiliates or licensees (other than Zai); (b) the gross negligence, illegal conduct or willful misconduct of Deciphera or any of its Affiliates or licensees (other than Zai), or (c) Deciphera's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, in each case of clauses (a) through (c) above, except to the extent Losses arise from, are based on, or result from any activity or occurrence for which Deciphera is obligated to indemnify the Zai Indemnitees under Section 13.1.

13.3. Defined Indemnification Terms . Either of the Zai Indemnitee or the Deciphera Indemnitee shall be an " **Indemnitee** " for the purpose of this ARTICLE 13, and the Party that is obligated to indemnify the Indemnitee under Section 13.1 or Section 13.2 shall be the " **Indemnifying Party** ."

13.4. Defense . If any such claims or actions are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such claim or action, subject to the terms of this ARTICLE 13.

13.5. Settlement . The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld or delayed.

13.6. Notice . The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Sections 13.1 or 13.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

13.7. Permission by Indemnifying Party . The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

13.8. Insurance . Zai shall procure and maintain for itself and its Affiliates during the Term and for a period [***] thereafter, insurance policies, including product liability and clinical trial insurance, adequate to cover its obligations hereunder with a company having a minimum of an A-rating by Best's rating; *provided* , *however* , that in no event shall such product liability insurance be written and in force in amounts not less than [***] per occurrence and [***] in the aggregate. Zai shall identify Deciphera as an additional insured and provide Deciphera with evidence of such insurance upon request and prior to expiration of any one coverage. Zai shall provide Deciphera with prompt written notice of cancellation, non-renewal or material change in such insurance, and shall provide such notice [***] any such cancellation, non-renewal or material change. Zai shall impose substantially identical obligations on its Affiliates (to the extent not named insureds under Zai's coverages) and Sublicensees. Such insurance shall not be construed to create a limit of the insured Party's liability with respect to its indemnification obligations under this ARTICLE 13.

13.9. LIMITATION OF LIABILITY . SUBJECT TO AND WITHOUT LIMITING THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTIONS 13.1 OR 13.2 OR LIABILITY AS A RESULT OF A BREACH OF ARTICLE 11 [***] , NO PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

ARTICLE 14

INTELLECTUAL PROPERTY

14.1. Inventions .

(a) **Ownership** . If any Inventions or intellectual property, including any Know-How generated for regulatory purposes relating to the Licensed Product, is created or generated by or on behalf of Zai as a result of Zai's Development or Commercialization activities in the Territory (the " **New IP** "), (i) Zai agrees and hereby assigns all such New IP (1) [***] , or (2) [***] (" **New Program IP** ") to Deciphera, and such New Program IP shall be (A) solely owned by Deciphera and (B) included in the Deciphera Program IP and licensed to Zai in the Field in the Territory under Section 2.1; (ii) Zai shall retain ownership of all other New IP, which shall be included in Zai IP and licensed to Deciphera under Section 2.4. In addition, Deciphera hereby grants to Zai a perpetual, irrevocable, non-exclusive, sublicenseable, fully-paid, royalty-free, worldwide license under the New Program IP described under Section 14.1(a)(i)(2) above (i.e., that constitutes an improvement to Deciphera IP) to research, develop, make, have made, use, sell, offer for sale, import, export, market and otherwise commercialize products other than Licensed Product.

(b) **Disclosure** . Zai shall promptly disclose to Deciphera all Inventions within the New IP, including all Invention disclosures or other similar documents submitted to Zai by its or its Affiliates' employees, agents, or independent contractors relating thereto, and shall also promptly respond to reasonable requests from Deciphera for additional information relating thereto.

(c) **Assignment of New Program IP.** Zai shall and hereby does assign to Deciphera all right, title and interest in and to all New Program IP. Zai shall take (and cause its Affiliates, sublicensees and their employees, agents, and contractors to take) such further actions reasonably requested by Deciphera to effectuate such assignment and to assist Deciphera in obtaining patent and other intellectual property rights protection for the New Program IP. Zai shall obligate its Affiliates, sublicensees and contractors to assign all New Program IP to Zai (or directly to Deciphera) so that Zai can comply with its obligations under this Section 14.1, and Zai shall promptly obtain such assignment.

14.2. Patent Prosecution of Deciphera Program Patents .

(a) As between the Parties, Deciphera shall have the first right to control the Patent Prosecution or maintenance of all Deciphera Program Patents and Patents claiming New Program IP at Deciphera's expense.

(b) Deciphera shall consult with Zai and keep Zai reasonably informed of the Patent Prosecution or maintenance of the Deciphera Program Patents in the Territory and shall provide Zai with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, Deciphera shall provide Zai with drafts of all proposed material filings and correspondence to any patent authority in the Territory in connection with the Patent Prosecution or maintenance of the Deciphera Program Patents for Zai's review and comment prior to the submission of such proposed filings and correspondence . Deciphera shall consider Zai's comments on Patent Prosecution or maintenance but shall have final decision-making authority under this Section 14.2(b) . Further, Deciphera shall notify Zai of any decision to cease Patent Prosecution or maintenance of any Deciphera Program Patents in the Territory at [***] any due date for filing, payment or other action to avoid loss of rights, in which case Zai shall have the right to continue the Patent Prosecution or maintenance of such Deciphera Program Patents in the Territory at Zai's discretion and expense.

14.3. Patent and Trademark Prosecution Cooperation . With respect to all Patent Prosecution or maintenance and trademark prosecution or maintenance, each Party shall:

(a) execute any instruments to document their respective ownership consistent with this Agreement as reasonably requested by the other Party;

(b) make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the appropriate Party hereunder to undertake its Patent Prosecution or maintenance responsibilities;

(c) cooperate, if necessary, with the other Party in gaining Patent term extensions; and

(d) act in good faith to coordinate its efforts under this Agreement with the other Party to minimize or avoid interference with the Patent Prosecution or maintenance of the other Party's Patents to a Licensed Product or trademarks.

14.4. Patent Enforcement .

(a) **Notice.** Each Party shall notify the other [***] becoming aware of any alleged or threatened infringement by a Third Party of any of the Deciphera Program Patents in the Territory, and any related declaratory judgment or equivalent action, including the filing of any application, litigation, administration action or similar action alleging the invalidity, unenforceability or non-infringement of any Deciphera Program Patents (collectively " **Product Infringement** ").

(b) **Enforcement Rights** . Zai shall have the first right to bring and control any legal action to enforce Deciphera Program Patents against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate, and Zai shall consider in good faith the interests of Deciphera in such enforcement of the Deciphera Program Patent s ; provided that Deciphera shall have the first right to control any proceedings as part of Patent Prosecution of Deciphera Program Patents in the Territory. If Zai or its designee fails to abate such Product Infringement in the Territory or to file an action to abate such Product Infringement in the Territory [***] a written request from Deciphera to do so, or if Zai discontinues the prosecution of any such action after filing without abating such infringement, then Deciphera shall have the right to enforce the Deciphera Program Patents against such Product Infringement in the Territory at its own expense as it reasonably determines appropriate; provided that neither Party shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Deciphera Program Patent without the prior written consent of the other Party (not to be unreasonably withheld, delayed or conditioned).

(c) **Cooperation** . At the request of the Party bringing an action related to Product Infringement, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action, at the enforcing Party's sole cost and expense.

(d) **Recoveries.** Any recoveries resulting from enforcement action under Section 14.4(b) relating to a Product Infringement shall be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall be retained by the enforcing Party; provided however [***] .

14.5. Infringement of Third Party Rights . If any Licensed Product used or sold by either Party, its Affiliates or sublicensee s becomes the subject of a Third Party's claim or assertion of infringement of a Patent or other intellectual property rights that are owned or controlled by such Third Party, such Party shall promptly notify the other Party [***] receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing along with an English summary of such summons or complaint. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

ARTICLE 15

TERMS AND TERMINATION

15.1. Term and Expiration .

(a) **Term** . This Agreement shall be effective as of the Effective Date, and shall continue, on a region-by-region and a Licensed Product-by-Licensed Product basis, in effect until the expiration of and payment by Zai of all Zai's payment obligations set forth in Section 10.4(b) applicable to such region (the " **Term** ", and the date of such expiration with respect to such Licensed Product and such region, the " **Expiration Date** ").

(b) **Expiration** . On a region-by-region and a Licensed Product-by-Licensed Product basis, upon the natural expiration of this Agreement as contemplated in this Section 15.1 , the licenses granted by Deciphera to Zai under this Agreement in such region with respect to the Licensed Product in the Field shall become fully paid-up, perpetual and irrevocable.

(c) [***] :

(1) [***] ;

(2) [***] ;

(3) [***]

(4) [***] .

[***] .

15.2. Termination for Convenience. Zai shall have the right to terminate this Agreement in its entirety for any or no reason upon [***] written notice to Deciphera. Zai shall terminate this Agreement upon [***] written notice to Deciphera if it determines that it shall permanently discontinue all Development and Commercialization activities with respect to the Licensed Product under this Agreement.

15.3. Termination for Material Breach .

(a) This Agreement may be terminated in its entirety at any time during the Term upon [***] written notice by either Party if the other Party materially breaches a material term of the Agreement and, if such breach is curable, such breach has not been cured within [***] of such written notic e ; provided that the applicable material breach cure period [***] where Deciphera shall have the right to terminate this Agreement [***] , subject to Section 15.3(c).

(b) F or the avoidance of doubt, the Parties agree that [***] .

(c) Notwithstanding the foregoing, if the alleged breaching Party disputes the existence or materiality of the alleged breach, the other Party shall not have the right to terminate this Agreement unless and until it is determined in accordance with ARTICLE 16 that the alleged breaching Party has materially breached this Agreement and fails to cure such breach within [***] after such determination.

15.4. Termination for Patent Challenge . Except to the extent the following is unenforceable under the laws of a particular jurisdiction, Deciphera may terminate this Agreement in its entirety (a) immediately upon written notice to Zai if Zai or its Affiliates or Sublicensees, commences a legal, administrative or other action challenging the validity, enforceability or scope of any Patent in the Territory in Schedule 1.37 or (b) [***] written notice to Zai if Zai or its Affiliates or Sublicensees, commences a legal, administrative or other action challenging the validity, enforceability or scope of any Patent owned or Controlled by Deciphera or its Affiliates anywhere in the world, unless such action is withdrawn during [***] period. Notwithstanding the foregoing, if Zai promptly terminates the sublicense agreement of any Sublicensee that commences a legal action challenging the validity, enforceability or scope of any Deciphera Program Patents anywhere in the world, Deciphera shall not have the right to terminate this Agreement under this Section 15.4 .

15.5. Termination for Insolvency . Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization under the Chapter 7 of the United States of Bankruptcy Code or other similar Applicable Law or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within ninety (90) days of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

15.6. Termination by Deciphera [***] . Deciphera shall have the right to terminate this Agreement [***] to the extent permitted under and in accordance with [***] .

15.7. Election to Terminate . If either Party has the right to terminate under Sections 15.2 through 15.5 , it may at its sole option, elect either to (a) terminate this Agreement and pursue any legal or equitable remedy available to it or (b) maintain this Agreement in effect and pursue any legal or equitable remedy available to it.

15.8. Effect of Termination .

(a) Upon the termination of this Agreement for any reason, all rights and licenses (including the rights and licenses with respect to the Licensed Product) granted to a Party herein shall immediately terminate, and all sublicenses of such rights and licenses shall also terminate; provided that the licenses granted by Zai to Deciphera pursuant to Section 2.4 shall become perpetual and irrevocable to Develop, Manufacture and Commercialize Licensed Products

worldwide , subject only to any terms and conditions of any upstream agreement(s) if such license includes a sublicense to intellectual property in-licensed by Zai from a Third Party. Upon termination of this Agreement, if a Sublicensee is then in good standing of its sublicense agreement with Zai, then at Deciphera's sole discretion , Deciphera may grant to such Sublicensee a direct license under the Deciphera IP that is the same scope as the sublicense granted by Zai on substantially the same terms and conditions set forth in this Agreement, and Section 15.8(b) below shall not apply to such Sublicensee. Termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.

(b) Upon termination of this Agreement for any reason, the following additional provisions shall apply:

(i) **Reversion of Rights to Deciphera** . Any rights and licenses with respect to the Licensed Product granted to Zai under this Agreement shall immediately terminate, and all such rights shall revert back to Deciphera.

(ii) **Regulatory Materials; Data.** Zai shall, and shall cause its Affiliates and Sublicensees to, [***] , to the maximum extent permitted by Applicable Laws at the time of any such termination to promptly (1) assign all Regulatory Submissions and Regulatory Approvals of Licensed Products to Deciphera, and (2) assign all data generated by or on behalf of Zai or its designee while conducting Development or Commercialization activities under the Agreement to Deciphera or its designee, including non-clinical and clinical studies conducted by or on behalf of Zai on Licensed Products and all pharmacovigilance data (including all Adverse Event database information) on Licensed Products.

(iii) **Trademarks.** Zai shall, and shall cause its Affiliates and Sublicensees, to promptly transfer and assign to Deciphera, [***] , all Product Marks.

(iv) **Transition Assistance** . Zai shall, and shall cause its Affiliates and Sublicensees, to provide assistance, [***] , as may be reasonably necessary or useful for Deciphera or its designee to commence or continue Developing or Commercializing Licensed Products in the Territory for a period of at least [***] after the effective date of such termination (the " **Transition Period** ") to the extent Zai is then performing or having performed such activities, including transferring or amending as appropriate, upon request of Deciphera, any agreements or arrangements with Third Party to Develop and Commercialize the Licensed Products in the Territory. To the extent that any such contract between Zai and a Third Party is not assignable to Deciphera or its designee, then Zai shall reasonably cooperate with Deciphera to arrange to continue to and provide such services from such entity.

(v) **Ongoing Clinical Trial.** If at the time of such termination, any Clinical Trials for the Licensed Products are being conducted by or on behalf of Zai, then, at Deciphera ' s election on a Clinical Trial-by-Clinical Trial basis: (1) Zai shall, and shall cause its Affiliates and Sublicensees to, (A) continue to conduct such Clinical Trial during the Transition Period or another period of time as determined by Deciphera after the effective date of such termination at Deciphera's cost, and (B) after such period, to (y) fully cooperate with Deciphera to transfer the conduct of all such Clinical Trial to Deciphera or its designee or (z) continue to conduct such Clinical Trials, at Deciphera's cost, for so long as necessary to enable such transfer to be completed without interruption of any such Clinical Trials and (C) Deciphera shall assume any and all liability and costs for such Clinical Trial after the effective date of such termination, and (2) Zai shall, and shall cause its Affiliates and Sublicensees to, at Zai ' s sole cost and expense (but subject to Section 15.8(d) below), orderly wind down the conduct of any such Clinical Trial which is not assumed by Deciphera under clause (1) .

(vi) **Inventory.** At Deciphera's election and request, Zai shall (1) transfer to Deciphera or its designee all inventory of the Licensed Product [***] then in possession or control of Zai, its Affiliates or Sublicensees; provided that Deciphera shall pay Zai a price equal to Zai's costs for such Licensed Products or (2) (A) continue to use Commercially Reasonable Efforts to Commercialize all inventory of the Licensed Products then in possession or control of Zai during the Transition Period and make the corresponding payments, including any milestone payments or royalties to Deciphera under this Agreement as though this Agreement had not been terminated and (B) after the Transition Period, transfer to Deciphera or its designee any remaining inventory of the Licensed Product to Deciphera or its designee at a price equal to Zai's costs for such Licensed Products.

(vii) **Return of Confidential Information** . At the Disclosing Party's election, the Receiving Party shall return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Product that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); provided that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic.

(c) **Other Remedies** . Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

(d) **Termination by Zai Due to Material Breach** . Notwithstanding anything to the contrary, upon the termination of this Agreement by Zai pursuant to Section 15.3 , all of the provisions of Section 15.8(b) shall apply, except that [***] .

15.9. Survival . Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. The following provisions shall survive the termination or expiration of this Agreement for any reason: Sections 1 (Definitions) , 10 (Payments and Milestones) (solely to the extent payments have accrued prior to the effective date of termination), 11 (Confidentiality ; Publication), 12.6 (No Other Representations or Warranties), 13 (Indemnification), 14.1 (Inventions), 15.1(b) (Expiration) (which shall survive only after the natural expiration (not early termination) of the Agreement), 15.1(c) ([***]) (which shall survive only after the natural expiration (not early termination) of the Agreement when all the conditions set forth in therein are met), 15.8 (Effect of Termination, to the extent applicable), 15.9 (Survival), 16 (Dispute Resolution), and 17 (Miscellaneous).

ARTICLE 16

DISPUTE RESOLUTION

16.1. General . The Parties recognize that a dispute may arise relating to this Agreement (a " **Dispute** "). Any Dispute, including Disputes that may involve the Affiliates of any Party, shall be resolved in accordance with this ARTICLE 16.

16.2. Continuance of Rights and Obligations during Pendency of Dispute Resolution . If there are any Disputes in connection with this Agreement, including Disputes related to termination of this Agreement under ARTICLE 15, all rights and obligations of the Parties shall continue until such time as any Dispute has been resolved in accordance with the provisions of this ARTICLE 16.

16.3. Escalation . Any claim, Dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement shall be referred to the Executive Officers set forth in Section 3.2(f) for attempted resolution. In the event the Executive Officers are unable to resolve such Dispute within [***] of such Dispute being referred to them, then, upon the written request of either Party to the other Party, the Dispute shall be subject to arbitration in accordance with Section 16.4 .

16.4. Arbitration .

(a) If the Parties fail to resolve the Dispute through escalation to the Executive Officers under Section 16.3 , and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for resolution in arbitration under the Rules of Arbitration of the International Chamber of Commerce (" **ICC Rules** "). There shall be three (3) arbitrators, the chairperson of whom shall be appointed by the two party arbitrators. The seat of arbitration shall be [***] and the language of the proceedings shall be English.

(b) The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction. The arbitral tribunal shall render its final award within nine months from the date on which the Request for Arbitration by one of the Parties wishing to have recourse to arbitration is received by the ICC Secretariat . The arbitral tribunal shall determine the dispute by applying the provisions of this Agreement and the governing law set forth in Section 17.5 .

(c) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order to avoid irreparable harm, maintain the status quo, preserve the subject matter of the Dispute, or aid the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

(d) EACH PARTY HERETO WAIVES: (I) ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY, AND (II) ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST.

(e) Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrator; provided, however, that the arbitrator shall be authorized to determine whether a Party is the prevailing party , and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the administrator and the arbitrator.

(f) Notwithstanding anything in this Section 16.4 , in the event of a Dispute with respect to (i) the validity, scope, enforceability or ownership of any Patent or other intellectual property rights, (ii) a matter for which this Agreement assigns decision-making to the Parties or to the JSC or requires the consent of one or both of the Parties, (iii) the necessity of obtaining a Third Party license by Zai in the Territory in accordance with Section 10.4(c)(iii), or (iv) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, and such Dispute is not resolved in accordance with Section 16.3 , such Dispute shall not be submitted to an arbitration proceeding in accordance with this Section 16.4 , unless otherwise agreed by the Parties in writing, and instead, either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

ARTICLE 17

MISCELLANEOUS

17.1. Force Majeure . Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God or any other deity, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

17.2. Assignment . Neither Party may assign this Agreement to a Third Party without the other Party's prior written consent (such consent not to be unreasonably withheld); except that (a) subject to Section 2.6, either Party may make such an assignment without the other Party's prior written consent to a successor to substantially all of the business of such Party to which this Agreement relates (whether by merger, sale of stock, sale of assets, exclusive license or other transaction), and (b) either Party may assign this Agreement to an Affiliate without the other Party's prior written consent for so long as such Affiliate remains an Affiliate of the Party making the assignment. For clarity, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates and each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. This Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assignees. Any assignment or transfer in violation of this Section 17.2 shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

17.3. Severability . If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

17.4. Notices . All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Deciphera:

Deciphera Pharmaceuticals, LLC
Address: 500 Totten Pond Road, Waltham, MA 02451, USA
Attn: Chief Business Officer
cc: General Counsel

with a copy to:

Ropes & Gray, LLP
Address: 36/F, Park Place, Nanjing Road West, Shanghai 200040, China
Attn: Geoffrey Lin
Email: Geoffrey.Lin@ropesgray.com
Fax: +86 21 6157 5299

If to Zai:

Zai Lab (Shanghai) Co., Ltd.
Address: 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210
Attn: President

with a copy to:

Cooley, LLP
Address: 3175 Hanover Street, Palo Alto, CA 94304
Attn: Lila Hope, Ph.D.
Email: lhope@cooley.com
Fax: +1 650 849 7400

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith **.** Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by facsimile on a Business Day; (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

17.5. Governing Law . This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S. without reference to any rules of conflict of laws.

17.6. Entire Agreement; Amendments . The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

17.7. Headings . The captions to the several Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the Sections of this Agreement.

17.8. Independent Contractors . It is expressly agreed that Deciphera and Zai shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Deciphera will report any payments received under the Agreement as payments from Zai. Neither Deciphera nor Zai shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

17.9. Waiver . The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

17.10. Waiver of Rule of Construction . Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

17.11. Construction . Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will ” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules , or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other

written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or" where applicable.

17.12. Counterparts . This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties.

17.13. Language . This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License Agreement to be executed by their duly authorized representatives as of the Effective Date.

Deciphera Pharmaceuticals, LLC	**Zai Lab (Shanghai) Co., Ltd.**
By:_____	By:_____
Name:_____	Name:_____
Title:_____	Title:_____
Date:_____	Date:_____

Schedule 1.26

Follow-On Compounds

1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
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Schedule 1.31
Deciphera Background Know-How

Deciphera Background Know-How includes:

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Schedule 1.37
Deciphera Program Know-How

[***]

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Schedule 1.38
Deciphera Program Patents

[***]

Schedule 2.6

[***]

Schedule 5.1(b)

[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.18

This letter agreement (this " **Letter Agreement** ") is made as of January 17th, 2020 (the "Effective Date"), by and between Deciphera Pharmaceuticals, LLC a limited liability company organized and existing under the laws of Delaware, U.S.A., located at 200 Smith Street, Waltham, MA 02451, U.S.A., ("Deciphera"), and Zai Lab (Shanghai) Co., Ltd., an exempted company organized and existing under the laws of P.R. of China, located at 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210 ("Zai") in connection with that certain License Agreement entered by and between Deciphera and Zai, dated as of June 10, 2019 (the " **License Agreement** "). Capitalized terms used herein and not otherwise defined shall have the meanings given to them in the License Agreement. The purpose of this Letter Agreement is to clarify several operational matters contemplated by the License Agreement. In connection therewith, the undersigned hereby agrees and acknowledges as follows:

1. [***]

2. For clarity, for Article 6 (Regulatory), Section 13.1(e) (By Zai) and Section 15.8 (Effect of Termination) of the License Agreement, the definition of "Regulatory Approval" shall be amended to mean,

> "with respect to a Licensed Product in a region or a country, each approval from the necessary Governmental Authority or Regulatory Authority necessary to conduct Clinical Trials, import, market or sell such Licensed Product in such region, including pricing approvals (but excluding reimbursement approvals)."

3. [***]

4. [***]

5. [***]

6. Zai shall comply, and shall cause its Affiliates, Sublicensees and subcontractors to comply, with all Applicable Laws, including without limitation GCP and regulations promulgated by the NMPA, in their conduct of all Clinical Trials in the Territory.

7. Notwithstanding anything to the contrary in Section 6.4 (Adverse Event Reporting) of the License Agreement, Zai shall be responsible for complying with all Applicable Laws governing Adverse Events in the Territory for all Clinical Trials conducted in the Territory and the Parties shall execute a Pharmacovigilance Agreement per the License Agreement to reflect the agreement among the Parties with respect to such matters, including that Zai will provide in English adverse events from Regional Studies for inclusion in a reporting system chosen by Deciphera.

8. Prior to Zai initiating any Clinical Trial in the Territory, Zai (a) shall have and maintain such type and amounts of clinical trial insurance covering the conduct of

each such Clinical Trial in the Territory that is normal and customary in the pharmaceutical industry generally for similarly situated companies to conduct each such C linical T rial ; and (b) shall name Deciphera and all its Affiliates as full named insured s thereunder who are each entitled to the full benefits of such insurance policy.

9. [***]

10. The governing law and dispute resolution provisions of the License Agreement, as amended from time to time, shall apply to the provisions of this letter agreement. Any notices or other communication required to be provided under the provisions of this Letter Agreement shall be provided in accordance with the notice provision of the License Agreement as amended from time to time. In the event of a conflict between a term or condition of this Letter Agreement and a term or condition of the License Agreement, the term or condition of this Letter Agreement shall control. This Letter Agreement may be executed in multiple counterparts which, taken together, shall constitute one and the same agreement. This Letter Agreement may only be amended with the written consent of both Parties hereto.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Letter Agreement to be executed by their duly authorized representatives as of the Effective Date.

Deciphera Pharmaceuticals, LLC	**Zai Lab (Shanghai) Co., Ltd.**
By: /s/ Steve Hoerter	By: /s/ Samantha Du
Name: Steve Hoerter	Name: Samantha Du
Title: President and Chief Executive Officer	Title: Chairman and Chief Executive Officer
Date: 17 th , Jan., 2020	Date: 17 th , Jan., 2020

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.19

COLLABORATION AND LICENSE AGREEMENT

BETWEEN

INCYTE CORPORATION

AND

ZAI LAB (SHANGHAI) CO. LTD.

JULY 1, 2019

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

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COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the " ***Agreement*** ") is made and entered into as of July 1, 2019 (the " ***Effective* Date** "), by and between **Incyte Corporation** , a United States of America corporation with a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803, U.S.A (" ***INCY*** ") and **Zai Lab (Shanghai) Co., Ltd.** , a Chinese company with its registered address at 4560 Jinke Road , Jinchuang Plaza , Building 1 , 4/F, Zhangjiang Hi-tech Park , Pudong, Shanghai 201210, P.R. China (" ***Zai Lab*** "). INCY and Zai Lab may be referred to below individually as a " ***Party*** " and collectively as the " ***Parties*** ."

Background

A. INCY is a pharmaceutical company specializing in the discovery, development and commercialization of chemical and biological pharmaceutical products for the treatment of cancer.

B. Zai Lab is a pharmaceutical company focusing on developing and commercializing pharmaceutical products in the PRC (as defined herein), Hong Kong, Macau and Taiwan.

C. Zai Lab desires to obtain a license from INCY to the Licensed Product(s) (defined below) with the goal of developing and commercializing biopharmaceutical products made using such molecule throughout such territory, and INCY is willing to grant such a license to Zai Lab, all on the terms and conditions set forth in this Agreement.

Agreement

The Parties hereby agree as follows:

1. DEFINITIONS

Capitalized terms used in this Agreement have the meanings ascribed to them or referenced in **Schedule 1 (Definitions)** .

2. GOVERNANCE

2.1 Establishment of JSC . The Parties will establish a Joint Steering Committee to review and oversee the Development and Commercialization of the Licensed Product(s) in the Zai Lab Territory and to coordinate the Parties' activities under this Agreement (the " ***Joint Steering Committee*** " or " ***JSC*** "). Within [***] after the Effective Date, each Party will appoint [***] representatives to the JSC, each of which will have sufficient seniority and relevant expertise to make decisions within the scope of the JSC's

responsibilities. The JSC may change its size from time to time by [***] ; *provided* that the JSC will consist at all times of [***] . Each Party may at any time replace any one or more of its JSC representatives upon written notice to the other Party.

2.2 [***] **of JSC** . Each of INCY and Zai Lab will select [***] for the JSC, and each Party may [***] . [***] of the JSC will be responsible for calling meetings, preparing and circulating an agenda and relevant materials (including drafts of, updates to, or any proposed changes to a Development Plan) to the other Party at least [***] Business Days in advance of each meeting, casting any votes on behalf of a Party at a JSC meeting, and within [***] Business Days after conclusion of a JSC meeting, preparing and issuing minutes of the meeting. Such minutes will be deemed agreed only after such minutes have been approved by [***] . The minutes should include any matters presented to the JDC for a vote and the vote cast by each of the chairpersons on behalf of a Party's members of the JSC.

2.3 **JSC Responsibilities** . The purpose of the JSC is generally to provide a forum for overall coordination and communication with respect to the Parties' activities under this Agreement. In particular, t he JSC will be responsible for the following items as they relate to the Zai Lab Territory:

2.3.1 **Development** . providing guidance, reviewing, and approving the implementation by the JDC of the Development strategy and the Development Plan for each of the Licensed Product(s), including the regulatory strategy and conduct of regulatory activities for each of the Licensed Product(s);

2.3.2 **Commercialization** . creating, reviewing, and approving the Commercialization strategy and the Commercialization plan for each of the Licensed Product(s), providing guidance on implementation of such strategy and plan, and reviewing associated sales forecast;

2.3.3 **Subcommittee and Working Group Formation and Guidance** . (a) forming subcommittees and working groups and (b) providing guidance and overseeing the activities of each such subcommittee or working group;

2.3.4 **Disputes** . discussing and seeking alignment on any disputed issues submitted to the JSC by the JDC, or any other committee or working group established by the JSC; and

2.3.5 **Compliance** . providing a forum to obtain updates on the development, implementation, and ongoing operation of Zai Lab's compliance program as it pertains to Licensed Product(s) in the Zai Lab Territory;

2.3.6 **Transition** . coordinating post-termination transition activities pursuant to Section 9.3.2 (Transition).

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2.4 JSC Meetings . The JSC will hold meetings (either in-person or by teleconference, videoconference or some other electronic means) at such times and places as the [***] may reasonably determine, *provided* that, unless the Parties agree otherwise, the JSC will meet at least once per [***] by teleconference, videoconference or some other electronic means. [***] costs associated with attending meetings of the JSC. Each Party may from time to time invite [***] . Each individual attending any JSC meeting hereunder (whether as a JSC member or invitee) will be bound by written non-use, non-disclosure terms and conditions at least as restrictive as those set forth in this Agreement with respect to the Confidential Information of the other Party.

2.5 Decision-making of JSC . The members of the JSC will discuss all matters reasonably and consider the other Party's views in good faith and attempt to make all d ecisions of the JSC by [***] . When voting on any matter properly before the JSC, each Party will have [***] cast by its respective [***] of the JSC. If the JSC is not able to reach consensus with respect to a particular matter (as demonstrated by the same vote by each of the Parties' respective [***]), and the JSC is unable to resolve the dispute after endeavoring for [***] Business Days to do so, then either Party's [***] may, by written notice to the other Party's [***] and other Party, refer such matter to the Parties' respective [***] , who will [***] . If the [***] cannot resolve such dispute within [***] Business Days after the matter is first referred to them, then, subject to Section 2.6 (Limitations on Authority of JSC), [***] will have the final decision-making authority on such matter to the extent the matter that is the subject of the dispute [***] .

2.6 Limitations on Authority of JSC . The JSC will have sole authority with respect to the responsibilities assigned to such committee in this Agreement. The JSC will not have any authority to (and so the [***] Executive Officer through his or her decision-making authority in Section 2.5 (Decision-making of JSC) may not):

2.6.1 Amend . amend, modify or waive compliance with any term of this Agreement, including taking an action specified to require the mutual agreement or mutual consent of the Parties;

2.6.2 Require Payment . require a Party to pay any costs or expenses incurred by the other Party not specified in this Agreement or above any amount specified for an activity (if so specified);

2.6.3 Create Obligations . assign to a Party or otherwise obligate a Party to conduct any duties not specified in this Agreement (including in any Development Plan or Commercialization plan);

2.6.4 Take Certain Actions . decide or authorize to take (or permit any other Affiliate, sublicensee or contractor to take) any action in connection with a Clinical Trial in the Zai Lab Territory if INCY reasonably believes [***] of a corresponding

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Licensed Product(s) outside of the Zai Lab Territory and provides its rationale for such belief in writing to Zai Lab;

2.6.5 **Cause Breach** . take any action which could cause Zai Lab to not be in compliance with the requirements of **Schedule 10.3 (Compliance)** ; or

2.6.6 **Vary Dosing in Clinical Trials for any Licensed Product** . without limiting Section 2.6.4 (Take Certain Actions) and subject to Section 3.6 (Dose in Clinical Trials for Each Licensed Product), decide to [***] .

2.7 **Establishment of the JDC** . In accordance with Section 2.3.3 (Subcommittee and Working Group Formation and Guidance), the Parties will establish a separate committee to review and oversee the Development of the Licensed Product(s) in the Zai Lab Territory and to coordinate the Parties' activities under this Agreement with respect to the Development of all of such Licensed Product(s) (such committee, the " ***Joint Development Committee*** " or " ***JDC*** "). Within [***] days after the Effective Date, each Party will appoint [***] representatives to the JDC, each of which will have sufficient seniority and relevant expertise to make decisions within the scope of the JDC's responsibilities. The JDC may change its size from time to time by [***] ; *provided* that the JDC will consist at all times of [***] . Each Party may at any time replace any one or more of its JDC representatives upon written notice to the other Party. A member of the JDC may also be a member of the JSC or any other committee or working group established by the JSC if so desired by the Party who appoints such member(s).

2.8 [***] **of JDC** . Each of INCY and Zai Lab will select [***] , and each Party may [***] . [***] of the JDC will be responsible for calling meetings, preparing and circulating an agenda and relevant materials to the other members of the JDC at least [***] Business Days in advance of each meeting, casting any votes on behalf of Party at a JDC meeting, and within [***] Business Days after conclusion of each JDC meeting, preparing and issuing minutes of the meeting. Such minutes will be deemed agreed only after such minutes have been approved by both Parties in writing. The minutes should include any matters presented to the JDC for a vote and the vote cast by each [***] on behalf of a Party's members of the JDC.

2.9 **JDC Responsibilities** . Each JDC will be responsible for the following items as they relate to the Licensed Molecule and the Licensed Product(s) in the Zai Lab Territory:

2.9.1 **Technology Transfer** . coordinating the initial transfer of INCY Technology from INCY to Zai Lab;

2.9.2 **Development Plan Creation** . creating the Development and regulatory strategies and Development Plan for the Licensed Product(s) for review and approval by the JSC;

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2.9.3 Development Oversight . overseeing and coordinating the Development and regulatory activities as articulated by the Development Plan approved by the JSC ;

2.9.4 Development Monitoring . monitoring the progress of work being done under the Development Plan approved by the JSC; and

2.9.5 Invention Sharing . serving as a forum for the sharing of Agreement Inventions.

2.10 JDC Meetings . The JDC will hold meetings (either in-person or by teleconference, videoconference or some other electronic means) at such times and places as [***] of the JDC may reasonably determine, *provided* that, unless the Parties agree otherwise, the JDC will meet at least once per [***] by teleconference, videoconference or some other electronic means and *further provided that* the Parties will use Commercially Reasonable Efforts to hold JDC meetings adjacent (in time) to [***] as much as reasonably possible. Each Party will bear its own costs associated with attending meetings. Each Party may from time to time invite a reasonable number of participants including its compliance program personnel or other representatives, to attend each JDC meeting in a non-voting capacity. Each individual attending any JDC meeting hereunder (whether as a JDC member or invitee) will be bound by written non-use, non-disclosure terms and conditions at least as restrictive as those set forth in this Agreement with respect to the Confidential Information of the other Party (for clarity, this may be through employment agreements with such individuals).

2.11 Decision-making of JDC . The members of the JDC will discuss all matters reasonably and consider the other Party's views in good faith, and attempt to make all decisions of the JDC by [***] . When voting on any matter properly before the JDC, each Party will have [***] cast by its respective [***] of the JDC. If the JDC is not able to reach consensus with respect to a particular matter (as demonstrated by the same vote by each of the Parties' respective [***]), and the JDC is unable to resolve the dispute after endeavoring for [***] Business Days to do so, then either Party's JDC [***] may, by written notice to the other Party's JDC [***] and the JSC, refer such matter to the JSC for discussion and resolution in accordance with Section 2.5 (Decision-making of JSC) above.

3. DEVELOPMENT

3.1 Transfer of Technology .

3.1.1 Initial Transfer by INCY . Within [***] days after INCY's receipt of the upfront payment due under Section 7.1 (Upfront Payment), INCY will deliver to Zai Lab an electronic copy of all Technology and Regulatory Materials (and to the extent required by Regulatory Authorities in the Zai Lab Territory, the notarizations of any such Technology and Regulatory Materials) that is Controlled by INCY or any of its Affiliates

as of the Effective Date and that is reasonably necessary for the Development of Licensed Products in the Zai Lab Territory in accordance with the terms and conditions of this Agreement, including those items listed on **Schedule 3.1 (INCY Technology)** or otherwise referred to or referenced in the initial Development Plan attached as **Schedule 3.4 (Development Plan)** on the Effective Date. To the extent that Zai Lab believes any of such Technology or Regulatory Materials was not delivered, Zai Lab may request delivery of additional Technology and Regulatory Materials, and INCY will [***] . INCY will deliver an electronic copy of the additional materials requested [***] .

3.1.2 Additional Disclosures . In addition to those additional disclosures by INCY pursuant to this Agreement , including pursuant to Section 3.11 (Collaboration Studies) or Section 3.12 (Ancillary Studies), from time to time throughout the Term, INCY may [***] disclose and deliver to Zai Lab a copy of additional INCY Technology and Regulatory Materials that INCY believes may be reasonably useful for the Development, Commercialization or packaging or labelling of the Licensed Products by Zai Lab and in connection with Zai Lab's activities under this Agreement.

3.1.3 INCY's Assistance . At Zai Lab's reasonable request, INCY will provide up to [***] of technical assistance before [***] , to assist Zai Lab with its understanding of such technology; provided that [***] . Starting on [***] , at Zai Lab's reasonable request, INCY will provide up to [***] of technical assistance per [***] after each transfer of Data to Zai Lab pursuant to Section 3.11.1 (INCY Collaboration Study) or Section 3.12 (Ancillary Studies) to assist Zai Lab with its understanding of such Data. [***] . INCY will [***] any additional technical assistance reasonably requested by Zai Lab to assist Zai Lab with its understanding of any of the INCY Technology and, if INCY [***] . For clarity, [***] .

3.1.4 Zai Lab's Assistance . Zai Lab will provide up to [***] of technical assistance per [***] after each transfer of Data to INCY pursuant to Section 3.11.2 (Zai Lab Collaboration Study) or Section 3.12 (Ancillary Studies) to assist INCY with its understanding of such Data. [***] . Zai Lab will [***] any additional technical assistance reasonably requested by INCY to assist INCY with its understanding of any of such Data and if Zai Lab agrees to provide such additional technical assistance then Zai Lab will provide such additional assistance [***] . For clarity, [***] .

3.2 Zai Lab Development Responsibility . As between the Parties, Zai Lab will be solely responsible for the Development of the Licensed Product(s) in the Field throughout the Zai Lab Territory, [***] . Zai Lab will use Commercially Reasonable Efforts to Develop the Licensed Product(s) to obtain Regulatory Approval in the Zai Lab Territory for [***] in accordance with the Development Plan and in compliance with Applicable Law, including GCP and ICH Requirements.

3.3 Manufacturing for Development . Within [***] days following the Effective Date, Zai Lab and INCY will initiate and thereafter conduct negotiations in good

faith for a separate clinical supply agreement for the manufacturing and supply of the Licensed Product(s) to be used in Clinical Trials for the Field in the Zai Lab Territory, [***] (such agreement, once mutually agreed, the " ***Clinical Supply Agreement*** "). Unless otherwise agreed or required by Applicable Law, the Clinical Supply Agreement will specify that: (a) INCY will supply (or cause its Affiliate or [***] to supply) such Licensed Product(s) packaged in [***] ; (b) to the extent that such Licensed Product(s) are the same as Licensed Product(s) manufactured by or on behalf of INCY outside the Zai Lab Territory, such Licensed Product(s) will be compliant with all requirements of the applicable Regulatory Authority(ies) and Applicable Laws in the Zai Lab Territory as packaged or as delivered in clause (a) of this Section 3.3 ; (c) such Licensed Product(s) supplied by INCY to Zai Lab [***] ; (d) Zai Lab will provide a [***] month rolling forecast (the " ***Rolling Forecast*** "); (e) Zai Lab will update the Rolling Forecast on the first Business Day of each Calendar Quarter; (f) the first [***] months of the Rolling Forecast will be binding on Zai Lab ; and (g) Zai Lab will be responsible for [***] to the Licensed Product(s) for use in the Zai Lab Territory.

3.4 Development Plans . The Development of the Licensed Product(s) in the Zai Lab Territory will be conducted by [***] pursuant to a plan that will include a description in reasonable detail of the Development activities to be performed in support of the Regulatory Approval of the Licensed Product(s) in the Zai Lab Territory, including [***] (each, a " ***Development Plan*** "). The initial Development Plan agreed to by the Parties is attached hereto as **Schedule 3.4 (Development Plan)** . Any material changes to the Development Plan will be proposed by the JDC to the JSC for the JSC's review and consideration , including the addition of any Clinical T rial protocols or any material changes thereto . The JDC will propose updates to the Development Plan no less frequently than on an [***] basis thereafter. In the event of any proposed change to the Development Plan [***] to review and discuss any such proposed changes and determine an appropriate revision (if any) to the Development Plan.

3.5 Clinical Trial Protocols . Zai Lab will provide INCY with a protocol for each planned Clinical Trial for each Licensed Product(s) to be conducted in the Zai Lab Territory. INCY will promptly review such protocol and may provide comments to Zai Lab. Zai Lab will consider in good faith any comments relating to the design and conduct of such activities and will not conduct any such Clinical Trial if INCY notifies Zai Lab that [***] and provides its rationale for such belief in writing to Zai Lab.

3.6 Dose in Clinical Trials for Each Licensed Product .

3.6.1 Dose in Clinical Trials for [***] . Zai Lab will conduct Clinical Trials for each [***] . If any bioequivalency data from Clinical Trials for the [***] demonstrate that a new or modified dose or schedule is necessary to be used with the local population of the Zai Lab Territory to achieve the same pharmacokinetic profile achieved by [***] when used in Clinical Trials in the Field conducted in [***] , then INCY will not withhold its approval to Zai Lab's proposed new or modified dose and schedule for Clinical

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Trials for [***] unless INCY believes that such dosing or schedule is reasonably likely to have a material adverse impact on the safety profile or commercial prospects of the [***] . If INCY withholds such an approval, then INCY will provide its rationale for such belief in writing to Zai Lab.

3.6.2 Dose in Clinical Trials for [***] . Zai Lab will conduct Clinical Trials for each [***] . If either (x) any [***] from Clinical Trials for a [***] conducted in the Zai Lab Territory demonstrate that [***] is necessary to be used with the local population of the Zai Lab Territory to achieve the [***] when used in Clinical Trials conducted in the Field in [***] ; (y) Zai Lab reasonably believes that a different dose of the [***] will be necessary or could reasonably be expected to benefit safety or efficacy when dosed as a component of a [***] ; or (z) a Regulatory Authority in the Zai Lab Territory requires or recommends that a different dose of the [***] be used when dosed as a component of a [***] as evidenced by written documentation or correspondence, then INCY will not withhold its approval to Zai Lab's proposed or modified new dose and schedule for Clinical Trials for the [***] unless INCY believes that such dosing or schedule is reasonably likely to have a material adverse impact on the safety profile of any [***] . If INCY withholds such an approval, then INCY will provide its rationale for such belief in writing to Zai Lab.

3.7 Development Records and Reporting .

3.7.1 Records . Zai Lab will, and will cause each of its Affiliates and Third Party Sublicensees to, maintain complete and accurate records of all work conducted by or on behalf of Zai Lab in furtherance of the Development of the Licensed Product(s) and all material results, Data and Developments made in conducting such activities. Such records will be maintained in sufficient detail and in good scientific manner appropriate for patent, audit, and regulatory purposes and in accordance with Applicable Law. On [***] prior written notice, INCY will have the right to conduct a GCP audit relating to Zai Lab's Development activities.

3.7.2 Reporting . Zai Lab will provide to the JDC, within [***] Business Days prior to [***] , in English, a summary (in Microsoft PowerPoint or Word) of Zai Lab's Development activities and Data from Clinical Trials related to the Licensed Product(s) in the Zai Lab Territory pursuant to the Development Plan. Zai Lab will promptly respond to INCY's reasonable questions or requests for additional information relating to such Development activities.

3.8 Regulatory Filings and Related Activities .

3.8.1 Regulatory Approval Activities .

(a) **Zai Lab Activities** . Subject to Section 3.13 (INCY Pipeline Combination Study and INCY Pipeline Combination Regimen in the Zai Lab Territory),

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Zai Lab will apply for (and maintain), [***] all INDs, BLAs and other Regulatory Materials and Regulatory Approvals of the Licensed Product(s) in the Zai Lab Territory. Zai Lab will be responsible for the preparation of all Regulatory Materials and all communications and interactions with Regulatory Authorities with respect to the Licensed Product(s) in the Zai Lab Territory, both prior to and subsequent to Regulatory Approval. Zai Lab will file all required regulatory dossiers to obtain (and maintain) Regulatory Approvals of the Licensed Product(s) in the Zai Lab Territory. INCY will provide up to [***] of assistance by phone or in person per [***] as reasonably requested from time to time to assist Zai Lab with its preparation for and communications with Regulatory Authorities in the Zai Lab Territory at no charge to Zai Lab, including by attending meetings with Regulatory Authorities with Zai Lab . [***] . INCY will provide such additional assistance to Zai Lab [***] . For clarity, [***] .

(b) **Zai Lab Assistance of INCY Activities** . Zai Lab will provide assistance by phone or in person as reasonably requested from time to time by INCY to assist INCY with its preparation for and communications with Regulatory Authorities, including by attending meetings with Regulatory Authorities with INCY, any of its Affiliates, or any of its or their sublicensees, with respect to any Data that is Controlled by Zai Lab and arising from any [***] . Zai Lab will provide up to [***] of assistance by phone or in person per [***] to assist INCY with its preparation for and communications with Regulatory Authorities at [***] , including by attending meetings with Regulatory Authorities with INCY. [***] . Zai Lab will provide such additional assistance to INCY [***] . For clarity, [***] .

3.8.2 Regulatory Approval Ownership .

(a) **Domestic Drug Registration Pathway** . For each of such Regulatory Approvals for Licensed Product(s) being pursued by the Domestic Drug Registration Pathway, Zai Lab will apply for Regulatory Approvals in the name of Zai Lab.

(b) **Import Drug Registration Pathway** . For each of such Regulatory Approvals for the Licensed Product(s) being pursued by Zai Lab by the Import Drug Registration Pathway, Zai Lab will apply for and hold Regulatory Approvals in the name of Zai Lab; *provided that* , [***] . To the extent later permitted by Applicable Law and requested by Zai Lab , INCY shall promptly cooperate with Zai Lab to [***]. The Parties shall use good faith efforts to cooperate to effectuate this Section 3.8.2(b) (Import Drug Registration Pathway).

(c) **Zai Lab Affiliates or Third Party Sublicensee** . An (i) Affiliate or (ii) Third Party Sublicensee of Zai Lab may apply for and hold a Regulatory Approval for a Licensed Product in a Region only upon Zai Lab's written request and with the advance, written consent of INCY. Upon or after making any such request, Zai Lab will discuss with INCY the rationale for such request. INCY will consider any such request by Zai Lab in good faith, and INCY will not unreasonably withhold, delay or condition its

consent. Zai Lab will cause any Affiliate or Third Party Sublicensee of Zai Lab that seeks such Regulatory Approvals under Section 3.8.2(a) (Domestic Drug Registration Pathway) and Section 3.8.2(b) (Import Drug Registration Pathway) to execute a written agreement with INCY binding such Affiliate to all applicable restrictions and obligations of Zai Lab under this Agreement, including the same restrictions and obligations of Zai Lab under Section 3.8.2(a) (Domestic Drug Registration Pathway) and Section 3.8.2(b) (Import Drug Registration Pathway).

(d) **No Others or Assignment** . For avoidance of doubt, with respect to the rights granted to Zai Lab under this Agreement, no Subcontractor or other Person (other than Zai Lab, or, with consent of INCY, its Affiliate or Third Party Sublicensee) may apply for or hold any Regulatory Approval for a Licensed Product. Moreover, except with assignment of this Agreement as permitted in accordance with Section 13.7 (Assignment), neither Zai Lab nor its Affiliate or Third Party Sublicensee may assign any Regulatory Approval to any Person without the advance, written consent of INCY.

3.9 Regulatory Materials and Meetings .

3.9.1 Materials and Correspondence .

(a) To the extent not prohibited by any Applicable Law or any Regulatory Authority, Zai Lab will provide INCY with : (i) an electronic copy and English-language summary of all material Regulatory Materials and material correspondence with Regulatory Authorities received from Regulatory Authorities related to any of the Licensed Product(s) within [***] Business Days after receipt by or on behalf of Zai Lab ; (ii) an electronic copy and English-language summary of any other Regulatory Materials as reasonably requested by INCY from time to time; and (iii) a complete translation of any material portions of any such materials as reasonably requested by INCY from time to time within [***] days after the request from INCY [***] .

(b) In addition to the foregoing, if Zai Lab receives any material correspondence from any Regulatory Authority related to any of the Licensed Product(s), including any acceptance or denial of any major filings (e.g., IND, BLA), within [***] Business Days after receipt by or on behalf of Zai Lab, Zai Lab will cause one of its members of the JSC or the chairperson of the JDC to contact one of INCY's members of the JSC or the chairperson of the JDC by telephone or videoconference and advise such member of the existence and a summary of the content of such material correspondence.

(c) Before submitting (or having submitted) any material Regulatory Materials or material correspondence to any Regulatory Authorities relating to the Licensed Product(s), Zai Lab will provide INCY with (i) for major filings (e.g., IND, BLA), an electronic copy and English language summary of such major filing at least [***] Business Days before filing with the applicable Regulatory Authority, [***] and (ii) with

respect to all other material Regulatory Materials or material correspondence, an electronic copy and English-language summary of such materials or correspondence at least [***] Business Days before filing with or submission to the applicable Regulatory Authority . [***] .

3.9.2 Meetings . Zai Lab will notify INCY of each scheduled meeting, conference or discussion with Regulatory Authorities (including advisory committee meetings and any other meeting of experts convened by a Regulatory Authority) regarding material issues involving any of the Licensed Product(s). To the extent not prohibited by any Applicable Law or Regulatory Authority, Zai Lab will use good faith efforts to provide such notice within [***] Business Days after Zai Lab receives notice of the scheduling of such meeting, conference, or discussion and at least [***] Business Days in advance of any such meeting, conference or discussion. To the extent not prohibited by any Applicable Law or Regulatory Authority, INCY will (a) be entitled to be present at all such meetings, conferences or discussions with Regulatory Authorities in the same manner in which such meeting, conference or discussion is conducted or (b) at its option, by telephone. [***] to the extent not prohibited by any Applicable Law or Regulatory Authority, INCY will consider in good faith any request by Zai Lab for INCY to (y) participate in any material meetings with Regulatory Authorities, including by providing appropriate technical experts, and (z) provide reasonable technical assistance to Zai Lab with respect to such material meetings.

3.10 Development Diligence Reversion Right .

3.10.1 Conditions . Without limiting the generality of the obligations of Zai Lab under this ARTICLE 3 (DEVELOPMENT), INCY will have the right (but not the obligation) to immediately (by notice to Zai Lab) revert all rights to the Licensed Molecule and all Licensed Products under this Agreement to INCY upon [***] days' written notice to Zai Lab, [***] , if either: (y) Zai Lab informs INCY that Zai Lab is no longer Developing any Licensed Product in the Field in the Zai Lab Territory or (z) subject to Section 3.10.2 (Extension for Delay), if Zai Lab fails to:

(a) [***] ;

(b) [***] ; or

(c) [***] .

For clarity, upon Zai Lab achieving all three conditions described in clauses (a), (b) and (c) of this Section 3.10.1 within the respective timelines, in each case subject to Section 3.10.2 (Extension for Delay), INCY's right to (by notice to Zai Lab) revert all right to the Licensed Molecule and all Licensed Products pursuant to this Section 3.10 (Development Diligence Reversion Right) will automatically expire.

3.10.2 Extension for Delay . Each of the deadlines provided in Section 3.10.1 (Conditions) above will be extended by the duration of any delays that are

encountered during the course of Development and caused by events outside of the control of Zai Lab, including:

(a) Force Majeure;

(b) Unforeseen bona fide regulatory delays;

(c) The failure of INCY to supply the required Licensed Product(s) to Zai Lab for use in Clinical Trials in accordance with timelines provided in the Clinical Supply Agreement and such failure results in a Zai Lab delay;

(d) Any extension agreed upon in writing by both Parties, for example, coincidentally with an amendment to the Development Plan; and

(e) Any other event that caused an actual delay for which INCY is responsible or accountable for (including if a Regulatory Authority places an INCY product on regulatory hold, resulting in regulatory hold being put in place for Zai Lab in the Zai Lab Territory or if an unforeseen delay occurs based upon an INCY Development activity that is reasonably necessary for Zai Lab to initiate or continue the Development of the Licensed Product(s) in the Zai Lab Territory to be completed).

3.11 Collaboration Studies .

3.11.1 INCY Collaboration Study . Each Clinical Trial that (x) is not an INCY Pipeline Combination Study , (y) is on-going as of the Effective Date or initiated after the Effective Date by INCY, and (z) is primarily intended to support the Development or Regulatory Approval of any Licensed Product(s) in the Field in the INCY Territory is referred to as an " ***INCY Collaboration Study*** ."

(a) With respect to any INCY Collaboration Study that includes any site for Clinical Trials in the Zai Lab Territory , INCY will present to Zai Lab for Zai Lab's potential participation in the study and provide the JDC with a study schematic and rationale for the study prior to initiation of such study for the JDC's review. For clarity, INCY will not conduct Clinical Trials in the Zai Lab Territory as part of an INCY Collaboration Study prior to presenting it to Zai Lab for Zai Lab's potential participation. INCY will not conduct any INCY Collaboration Study that includes a site for Clinical Trials in the Zai Lab Territory if Zai Lab reasonably believes such study would have a material adverse impact on the safety profile of the applicable Licensed Product in the Zai Lab Territory and provides its rationale for such belief in writing to INCY. With respect to any INCY Collaboration Study that, based on its then-current trial design, does not involve any site for Clinical Trials in the Zai Lab Territory, whether or not INCY would be willing to include adding sites for Clinical Trials in the Zai Lab Territory, INCY may, but is not obligated to, present to Zai Lab for Zai Lab's potential participation in the study and provide the applicable JDC with a study schematic and rationale for the study for Zai

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Lab's consideration whether or not to participate in such INCY Collaboration Study. INCY Collaboration Studies that are underway as of the Effective Date and for which Zai Lab has elected to participate are listed **Schedule 3.11.1 (INCY Collaboration Studies Underway)** .

(b) If the Parties mutually agree to further discuss the potential of collaborating on an INCY Collaboration Study after INCY presents it to Zai Lab pursuant to Section 3.11.1(a) , then the Parties will discuss potential study design, a final protocol and budget. If the Parties ultimately mutually agree on study design, protocol and budget, then Zai Lab would have the right to participate in such INCY Collaboration Study by [***] .

(c) For any INCY Collaboration Study involving Clinical Trial sites in the Zai Lab Territory in which Zai Lab elects to participate pursuant to Section 3.11.1(a) and Section 3.11.1(b) , Zai Lab will be responsible for all activities (if any) associated with conducting the study in the Zai Lab Territory as outlined in the plan for such INCY Collaboration Study, unless mutually agreed otherwise. [***] . For any such INCY Collaboration Study that is not an Ancillary Study, for which Zai Lab seeks to use the Data to advance Development or Regulatory Approval in the Zai Lab Territory, [***] .

(d) If Zai Lab elected not to participate in an INCY Collaboration Study the first time the opportunity was presented by INCY to Zai Lab pursuant to Section 3.11.1(a) or the Parties are not able to agree upon how Zai Lab would so participate within [***] days of INCY presenting such INCY Collaboration Study to Zai Lab pursuant to Section 3.11.1(a) and Section 3.11.1(b) , then (i) INCY must keep Zai Lab reasonably informed of any progress of any such INCY Collaboration Study if, and only if, the study involves any site for Clinical Trials in the Zai Lab Territory and (ii) INCY will consider in good faith any comments or suggestions provided by Zai Lab related to any such INCY Collaboration Study that involves any site for Clinical Trials in the Zai Lab Territory.

(e) If Zai Lab elected not to participate in any INCY Collaboration Study involving Clinical Trial sites in the Zai Lab Territory the first time the opportunity was presented by INCY to Zai Lab pursuant to Section 3.11.1(a) and Section 3.11.1(b) or the Parties were not able to agree upon how Zai Lab would so participate within [***] days of INCY presenting such INCY Collaboration Study to Zai Lab, but Zai Lab later desires to have access to the Data generated from such INCY Collaboration Study, then INCY will provide Zai Lab [***] . INCY will provide to Zai Lab a summary of the results of such Data reasonably requested by Zai Lab to help Zai Lab determine whether or not [***] .

(f) Notwithstanding anything to the contrary in this Section 3.11.1 (INCY Collaboration Study), for any INCY Collaboration Study that (i) (1) INCY does not present to Zai Lab for potential participation pursuant to clause (a) and (b) of this

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Section 3.11.1 (INCY Collaboration Study) or (2) was presented to Zai Lab for potential participation but does not involve any site for Clinical Trials in the Zai Lab Territory, (ii) has been completed and has Data arising from such study that is Controlled by INCY, and (iii) that INCY or its Affiliate is not otherwise restricted from presenting to Zai Lab or providing Zai Lab access and Right of Reference in the Field in the Zai Lab Territory to such Data by any Applicable Law or contract with a Third Party, then, at Zai Lab's request, INCY will provide Zai Lab [***] . INCY will provide to Zai Lab a summary of the results of such Data to help Zai Lab determine [***] . If such Data is requested by Zai Lab, then INCY will disclose to Zai Lab such Data [***] , unless disclosure of such Data to Zai Lab is not permitted in accordance with customary industry practices, including requirements for database lock, in which case, INCY will disclose such Data promptly after disclosure becomes permissible under customary industry practices.

3.11.2 Zai Lab Collaboration Study . Each Clinical Trial that is conducted by Zai Lab and primarily intended to support the Development or Regulatory Approval of any Licensed Product(s) in the Field in the Zai Lab Territory is referred to as a " ***Zai Lab Collaboration Study*** ."

(a) Prior to initiation of any Zai Lab Collaboration Study, Zai Lab will provide to the JDC a study schematic and the rationale for the study prior to initiation of such study for the JDC's review. Zai Lab will also provide the protocol for the study to INCY if requested by INCY . Zai Lab may, but is not obligated to, elect to present to INCY the right to potentially participate in the Zai Lab Collaboration Study. Whether or not presented to INCY for its participation, Zai Lab will not conduct any Zai Lab Collaboration Study if INCY reasonably believes such study would have a material adverse impact on the safety profile of any Licensed Product and provides its rationale for such belief in writing to Zai Lab.

(b) If the Parties mutually agree to further discuss the potential of collaborating on a Zai Lab Collaboration Study after Zai Lab presents it to INCY pursuant to Section 3.11.2(a) , then the Parties will discuss potential study design, a final protocol and budget. If the Parties ultimately mutually agree on study design, protocol and budget, then INCY would have the right to participate in such Zai Lab Collaboration Study by [***] .

(c) For any Zai Lab Collaboration Study that involves Clinical Trial sites in the INCY Territory in which INCY elects to participate pursuant to Section 3.11.2(a) and Section 3.11.2(b) , INCY will be responsible for all activities (if any) associated with conducting the study in the INCY Territory as outlined in the plan for such Zai Lab Collaboration Study, unless mutually agreed otherwise. [***] . For any such Zai Lab Collaboration Study that is not an Ancillary Study for which INCY seeks to use the Data to advance Development or Regulatory Approval in the INCY Territory, [***] .

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(d) If INCY elected not to participate in a Zai Lab Collaboration Study the first time the opportunity was presented to INCY by Zai Lab pursuant to Section 3.11.2(a) or the Parties were not able to agree upon how INCY would so participate within [***] days of Zai Lab presenting such Zai Lab Collaboration Study to INCY pursuant to Section 3.11.2(a) and Section 3.11.2(b) , but INCY later desires to have access to the Data generated from such Zai Lab Collaboration Study, then Zai Lab will provide INCY access [***] . Zai Lab will provide to INCY a summary of the results of such Data reasonably requested by INCY to help INCY determine [***] .

(e) Notwithstanding anything to the contrary in this Section 3.11.2 (Zai Lab Collaboration Study), for any Zai Lab Collaboration Study that (i) (1) Zai Lab does not present to INCY for potential participation pursuant to clause (a) and (b) of this Section 3.11.2 (Zai Lab Collaboration Study) or (2) was presented to INCY for potential participation but does not involve any site for Clinical Trials in the INCY Territory, (ii) has been completed and has Data arising from such study that is Controlled by Zai Lab, and (iii) that Zai Lab or its Affiliate is not otherwise restricted from presenting to INCY or providing INCY access and Right of Reference in the Field outside the Zai Lab Territory to such Data by any Applicable Law or contract with a Third Party, then, at INCY's request, Zai Lab will provide INCY [***] . Zai Lab will provide to INCY a summary of the results of such Data, if such Zai Lab Collaboration Study has been completed at the time of INCY's request to help INCY determine whether or not [***] . If such Data is requested by INCY, then Zai Lab will disclose to INCY such Data [***] , unless disclosure of such Data to INCY is not permitted in accordance with customary industry practices, including requirements for database lock, in which case, Zai Lab will disclose such Data promptly after disclosure becomes permissible under customary industry practices.

3.11.3 Joint Collaboration Study . From time to time, the Parties might want to discuss jointly conducting a Phase II Clinical Trial or a Phase III Clinical Trial upon terms different than those described in Section 3.11.1 (INCY Collaboration Study) or Section 3.11.2 (Zai Lab Collaboration Study). Each such Phase II Clinical Trial or Phase III Clinical Trial that both Parties mutually agree to conduct and that are intended to support the Development or Regulatory Approval of any Licensed Product(s) anywhere in the world is referred to as a " ***Joint Collaboration Study*** ." Prior to the commencement of any such Joint Collaboration Study, the Parties will agree on at least the following: (i) the design of such Joint Collaboration Study; (ii) the number or proportion of subjects from the Zai Lab Territory to be enrolled in such Joint Collaboration Study; (iii) the number or proportion of subjects from the INCY Territory to be enrolled in such Joint Collaboration Study; (iv) each Party's operational responsibilities with respect to such Joint Collaboration Study; (v) [***] and (vi) access to the Data and Rights of Reference arising from any such Joint Collaboration Study.

3.11.4 Joint [***] **Collaboration Study** . The Parties will conduct a [***] to support the Development or Regulatory Approval of a Licensed Product to treat [***]

(the " [***] ***Collaboration Study*** "); *provided that* in the event Regulatory Authorities do not permit Zai Lab or INCY to conduct such Joint [***] Collaboration Study or Zai Lab or INCY reasonably determines in good faith that it would not be feasible to conduct such Joint [***] Collaboration Study, the Parties will not be obligated to conduct the Joint [***] Collaboration Study and will use good faith efforts to mutually agree to replace the Joint [***] Collaboration Study with another study of similar size. The Joint [***] Collaboration Study will be conducted in accordance with the Clinical Trial design set forth on **Schedule 3.11.4 (Joint** [***] **Collaboration Study)** and such other terms as may be mutually agreed, including the items described in Section 3.11.3 (Joint Collaboration Study) for a Joint Collaboration Study.

3.12 Ancillary Studies. Each Party hereby grants to the other Party a Right of Reference to, and will promptly disclose to such other Party upon such other Party's request, certain Data generated in any completed Ancillary Studies [***] , as further provided in Section 6.5 (Rights of Reference).

3.13 INCY Pipeline Combination Study and INCY Pipeline Combination Regimen in the Zai Lab Territory . As between the Parties, INCY retains the exclusive right to conduct (or have conducted by or license to its Affiliates or Third Parties) INCY Pipeline Combination Studies in the Zai Lab Territory, [***] subject to this Section 3.13 (INCY Pipeline Combination Study and INCY Pipeline Combination Regimen in the Zai Lab Territory). Unless otherwise mutually agreed or as specified below, Zai Lab has no right to participate in, receive any efficacy Data from, or receive any Right of Reference with respect to any Data, Regulatory Materials or Regulatory Approvals related to, any INCY Pipeline Combination Regimen.

3.13.1 Study Conditions .

(a) Prior to initiating any INCY Pipeline Combination Study in the Field in the Zai Lab Territory, INCY will provide to the JDC a study schematic for the INCY Pipeline Combination Study. INCY will not initiate the INCY Pipeline Combination Study if Zai Lab reasonably believes that such study would have a material adverse impact on the safety profile of a corresponding Licensed Product(s) in the Field in the Zai Lab Territory and Zai Lab provides its rationale for such belief.

(b) After initiating any INCY Pipeline Combination Study in the Zai Lab Territory, INCY will permit Zai Lab to review and comment on, and allow Zai Lab to participate in, any material interactions with Regulatory Authorities in the Zai Lab Territory that relate solely to the Licensed Product(s) being evaluated in the INCY Pipeline Combination Study (excluding interactions with Regulatory Authorities in the Zai Lab Territory that relate to an INCY Pipeline Assets) and will consider in good faith any Zai Lab comments relating to such regulatory interactions until such time as the associated Licensed Product(s) is the subject of a Regulatory Approval in the Zai Lab Territory.

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3.13.2 R ight to Seek Regulatory Approval Associated with INCY Combination Regimens .

(a) INCY or its Affiliate (or a Third Party on behalf of INCY or its Affiliate) may seek Regulatory Approval in the Zai Lab Territory for the INCY Pipeline Asset(s) as one or more component(s) of an INCY Pipeline Combination Regimen. To the extent that INCY has the right to grant Zai Lab or its Affiliates, as applicable, the ability to conduct such activities, Zai Lab, or, subject to INCY's advance written consent under and Zai Lab's compliance with Section 3.8.2(c) (Zai Lab Affiliates or Third Party Sublicensee), Affiliates of Zai Lab, may seek Regulatory Approval in the Zai Lab Territory for the associated Licensed Product(s) that constitute the component(s) of an INCY Pipeline Combination Regimen. For clarity, the preceding sentence will not limit the licenses granted to Zai Lab by INCY pursuant to Section 6.1 (License to Zai Lab) in any way. Zai Lab will grant to INCY a Right of Reference in the Field outside the Zai Lab Territory to the applicable Regulatory Materials for seeking such Regulatory Approval. INCY will grant to Zai Lab a Right of Reference in the Field in the Zai Lab Territory to the applicable Regulatory Materials for seeking such Regulatory Approval.

(b) I f INCY seeks Regulatory Approval for an INCY Pipeline Asset as one or more component(s) of an INCY Pipeline Combination Regimen and Zai Lab seeking Regulatory Approval for the associated Licensed Product(s) as one or more component(s) of the INCY Pipeline Combination Regimen is required by NMPA for INCY to seek Regulatory Approval of the INCY Pipeline Asset as one or more component(s) of an INCY Pipeline Combination Regimen, then Zai Lab shall initiate the process for seeking such Regulatory Approval within [***] months after notice thereof from INCY, and thereafter shall use Commercially Reasonable Efforts to obtain and maintain such Regulatory Approval. The Parties shall coordinate with each other in good faith on the timing and filing of their respective Regulatory Approvals for their respective component(s) of the subject INCY Pipeline Combination Regimen, taking into account the other Party's efforts to seek Regulatory Approval for its component(s) of the subject INCY Pipeline Combination Regimen. Zai Lab may cross-reference Regulatory Material that is Controlled by INCY and that is necessary for Zai Lab to seek Regulatory Approval in the Zai Lab Territory for the Licensed Product(s) as one or more component(s) of the INCY Pipeline Combination Regimen. For the avoidance of doubt, (i) Zai Lab is not permitted to seek, and will not seek, Regulatory Approval for [***] and (ii) INCY is not permitted to seek, and will not seek, Regulatory Approval for [***] .

(c) Z ai Lab will (i) have the exclusive right to Commercialize a Licensed Product(s) in the Zai Lab Territory in accordance with its Regulatory Approval for such Licensed Product(s) as one or more component(s) of an INCY Pipeline Combination Regimen in the Zai Lab Territory pursuant to this Section 3.13.2 (Right to Seek Regulatory Approval Associated with INCY Combination Regimens) and (ii) use Commercially Reasonable Efforts to Commercialize each such Licensed Product(s) in accordance with its Regulatory Approval for such Licensed Product(s) as component(s) of

an INCY Pipeline Combination Regimen if Zai Lab obtains Regulatory Approval therefor. To the extent that INCY has the right to grant Zai Lab or its Affiliates, as applicable, the ability to conduct such activities, as part of such Commercialization of the Licensed Product(s) as one or more component(s) of an INCY Pipeline Combination Regimen, Zai Lab may promote, Detail and Commercialize the Licensed Product(s) in the Zai Lab Territory as one or more component(s) of an INCY Pipeline Combination Regimen in the Zai Lab Territory subject to and in accordance with Section 4.9.2 (INCY Pipeline Combination Regimen Detailing). For clarity, the preceding sentence will not in any way limit the licenses granted to Zai Lab by INCY pursuant to Section 6.1 (License to Zai Lab) with respect to Zai Lab's right or ability to exclusively sell, offer to sell or book sales for such Licensed Product(s) in the Zai Lab Territory.

3.14 Global Safety Databases; PVA Agreements . As between the Parties, INCY will establish, hold and maintain a global safety database for each Licensed Product(s) (the " ***Global Safety Database*** "). The Parties will mutually agree to the terms of a pharmacovigilance agreement for the Licensed Molecule and the Licensed Product(s) (each such agreement, once agreed, a " ***Pharmacovigilance Agreement*** ") within [***] days after the Effective Date. The terms of such agreement will include provisions customary for such agreements, including audit rights. INCY will enter into each Global Safety Database information on all adverse events concerning a Licensed Product(s) occurring anywhere in the world and reported to either of the Parties in accordance with the applicable Pharmacovigilance Agreement. Zai Lab will submit required safety data (*e.g.* serious adverse events and special events) from its Clinical Trials to INCY as set forth in Pharmacovigilance Agreements as necessary for INCY's maintenance of the Global Safety Database. Regardless of whether Zai Lab co-funded any INCY Collaboration Study, Zai Lab shall have the right to reference any and all safety data specific to the Licensed Products solely as outlined in the associated INCY drug safety update reports and periodic safety update reports for such Licensed Products as necessary for the Development and Commercialization of the applicable Licensed Products in the Field and in the Zai Lab Territory.

3.15 Core Data Sheet . As between the Parties, [***] will establish, hold and maintain the core data sheet for each Licensed Product(s) (the " ***Core Data Sheet*** "). Each Core Data Sheet will provide a summary of safety data associated with the Licensed Product(s) from everywhere in the world. Zai Lab will submit required safety data (e.g. adverse events) from its Clinical Trials to INCY as set forth in Pharmacovigilance Agreements, as necessary for INCY's maintenance of the Core Data Sheet. Regardless of whether Zai Lab co-funded any INCY Collaboration Study, Zai Lab shall have the right to reference any and all safety data expressly contained in such Core Data Sheets, as necessary for the Development and Commercialization of the applicable Licensed Products in the Field and in the Zai Lab Territory, and INCY shall provide Zai Lab with access to any and all safety data contained in such Core Data Sheets. Regardless of whether Zai Lab co-funded any INCY Collaboration Study, Zai Lab shall have the right to reference any and all safety data that is specific to the Licensed Product in the associated Core Data Sheet, as necessary for the

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Development and Commercialization of the applicable Licensed Products in the Field and in the Zai Lab Territory, and INCY shall provide Zai Lab with access to any and all such safety data contained in such Core Data Sheets.

3.16 Remedial Actions . Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product(s) may be subject to any recall, corrective action or other regulatory action with respect to such product taken by virtue of Applicable Law (a " ***Remedial Action*** "). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Each Party will, and will ensure that its Affiliates and Sublicensees will, maintain adequate records to permit the Parties to trace the manufacture, distribution and use (to the extent possible) of the Licensed Product(s). As between the Parties, Zai Lab will have sole discretion with respect to any matters relating to any Remedial Action for the Licensed Product(s) in the Zai Lab Territory and INCY will have sole discretion with respect to any matters relating to any Remedial Action for the Licensed Product(s) in the INCY Territory . In the event that a Party determines that any Remedial Action with respect to the Licensed Product(s) in its Territory should be commenced, or if Remedial Action is required by any Regulatory Authority having jurisdiction over the matter in its Territory, such Party will control and coordinate all efforts necessary to conduct such Remedial Action and will be responsible for [***] of such Remedial Action in its territory; *provided, however* , that (a) if such Remedial Action in the Zai Lab Territory is attributable to any inaction or action of INCY, any of its Affiliates, or a Third Party on behalf of INCY or any of its Affiliates, then INCY will be responsible for all cost and expense of such Remedial Action in the Zai Lab Territory, and (b) if such Remedial Action in the INCY Territory is attributable to any inaction or action of Zai Lab, any of its Affiliates, any sublicensee or any Third Party on behalf of Zai Lab or any of its Affiliates or sublicensees, then Zai Lab will be responsible for all cost and expense of such Remedial Action in the INCY Territory.

4. COMMERCIALIZATION

4.1 Zai Lab Responsibility . Zai Lab will use Commercially Reasonable Efforts to Commercialize at least one Licensed Product(s) in the Zai Lab Territory after Regulatory Approval of the Licensed Product(s) has been obtained. Subject to Section 2.3 (JSC Responsibilities), Zai Lab will [***] , whether such Licensed Product(s) is sold as a monotherapy or as one or more component(s) of a combination therapy. Zai Lab will conduct all Commercialization activities with respect to Licensed Product(s) in accordance with all Applicable Law.

4.2 Commercialization Reports . Zai Lab will update the JSC at least [***] at regularly scheduled JSC meetings regarding Zai Lab's Commercialization activities with respect to the Licensed Product(s) in the Zai Lab Territory. Each such update will be in a form to be agreed by the JSC and will summarize Zai Lab's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Licensed Product(s) in the Zai

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Lab Territory. Zai Lab will consider in good faith any comments or suggestions provided by INCY related to such Commercialization activities. In addition, Zai Lab will make available to INCY such additional information about its Commercialization activities as may be reasonably requested by INCY from time to time.

4.3 **Commercial Supply Agreement** . Promptly after the first submission of a BLA for a Licensed Product(s) in the Zai Lab Territory, Zai Lab and INCY will initiate and thereafter conduct negotiations in good faith for a separate commercial supply agreement for the manufacturing and supply of Licensed Product(s) to be sold for commercial purposes (after Regulatory Approval) for the Field in the Zai Lab Territory (such agreement, once mutually agreed, the " ***Commercial Supply Agreement*** "). Unless otherwise agreed or required by Applicable Law, the Commercial Supply Agreement will specify that (a) INCY will supply (or cause its Affiliate or a Third Party to supply) such Licensed Product(s) packaged [***] ; (b) to the extent that such Licensed Product(s) are the same as Licensed Product(s) manufactured by or on behalf of INCY outside the Zai Lab Territory, such Licensed Product(s) will be compliant with all requirements of the applicable Regulatory Authority(ies) and Applicable Laws in the Zai Lab Territory as packaged or as delivered in clause (a) of this Section 4.3 ; (c) such Licensed Product(s) supplied by INCY to Zai Lab [***] ; (d) Zai Lab will provide a [***] Rolling Forecast; (e) Zai Lab will update the Rolling Forecast on the [***] ; (f) [***] of the Rolling Forecast will be binding on Zai Lab; and (g) Zai Lab will be responsible for applying approved labels to the Licensed Product(s) for use in the Zai Lab Territory.

4.4 **Manufacturing in the PRC** .

4.4.1 [***].

4.4.2 [***] .

4.4.3 [***] .

4.5 **Packaging and Labelling Outside the Zai Lab Territory** . If Zai Lab pursues Regulatory Approval in the PRC for a Licensed Product using the Import Drug Registration Pathway, Zai Lab may request that INCY contract with a contract manufacturing organization for the additional/secondary packaging and labelling of the Licensed Product(s) outside the Zai Lab Territory (" ***Packaging CMO*** ") to be supplied to Zai Lab solely for Commercialization in the Field in the Zai Lab Territory in accordance with the terms and conditions of this Agreement. Zai Lab may suggest to INCY potential Packaging CMO candidates. If any Packaging CMO is identified that meets INCY's requirements, including those set forth on [***] , then INCY would use reasonable efforts to enter into a contract with such Packaging CMO to perform such activities. Zai Lab may suggest to INCY potential terms and conditions applicable to the Packaging CMO's activities. If INCY enters into a contract with a Packaging CMO, then INCY will invoice Zai Lab for [***] . If INCY decides not to contract with any Packaging CMO, then the

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Parties will negotiate in good faith for an alternative solution to add additional/secondary packaging and labelling to Licensed Product(s) supplied by or on behalf of INCY or its Affiliates.

4.6 Two-Invoice Policy and Tendering Policy .

4.6.1 Zai Lab Holds Regulatory Approval . In the event that Zai Lab pursues the Import Drug Registration Pathway for a Licensed Product and obtains the Regulatory Approval for such Licensed Product, for distribution channels in the PRC in which the Two-Invoice Policy applies, INCY will consider in good faith whether to permit an Affiliate of Zai Lab established outside of the PRC to purchase Licensed Product(s) from INCY under the Clinical Supply Agreement for importation into and distribution in the PRC, which permission by INCY will not be unreasonably withheld, delayed or conditioned.

4.6.2 INCY Holds Regulatory Approval . If (a) Zai Lab pursues the Import Drug Registration Pathway for a Licensed Product but INCY obtains and holds the Regulatory Approval for such Licensed Product because Zai Lab is prohibited from doing so by Applicable Law, (b) under the Two-Invoice Policy and Applicable Law in a given Province in the Zai Lab Territory at such time , neither Zai Lab nor any of its Affiliates can, based on their existing qualifications, distribute the Licensed Product for such Province directly or indirectly in such Province and (c) any distributor for the Licensed Product in the Province is required in such Province to have a direct contractual agreement for the supply of the Licensed Product with the owner of the Foreign Marketing Approval of the Licensed Product, then, subject to Applicable Law, INCY will [***] . The Parties will discuss in good faith necessary alternative arrangements for the distribution of the Licensed Product in such Province to comply with the Two-Invoice Policy as implemented in such Province; *provided that* the responsibilities and economic interests of the Parties as agreed under this Agreement and the Commercial Supply Agreement are maintained.

4.7 Commercial Diligence Buy-Back Rights . Without limiting the obligation of Zai Lab under Section 4.1 (Zai Lab Responsibility):

4.7.1 Commercial Reversion Rights . If Zai Lab does not achieve aggregate Net Sales of all Licensed Product(s) being Commercialized in the Zai Lab Territory during the period from [***] to [***] after the First Commercial Sale in the PRC of the first Licensed Product for an Indication other than a Niche Indication (the " [***] ***Period*** ") of at least [***] , then INCY will have the right (but not an obligation) to revert all rights to the Licensed Molecule and all Licensed Products under this Agreement to INCY upon [***] days' written notice to Zai Lab, [***] , by paying to Zai Lab a purchase price of [***] for such [***] Period, [***] . For clarity, upon Zai Lab achieving such aggregated Net Sales during the [***] Period, INCY's right to revert any or all rights to the Licensed Molecule and all Licensed Products under this Section 4.7 will automatically expire.

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4.7.2 [***] **for Commercial Reversion Right** . If, at the time when INCY exercises its reversion right under any of Section 4.7.1 (Commercial Reversion Rights), Zai Lab either (a) had commenced dosing of the first patient in a Pivotal Trial, but such Pivotal Trial was not yet completed (as demonstrated by lockdown of the corresponding Data), or (b) had completed a Pivotal Trial (as demonstrated by lockdown of the corresponding Data) within [***] months before INCY exercised its reversion right , in either case (a) or (b), for a Licensed Product(s) for an Indication that at such time had not been approved for any other Licensed Product(s), the applicable [***] will be [***] . Otherwise the applicable [***] is [***] .

4.8 **INCY Co-Promotion Option** . On a Licensed Product(s)-by-Licensed Product(s) basis, INCY has the right, but not an obligation, to co-promote each Licensed Product(s) under the direction of Zai Lab in the Zai Lab Territory; *provided that* INCY will provide a written notice to Zai Lab of its intention to co-promote at least [***] months before the anticipated First Commercial Sale of such Licensed Product in the PRC. When exercising such option, INCY may elect to field either (a) [***] FTEs or (b) up to [***] of the FTEs dedicated by Zai Lab to providing Detailing in the Zai Lab Territory for such Licensed Product(s) spread across multiple major metropolitan areas of each Region as further specified the initial Co-Promotion Plan attached as **Schedule 4.8 (Co-Promotion Plan)** , which may be updated from time to time; *provided that* INCY agrees that (y) all INCY's co-promotion activities in the Zai Lab Territory after it exercises such option will be in all aspects in compliance with Zai Lab's Commercialization and Detailing standards generally applicable to Zai Lab's own employees ; and (z) any and all information, procedures and other Know-How of Zai Lab that are specific to the Licensed Product and that are not Confidential Information of INCY that INCY learns or accesses from or as a result of such co-promotion activities will be Confidential Information of Zai Lab, and subject to the terms and conditions of ARTICLE 8 (Confidentiality).

4.9 **Commercialization of the INCY Pipeline Combination Regimen** .

4.9.1 **Commercialization Plans** . For any INCY Pipeline Combination Regimen, within [***] months prior to the anticipated date of the later of (a) INCY or its Affiliate (or a Third Party on behalf of INCY or its Affiliate) obtains the Regulatory Approval in the Zai Lab Territory for the INCY Pipeline Asset(s) as one or more component(s) of such INCY Pipeline Combination Regimen or (b) Zai Lab or its Affiliates obtains the Regulatory Approval in the Zai Lab Territory for the Licensed Product(s) as one or more component(s) of such INCY Pipeline Combination Regimen in accordance with Section 3.13 (INCY Pipeline Combination Study and INCY Pipeline Combination Regimen in the Zai Lab Territory), the Parties shall discuss in good faith and agree on (y) Zai Lab's plan to Commercialize the Licensed Product(s) as a component of the INCY Pipeline Combination Regimen in the Zai Lab Territory in accordance with clause (c) of Section 3.13.2 (Right to Seek Regulatory Approval Associated with INCY Combination Regimens), and (z) upon INCY's sole discretion and request, INCY's plan to

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Commercialize the INCY Pipeline Asset(s) as component(s) of such INCY Pipeline Combination Regimen in the Zai Lab Territory.

4.9.2 INCY Pipeline Combination Regimen Detailing . Notwithstanding Section 4.9.1 (Commercialization Plans) and as provided under clause (c) of Section 3.13.2 (Right to Seek Regulatory Approval Associated with INCY Combination Regimens), to the extent that INCY has the right to grant Zai Lab or its Affiliates, as applicable, the ability to conduct such activities, Zai Lab may conduct INCY Pipeline Combination Regimen Detailing in a manner consistent with the terms of this Agreement. Unless otherwise agreed to in writing by the Parties, all INCY Pipeline Combination Regimen Detailing by Zai Lab must be performed in accordance with all Applicable Laws and industry standards and with the quality of similar presentations made by Zai Lab's sales representatives for Zai Lab's other products, if applicable. During any INCY Pipeline Combination Regimen Detailing, Zai Lab sales representatives will only discuss the INCY Pipeline Asset as it relates to a component of the INCY Pipeline Combination Regimen as it relates to the information in the approved label(s) of the Licensed Product(s) in the Zai Lab Territory, including (a) recent major changes, (b) indications and usage, (c) warnings and precautions, (d) adverse reactions, (e) dosage and administration, and (f) clinical data. Unless otherwise mutually agreed by the Parties or required by a Regulatory Authority, Zai Lab sales representatives will not discuss any other data that relates to the INCY Pipeline Asset that is not contained in the approved label(s) of such Licensed Product(s). The Zai Lab sales representative will refer all health care professionals to a sales representative acting on behalf of INCY for the purpose of such discussion. Notwithstanding anything in this Agreement, INCY or its Affiliate (or a Third Party on behalf of INCY or its Affiliate) shall retain the exclusive right to Commercialize the INCY Pipeline Asset and the INCY Pipeline Combination Regimen, subject to Zai Lab exclusive right to Commercialize the Licensed Product(s) component(s) of the INCY Pipeline Combination Regimen.

4.10 Commercialization Exclusivity .

4.10.1 Anti-PD-1/-L1 Monoclonal Antibodies in the Zai Lab Territory in the Field .

(a) Except pursuant to and in accordance with the terms of this Agreement, neither Party will Commercialize or grant any license to an Affiliate or a Third Party to Commercialize any [***] in the Field in the Zai Lab Territory (the " ***Competing*** [***] "); *provided, however, that* the foregoing does not apply to (and so either Party is not prohibited from Commercializing) any antibody or molecule that [***] ; and *provided further, however,* that the foregoing does not apply to (and so either Party is not prohibited from Commercializing), any [***] .

(b) In the event that a Party or any of its Affiliates undergoes a Change of Control involving a Third Party (an " ***Acquirer*** ") or in the event a Third Party becomes an Affiliate of a Party or any of its Affiliates (whether by way of a merger,

consolidation or similar transaction), Section 4.10.1 ([***] in the Zai Lab Territory in the Field) shall not apply to any Competing [***] that is actively being developed, manufactured or commercialized in the Zai Lab Territory by the Acquirer or its affiliates at the closing of the applicable Change of Control transaction or that such Acquirer has rights to develop, manufacture, or commercialize in the Zai Lab Territory, so long as (1) except to the extent any of the following is publicly available at the time of use, no Patents, Technology or Data that is included as part of a license or Right of Reference from the other Party under this Agreement or that is otherwise generated from activities performed under this Agreement or Confidential Information of the other Party is used by or on behalf of such Party or Acquirer, as applicable, or their respective Affiliates in connection with any development, manufacture, or commercialization of such Competing [***] , and (2) such Party or Acquirer, as applicable, or their respective Affiliates, Segregates the development, manufacture, and commercialization of the Competing [***] from the Development, manufacture, and Commercialization of the Licensed Molecule and Licensed Product .

4.10.2 Licensed Products Outside the Field in the Zai Lab Territory . Except pursuant to and in accordance with the terms of this Agreement, neither Party will Commercialize or grant any license to an Affiliate or a Third Party to Commercialize any Licensed Molecule or Licensed Product for application outside the Field in the Zai Lab Territory.

4.10.3 Other [***] **Outside Field** . Subject to the Intellectual Property Rights Controlled by each Party but not granted to the other Party and subject to Sections 4.10.1 ([***] in the Zai Lab Territory in the Field) and Section 4.10.2 (Licensed Products Outside the Field in the Zai Lab Territory), nothing in this Agreement is intended to, nor does, prohibit either Party from Commercializing any [***] or [***] outside of the Field in the Zai Lab Territory so long as any such [***] is not a Licensed Molecule or a Licensed Product.

4.11 Export and Import Restrictions .

4.11.1 No Exploitation by Zai Lab Outside of Zai Lab Territory . Zai Lab will not, and will cause its Affiliates, Subcontractors and Sublicensees to not: (a) Develop, offer to sell, sell, export or otherwise Commercialize any Licensed Molecule or Licensed Product(s) outside the Field or outside the Zai Lab Territory; or (b) offer to sell or sell any Licensed Molecule or Licensed Product(s) to any Affiliate or Third Party knowing or after having a reasonable expectation that such Affiliate or Third Party will, directly or indirectly, resell or export any of such products outside the Zai Lab Territory or for use outside the Field. If Zai Lab or any of its Affiliates, Subcontractors or Sublicensees becomes aware that any distributor, retailer or other Person to which Zai Lab or any of its Affiliates, Subcontractors or Sublicensees has sold or otherwise provided Licensed Product(s) has exported Licensed Product(s) outside the Zai Lab Territory or Commercialized Licensed Product(s) for any application outside the Field, then Zai Lab

will, and will cause each of its Affiliates, Subcontractors and Sublicensees to, immediately cease providing any further quantities of Licensed Product(s) to such Person.

4.11.2 No Exploitation by INCY in the Field in the Zai Lab Territory . Unless expressly specified under this Agreement, INCY will not and will cause each of its Affiliates, Subcontractors and Sublicensees to not: (a) Develop, offer to sell, sell, export or otherwise Commercialize any Licensed Molecule or Licensed Product(s) in the Field in the Zai Lab Territory , or (b) offer to sell or sell any Licensed Molecule or Licensed Product(s) to any Affiliate or Third Party in the Field in the Zai Lab Territory knowing or after having a reasonable expectation that such Affiliate or Third Party will, directly or indirectly, resell or export any of such products in the Field in the Zai Lab Territory. If INCY or any of its Affiliates, Subcontractors or Sublicensees becomes aware that any distributor, retailer or other Person to which INCY or any of its Affiliates, Subcontractors or Sublicensees has sold or otherwise provided a Licensed Product(s) has exported a Licensed Product(s) into the Zai Lab Territory for use in the Field, then INCY will, and will cause each of its Affiliates, Subcontractors and Sublicensees to, immediately cease providing any further quantities of Licensed Product(s) to such Person.

4.11.3 No Unauthorized Purchases from Third Parties . Except for its purchase and import of Licensed Product(s) pursuant to a Clinical Supply Agreement or Commercial Supply Agreement, and subject to Section 4.4 (Manufacturing in the PRC), Section 4.6 (Two-Invoice Policy and Tendering Policy) and Section 4.5 (Packaging and Labelling outside the Zai Lab Territory), Zai Lab will not purchase or import any Licensed Molecule or Licensed Product(s) from any Third Party.

5. INTELLECTUAL PROPERTY

5.1 Ownership .

5.1.1 Inventions, Joint Inventions and Joint Patents . Inventorship of all inventions and discoveries, including improvements, whether or not patentable, conceived by or on behalf of each Party or its Affiliate in connection with the activities conducted under this Agreement (" ***Agreement Inventions*** "), including any improvements to the Licensed Molecule or any Licensed Product(s) and know-how, will be determined in accordance with U.S. patent laws. Ownership of Agreement Inventions will be allocated between the Parties consistent with such inventorship determination. Except to the extent restricted by the licenses granted to the other Party under this Agreement, any other provision of this Agreement, or any other agreement between the Parties, each joint owner of an Agreement Invention jointly owned by the Parties pursuant to the preceding sentence (" ***Joint Inventions*** ") or any Patent that Covers any such jointly owned Agreement Invention (" ***Joint Patents*** ") may independently exploit the subject Agreement Invention and Patent without the duty of accounting or seeking consent from the other joint owner(s).

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5.1.2 Works and Joint Works . Authorship of all works of authorship created by or on behalf of each Party or its Affiliate in the performance of its obligations or exercise of its rights under this Agreement (" ***Agreement Works*** "), including those reflecting know-how, will be determined in accordance with U.S. copyright laws. As between the Parties, ownership of Agreement Works will be determined consistent with such authorship determination. Except to the extent restricted by the licenses granted to the other Party under this Agreement, any other provision of this Agreement, or any other agreement between the Parties, each joint owner of any Agreement Works jointly owned pursuant to the preceding sentence may independently exploit the Agreement Work without the duty of accounting or seeking consent from the other joint owner(s).

5.2 Sharing of Agreement Inventions . At each meeting of the JDC, each Party will disclose to the JDC each new Agreement Invention that a Party has recognized as such for each Licensed Product(s) corresponding to the Licensed Molecule since the preceding JDC meeting. Each Party will provide a general disclosure of such Agreement Invention(s) in writing in advance of the JDC meeting. At the meeting, a Party would present in reasonable level of detail the Agreement Invention(s), and the other Party would be entitled to ask questions and receive answers. At or after the JDC meeting at which an Agreement Invention is disclosed, a Party may also request a reasonable amount of further details and backup documentation describing the Agreement Invention(s), and the Party will respond in good faith to such reasonable requests. [***] .

5.3 Patent Prosecution and Maintenance .

5.3.1 Patents Owned by One Party . Except as otherwise mutually agreed in writing between the Parties, each Party will have the first right (but not the obligation) to file, prosecute and maintain, [***] , all Patents that are Controlled by such Party or its Affiliate(s).

5.3.2 Joint Patents . T he Parties will [***] . INCY will have the first right (but not the obligation) to file, prosecute and maintain Joint Patents and inform Zai Lab of any progress of any such prosecution and maintenance; *provided that* INCY will consider in good faith any reasonably comments Zai Lab may have on such prosecution and maintenance of the Joint Patents. If INCY decides not to file, prosecute or maintain a Joint Patent, INCY will notify and consult with Zai Lab of such decision or intention at least [***] days prior to the date of a public disclosure, filing deadline, or other event after which patentability of the subject matter could be substantially impaired, or after which such Joint Patent will become abandoned. Zai Lab will thereupon have the right (but not the obligation) to assume the filing, prosecution and maintenance thereof with counsel of its choice. Each Party will provide the other Party all reasonable coordination, assistance and cooperation in the patent prosecution efforts under this Agreement, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution or maintenance of Joint Patents.

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5.4 Patent Enforcement .

5.4.1 Notice . If any Party learns of an infringement or threatened infringement by a Third Party of any Patent in the Zai Lab Territory that Covers any Licensed Molecule or Licensed Product(s) or any actual or threatened proceeding by a Third Party that does or is expected to require a Defense of any Patent in the Zai Lab Territory that Covers any Licensed Molecule or Licensed Product(s), then such Party will notify the other Party promptly and will provide such other Party with available evidence of such infringement (provided neither Party will be required to share privileged information or attorney work product), if applicable. Following such notification, the Parties will confer.

5.4.2 Enforcement and Defense of Zai Lab Patents . As between the Parties, Zai Lab will have the sole right (but not the obligation) to threaten, institute, maintain, and control any action or proceeding regarding any infringement or Defense of any Zai Lab Patent, [***] , using counsel of its own choice, in Zai Lab's own name and under Zai Lab's direction and control. Zai Lab will have the right to retain all awards, damages, amounts paid in settlement or other recoveries resulting from such activities.

5.4.3 Enforcement and Defense of INCY Patents .

(a) As between the Parties, [***] will have the first right (but not the obligation) to threaten, institute, maintain, control and settle (in a manner not in violation of any other provision of this Agreement) any negotiations, action or proceeding regarding any enforcement or Defense of any INCY Patent in the Zai Lab Territory, [***] , using counsel of its own choice, [***] . Any awards, damages, amounts paid in settlement or other recoveries, in each case received by the Parties, resulting from such activities will be used [***] . Any remainder of such awards, damages, amounts or other recoveries attributable to Competitive Product Infringement will be [***] .

(b) If a Third Party is infringing an issued INCY Patent for which a Valid Claim exists that Covers a composition of matter, formulations or a method of treatment or use of a Licensed Product(s), in a Region of the Zai Lab Territory through the use, sale or offer for sale of a product that has obtained Regulatory Approval for treatment of the same Indication as a Licensed Product(s) in the Zai Lab Territory for which Zai Lab is conducting Clinical Trials or has applied for or obtained Regulatory Approval in the Field in the Zai Lab Territory (" ***Competitive Product Infringement*** "), and if INCY is not able to cause such Third Party to cease such use, sales and offers for sale of the product that is subject to the Competitive Product Infringement within [***] days after notice of the Competitive Product Infringement by Zai Lab to INCY and does not initiate a lawsuit to stop such Competitive Product Infringement within such [***] period, then, subject to the rights of Partner in such INCY Patent, if applicable, Zai Lab will have the right (but not the obligation) to threaten, institute, maintain control and settle (in a manner not in violation of any other provision of this Agreement) any negotiations, action or

proceeding regarding any enforcement of any claim of any such INCY Patent issued in the Zai Lab Territory that Covers the Competitive Product Infringement in Zai Lab's name with reasonable cooperation and assistance from Zai Lab. If Zai Lab exercises such enforcement right, then INCY will have the right, but not the obligation, to control the Defense of any such INCY Patent with reasonable cooperation from Zai Lab . Any awards, damages, amounts paid in settlement or other recoveries , in each case received by the Parties, resulting from such activities will be used [***] .

5.4.4 Enforcement and Defense of Joint Patents . Promptly after notice under Section 5.4.1 (Notice) with respect to a Joint Patent, the Parties will meet to discuss whether they wish to enforce or Defend such Joint Patent, as applicable. Absent mutual agreement to the contrary within [***] days after such notice, Zai Lab may proceed to enforce or Defend such Joint Patent in the Zai Lab Territory, [***] , using counsel of its own choice, in its own name and under its direction and control, and INCY may proceed to enforce or Defend such Joint Patent in the INCY Territory [***] , in the INCY Territory, using counsel of its own choice, in its own name and under its direction and control. All awards, damages, amounts paid in settlement or other recoveries resulting from such activities will be first used [***] . Any amount remaining after such reimbursement may be [***] . If a Party exercises its right to enforce a Joint Patent in accordance with the terms of this Section 5.4.4 (Enforcement and Defense of Joint Patents), then the other Party may not and will not grant a license in the Joint Patent to the alleged infringer without the written consent of the Party who enforced such Joint Patent.

5.4.5 Cooperation . At the request and expense of the Party bringing an action under Section 5.4.2 (Enforcement and Defense of Zai Lab Patents), Section 5.4.3 (Enforcement and Defense of INCY Patents) or Section 5.4.4 (Enforcement and Defense of Joint Patents), the other Party will provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required to give the other Party standing to sue. In connection with any such proceeding involving a Joint Patent, the enforcing Party will keep the other Party reasonably informed on the status of such action. The Party who does not Control any such Patent will not enter into any settlement admitting the invalidity of, or otherwise impairing the other Party's rights in, the relevant Patents without the prior written consent of the other Party.

5.5 Defense of Claims Brought by Third Parties. Subject to ARTICLE 11 (INDEMNITY), if a claim is brought by a Third Party alleging infringement of a Patent of such Third Party by the Development, manufacture or Commercialization of the Licensed Molecule or Licensed Product(s) in the Zai Lab Territory, the Party first having notice of the claim or assertion will promptly notify the other Party, the Parties will agree on and enter into an " ***Common Interest Agreement*** " wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties will promptly meet to consider the claim or assertion, and the appropriate course of action. Each Party will be entitled to represent itself in any litigation to which it is a party, at its own

expense, unless otherwise agreed upon by the Parties or as otherwise set forth in this Agreement or such Common Interest Agreement.

5.6 Trademarks .

5.6.1 Zai Lab Trademarks . As between the Parties, Zai Lab will select and own the Trademarks (both English and Chinese versions) to be used in connection with Zai Lab's Commercialization of Licensed Product(s) in the Zai Lab Territory (excluding any house marks of Zai Lab) (" ***Zai Lab Trademarks*** "), and Zai Lab will have the right to register and maintain the Zai Lab Trademarks at the competent authority in the Zai Lab Territory; *provided, however,* that Zai Lab will not file for registration of or otherwise attempt to register or obtain any rights, title or interest in or to any Trademark that is or contains any Trademark registered by INCY anywhere in the world or any translation thereof. Zai Lab will be the party to file application of and maintain the registration of Zai Lab Trademarks and to defend the registration against any Third Party's challenge including, without limitation, filing of invalidation trial. Zai Lab will be responsible for the costs and fees incurred in relation to filing application of, maintaining and defending the registration of the Zai Lab Trademarks. Zai Lab will have the sole right to enforce the Zai Lab Trademarks against infringements or other violations thereof, will be responsible for all costs and fees incurred in relation to such activities, and will be entitled to retain all awards or damages in connection with such activities.

5.6.2 No License to INCY Trademarks . INCY does not grant to Zai Lab a license to use, and Zai Lab will not use, any Trademark Controlled by INCY or any of its Affiliates or any mark confusingly similar to any Trademark Controlled by INCY (including any Trademark used by INCY in connection with Licensed Product(s) in the INCY Territory), whether in connection with any Licensed Product(s) or otherwise in connection with Zai Lab's exercise of its rights granted to it under this Agreement. If Zai Lab desires to use any Trademark Controlled by INCY or any of its Affiliates in connection with Licensed Product(s) or otherwise in connection with Zai Lab's exercise of its rights under this Agreement, Zai Lab may notify INCY and the Parties will discuss in good faith the circumstances and associated terms and conditions related to such use. Any license resulting from such good faith discussions will be royalty free.

5.6.3 INCY Trademarks in Zai Lab Territory . As between the Parties, INCY will select and own the Trademarks to be used in connection with INCY's Commercialization of the INCY Pipeline Asset(s) contained in the INCY Pipeline Combination Regimen, and INCY will have the right to register and maintain such Trademarks at the competent authority in the Zai Lab Territory; *provided, however,* that INCY will not file for registration of or otherwise attempt to register or obtain any rights, title or interest in or to any Trademark that is or contains any Trademark registered by Zai Lab anywhere in the world or any translation thereof. INCY will be the party to file application of and maintain the registration of such Trademarks and to defend the registration against any Third Party's challenge including, without limitation, filing of

invalidation trial. INCY will be responsible for the costs and fees incurred in relation to filing application of, maintaining and defending the registration of such Trademarks. INCY will have the sole right to enforce such Trademarks against infringements or other violations thereof, will be responsible for all costs and fees incurred in relation to such activities, and will be entitled to retain all awards or damages in connection with such activities. If INCY desires to use any Trademark Controlled by Zai Lab or any of its Affiliates in connection with Licensed Product(s) or otherwise in connection with INCY's exercise of its rights under this Agreement, INCY may notify Zai Lab and the Parties will discuss in good faith the circumstances and associated terms and conditions related to such use. Any license resulting from such good faith discussions will be royalty free.

6. LICENSES

6.1 License to Zai Lab . Subject to the terms and conditions of this Agreement, INCY hereby grants to Zai Lab a royalty bearing license/sublicense under the INCY IP, Regulatory Materials and Regulatory Approvals to Develop, import, and add additional/secondary packaging and labeling to Licensed Product supplied by or on behalf of INCY or its Affiliates, and use, offer for sale, sell or otherwise Commercialize the Licensed Products, in each case, in the Field and in the Zai Lab Territory. Except as otherwise stated in Section 6.2 (Retained Rights) and subject to any of Partner's rights with respect to the Licensed Product under the Partner License Agreement, the foregoing license/sublicense described in the preceding sentence is exclusive (even as to INCY and its Affiliates) . The foregoing license/sublicense further includes the right to sublicense solely upon the terms set forth in Section 6.3 (Sublicenses).

6.2 Retained Rights . Subject to the terms and conditions of this Agreement, and notwithstanding anything to the contrary in Section 6.1 (License to Zai Lab), INCY retains for itself:

6.2.1 INCY Pipeline Combination Regimen . subject to Section 3.11 (Collaboration Studies), Section 3.13 (INCY Pipeline Combination Study and INCY Pipeline Combination Regimen in the Zai Lab Territory) and Section 4.9 (Commercialization of the INCY Pipeline Combination Regimen), a non-exclusive right to practice the INCY IP in the Field and in the Zai Lab Territory with respect to any INCY Collaboration Study, Zai Lab Collaboration Study, Joint Collaboration Study and Joint [***] Collaboration Study and any INCY Pipeline Combination Regimen; and

6.2.2 Support to Zai Lab . a non-exclusive right to practice the INCY IP in the Field and in the Zai Lab Territory, as reasonably necessary to perform INCY's obligations or support the activities of Zai Lab under this Agreement.

6.3 Sublicenses . The rights licensed/sublicensed to Zai Lab under Section 6.1 (License to Zai Lab) include the right to sublicense to Affiliates of Zai Lab in the Zai Lab Territory [***] . Each sublicense agreement must be consistent with, and will be subject to,

the terms and conditions of this Agreement, must terminate automatically upon termination of the license granted under Section 6.1 (License to Zai Lab), and may not grant the right to further sublicense. Zai Lab remains responsible for the performance of its obligations under this Agreement, regardless of whether Zai Lab may have delegated those obligations to any sublicensee(s), and Zai Lab will be responsible for the acts of its sublicensees as if they were acts of Zai Lab. Zai Lab will, within [***] days after granting any sublicense, notify INCY of the grant of such sublicense and provide INCY with a copy of such sublicense; provided that Zai Lab may redact any portion of such sublicense agreement to the extent not necessary for INCY to determine Zai Lab's compliance with this Agreement.

6.4 License to INCY . Subject to the terms and conditions of this Agreement, and in consideration of the mutual covenants of the Parties under this Agreement, Zai Lab hereby grants to INCY a fully paid up and non-exclusive license, including the right to sublicense (in accordance with Section 6.3 (Sublicenses), applied *mutatis mutandis* to INCY), under all of Zai Lab's Intellectual Property Rights in Agreement Inventions and Agreement Works (a) to manufacture and supply Licensed Product(s) to Zai Lab in accordance with the terms of the Clinical Supply Agreement and Commercial Supply Agreement and otherwise as reasonably necessary to perform INCY's obligations or support the activities of Zai Lab under this Agreement, (b) subject to Section 3.11 (Collaboration Studies) and Section 3.12 (Ancillary Studies), to research, Develop and manufacture the Licensed Product(s) anywhere in the world to Commercialize the Licensed Product(s) in the Field in the INCY Territory, and (c) subject to Section 3.13 (INCY Pipeline Combination Study and INCY Pipeline Combination Regimen in the Zai Lab Territory) and Section 4.9 (Commercialization of the INCY Pipeline Combination Regimen), to research, Develop, manufacture, and Commercialize the INCY Pipeline Combination Regimen in the Field anywhere in the world.

6.5 Rights of Reference .

6.5.1 INCY Controlled Ancillary Study Data .

(a) Subject to the terms and conditions of this Agreement, INCY hereby grants to Zai Lab a Right of Reference to any and all Data that (i) is Controlled by INCY, (ii) is requested by Zai Lab, (iii) is reasonably necessary for Zai Lab to exploit the rights granted to Zai Lab by INCY pursuant to this Agreement, and (iv) arises from clause (a) of the definition of Ancillary Study.

(b) Subject to the terms and conditions of this Agreement, INCY hereby grants to Zai Lab a Right of Reference to pharmacokinetic and bioequivalency Data only that (i) is Controlled by INCY, (ii) is requested by Zai Lab, (iii)is reasonably necessary for Zai Lab to exploit the rights granted to Zai Lab by INCY pursuant to this Agreement, and (iv) arises from clause (b) of the definition of Ancillary Study.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

(c) All such Data referenced in clauses (a) and (b) of this Section 6.5.1 is (i) considered part of the INCY Technology and (ii) will be provided to Zai Lab promptly after completion of such Ancillary Study without any payment to INCY, except as otherwise specified in Section 3.11.1 (INCY Collaboration Study) or pursuant to Section 3.11.3 (Joint Collaboration Study) or Section 3.11.4 (Joint [***] Collaboration Study).

6.5.2 Zai Lab Controlled Ancillary Study Data .

(a) Zai Lab hereby grants to INCY a Right of Reference to any and all Data that (i) is Controlled by Zai Lab, (ii) is requested by INCY, (iii) is reasonably necessary for INCY to exploit the rights granted to INCY by Zai Lab pursuant to this Agreement, and (iv) arises from clause (a) of the definition of Ancillary Study.

(b) Zai Lab hereby grants to INCY a Right of Reference to pharmacokinetic and bioequivalency Data only that (i) is Controlled by Zai Lab, (ii) is requested by INCY, (iii) is reasonably necessary for INCY to exploit the rights granted to INCY by Zai Lab pursuant to this Agreement, and (iv) arises from clause (b) of the definition of Ancillary Study.

(c) All such Data referenced in clauses (a) and (b) of this Section 6.5.2 shall be (i) owned by Zai Lab and (ii) provided to INCY promptly after completion of such Ancillary Study without any payment to Zai Lab except as otherwise specified in Section 3.11.1 (INCY Collaboration Study) or Section 3.11.2 (Zai Lab Collaboration Study), or pursuant to Section 3.11.3 (Joint Collaboration Study) or Section 3.11.4 (Joint [***] Collaboration Study).

6.6 Reservation of Rights . Except as expressly set forth in this Agreement, neither Party acquires any license or other right or interest, by implication or otherwise, under any know-how, patents, trademarks, copyrights, or any other intellectual property of the other Party. Zai Lab will not, and it will not permit any of its Affiliates or Sublicensees to, practice any INCY IP outside the scope of the license expressly granted to it under Section 6.1 (License to Zai Lab) and Section 6.3 (Sublicenses), including with respect to any product that is not a Licensed Product(s), such as those combinations that are specifically excluded from the definition of Licensed Product(s). Notwithstanding anything to the contrary in this Agreement, each right and license granted under this Agreement is in all respects subject to the applicable terms and conditions of the Partner License Agreement, as described on **Schedule 6.6 (Partner Terms and Conditions)** .

6.7 After-Acquired IP . For the purpose of defining whether any Intellectual Property Right, Technology or Confidential Information is Controlled by a Party, if such Intellectual Property Right, Technology or Confidential Information is first acquired, licensed or otherwise made available to such Party after the Effective Date (“ ***After-Acquired IP*** ”), and if the exploitation thereof by or on behalf of the other Party, its

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Affiliates or Sublicensees in accordance with the terms of this Agreement would require the first Party to pay any amounts to the Third Party from which the first Party acquired, licensed or otherwise obtained such Intellectual Property Rights, Technology or Confidential Information (" ***Additional Amounts*** "), then such Intellectual Property Rights, Technology or Confidential Information will be deemed to be Controlled by the first Party only if the other Party agrees to pay (if necessary) and does in fact pay all Additional Amounts with respect to such other Party's use of or license to such Intellectual Property Rights, Technology or Confidential Information.

6.8 Subcontracting . Notwithstanding Section 6.3 (Sublicenses), Zai Lab will have the right to engage Subcontractors to perform Development, packaging and labeling, and Commercialization within the scope of the rights licensed to Zai Lab under Section 6.1 (License to Zai Lab), without the prior written consent of INCY, subject to the provisions of this Section 6.8 (Subcontracting). Zai Lab will enter into an appropriate written agreement with any Subcontractor such that (a) such contractor will be bound by provisions that are consistent with all applicable provisions of this Agreement to the same extent as Zai Lab, (b) any such contractor to whom Zai Lab discloses Confidential Information of INCY will enter into an appropriate written agreement obligating such contractor to be bound by obligations of confidentiality and restrictions on use of such INCY Confidential Information that are no less restrictive than the obligations in this Agreement, and (c) such contractor agrees to assign or license (with the right to grant sublicenses) to Zai Lab any inventions related to the Licensed Molecule or Licensed Product(s) (and any Patent covering such inventions) made by such contractor in performing such Development or manufacturing work for Zai Lab. Zai Lab remains responsible for the performance of its obligations under this Agreement, regardless of whether Zai Lab may have delegated those obligations to any Subcontractor(s), and Zai Lab will be responsible for the acts of its Subcontractor(s) as if they were acts of Zai Lab. Zai Lab will consider in good faith any objections that INCY might raise with Zai Lab regarding the use of any particular Subcontractor for any particular activities involving a Licensed Product(s).

7. FINANCIAL TERMS

7.1 Upfront Payment . As consideration to INCY for the services performed in licensing and developing the Licensed Molecule, and rights and licenses granted to Zai Lab under this Agreement, within [***] days after the Effective Date, Zai Lab will pay to INCY a one-time, non-refundable and non-creditable upfront license fee of $17,500,000 in cash.

7.2 Milestone Payments .

7.2.1 Development Milestones .

(a) As consideration for the services performed in licensing and developing the Licensed Molecule so that Zai Lab could achieve the corresponding milestone, Zai Lab will pay to INCY [***] within [***] days following the first

achievement of the corresponding milestone events set forth in **Table 7.2.1** (Development Milestones) by Zai Lab or its Affiliate or sublicensee by any Licensed Product(s) (each a " ***Development Milestone*** ") . E ach of the milestone payments set forth **Table 7.2.1** (Development Milestones) is payable only upon the first achievement of such milestone by the first Licensed Product to achieve such Development Milestone and shall not be payable by any subsequent Licensed Product should such Licensed Product also achieve such Development Milestone , whether such milestone is achieved through any Licensed Products that consist of the Licensed Molecule alone or with any active ingredient (s). For clarity, none of the Development Milestone payments shall be payable more than once.

(b) **Table 7.2.1** (Development Milestones):

Table 7.2.1 (Development Milestones)			
Development and Regulatory Milestone Event	**Payment for INCMGA012 *in millions of USD***		
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Maximum Possible Total	[***]		

7.2.2 Sales-Based Milestones .

(a) Zai Lab will pay to INCY [***] upon reaching the corresponding amount of aggregate Net Sales in the Zai Lab Territory of all Licensed Products by Zai Lab, its Affiliates and its sublicensees in a Calendar Year (each a " ***Sales-Based Milestone*** "). For clarity, (i) each such payment is due within [***] days following the time when such amount is first reached in a Calendar Year and is payable once; and (ii) none of the Sales-Based Milestone payments shall be payable more than once.

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(b) **Table 7.2.2** (Sales-Based Milestones):

Table 7.2.2 (Sales-Based Milestones)	
Net Sales of all Licensed Products in a Calendar Year	**Payment for INCMGA012 *in millions of USD***
Exceed [***]	[***]
Exceed [***]	[***]
Exceed [***]	[***]
Exceed [***]	[***]
Maximum Possible Total	[***]

7.3 Royalties .

7.3.1 Generally .

(a) Subject to the remainder of this Section 7.3 (Royalties), Zai Lab will pay to INCY [***] . For each Calendar Year, the below tiered royalties shall be calculated such that the higher tiered royalty rates are only used after Net Sales in each Calendar Year exceed the top threshold of the previous tier of Net Sales, and such higher tiered royalty rate shall only apply to the portion of Net Sales that falls within that tier.

(b) **Table 7.3.1** (Royalty Rates):

Table 7.3.1 (Royalty Rates)	
Portion of Annual Net Sales in the Zai Lab Territory	**Royalty Rate for INCMGA012**
Less than or equal to [***]	[***]
Greater than [***] but less than or equal to [***]	[***]
Greater than [***] but less than or equal to [***]	[***]
Greater than [***]	[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

7.3.2 Royalty Term . Royalties will be payable on a Region-by-Region and Licensed Product-by-Licensed Product basis from the First Commercial Sale of a Licensed Product in the Zai Lab Territory until the last to occur of: (a) when no Valid Claim of an INCY Patent Covering the composition of matter, formulations or a method of treatment or use of such Licensed Product in such Region exists; (b) expiration of the Regulatory Exclusivity Period of such Licensed Product in such Region; or (c) [***] years from the First Commercial Sale of such Licensed Product in such Region (the " ***Royalty Term*** "). Upon payment by Zai Lab of all royalties accrued with respect to a Licensed Product in a Region and milestone payments due under this Agreement with respect to such Licensed Product, the license granted under this Agreement with respect to such Licensed Product in such Region will be deemed [***] .

7.3.3 Royalty Conditions . The calculation of Net Sales and corresponding royalties under this Section 7.3 (Royalties) will be subject to the following conditions:

(a) only one (1) royalty will be due with respect to each unit of Licensed Product(s), without regard to whether there is more than one Valid Claim Covering such Licensed Product(s);

(b) no Net Sales (or corresponding royalties) will accrue upon the sale or other transfer of the Licensed Product(s) among Zai Lab and its Affiliates, so long as such Affiliate resells the Licensed Product(s), but in such cases the royalty will be due and calculated upon Zai Lab's or its Affiliate's Net Sales of Licensed Product(s) to the first independent Third Party;

(c) no Net Sales (or corresponding royalties) will accrue on the disposition of Licensed Product(s), as provided in the last paragraph of the definition of Net Sales; and

(d) Notwithstanding Zai Lab's right [***] for Licensed Product(s) as set forth in Section 4.1 (Zai Lab Responsibility), INCY will be paid royalties on each Licensed Product based on the higher of A, B or C, wherein (i) " ***A*** " is [***] ; (ii) " ***B*** " is calculated as [***] ; and (iii) " ***C*** " is calculated, for each Calendar Quarter in such Calendar Year, as [***] . If B or C is higher than A, then Zai Lab must pay to INCY, within [***] days after the end of such Calendar Year, an amount equal to the difference in the highest royalties that would have been paid to INCY if the royalties had been paid based upon the calculation of the higher of B or C. [***] .

7.3.4 Royalty Reduction. The royalty payment due and payable to INCY for Net Sales of a Licensed Product in a Region in the Zai Lab Territory pursuant to Section 7.3 (Royalties) will be reduced, on a Licensed Product-by-Licensed Product and Region-by-Region basis, by:

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(a) [***] of the amount otherwise due on those Net Sales of the Licensed Product in such Region accrued during the Royalty Term but after the later to occur of (i) expiration of the last-to-expire INCY Patent in such Region having a Valid Claim that Covers the composition of matter , formulations or a method of treatment or use of such Licensed Product and (ii) expiration of Regulatory Exclusivity Period for such Licensed Product ; and

(b) [***] of the amount otherwise due on those Net Sales of the Licensed Product in such Region accrued during the Royalty Term during such time as the Royalty Term is in effect [***] .

7.3.5 Royalty Floor . Notwithstanding the foregoing Section 7.3.1 (Generally) through Section 7.3.4 (Royalty Reduction), the royalties on Net Sales due to INCY pursuant to this Section 7.3 for any given Calendar Quarter shall be calculated at a rate that is [***] .

7.4 Zai Lab Contribution to INCY Collaboration Studies . INCY will invoice Zai Lab for Zai Lab's share of funding INCY Collaboration Studies, under clause (c) of Section 3.11.1 (INCY Collaboration Studies), on a [***] basis within [***] days after the end of [***] in which any of such study activities took place. If Zai Lab does not agree to share in funding INCY Collaboration Studies under clause (c) of Section 3.11.1 (INCY Collaboration Studies), but later elects to share in such funding under clause (e) of Section 3.11.1 (INCY Collaboration Studies), then INCY will invoice Zai Lab for its share of funding activities that have occurred before Zai Lab made such election, and if the INCY Collaboration Study is not yet completed, INCY will invoice Zai Lab for Zai Lab's share of funding INCY Collaboration Studies under clause (e) of Section 3.11.1 (INCY Collaboration Studies) on a [***] basis within [***] days after the end of each [***] in which any of such study activities took place. INCY will invoice Zai Lab for Zai Lab's share of funding INCY Collaboration Studies under clause (e) of Section 3.11.1 (INCY Collaboration Study) promptly after Zai Lab's election to receive access and Right of Reference to the Data arising from such INCY Collaboration Studies. INCY will invoice Zai Lab for Zai Lab's share of funding INCY Collaboration Studies under clause (f) of Section 3.11.1 (INCY Collaboration Study) promptly after Zai Lab's election to receive access and Right of Reference to the Data arising from such INCY Collaboration Studies. Each such invoice will be accompanied by an accounting showing in reasonable detail all [***] actually incurred in connection with the subject INCY Collaboration Study. Payment of each invoice is due within [***] days of date of invoice.

7.5 INCY Contribution to Zai Lab Collaboration Studies . Zai Lab will invoice INCY for INCY's share of funding Zai Lab Collaboration Studies under clause (c) of Section 3.11.2 (Zai Lab Collaboration Studies) on a [***] basis within [***] days after the end of each [***] in which any of such study activities took place. If INCY does not agree to share in funding Zai Lab Collaboration Studies under clause (c) of Section 3.11.2 (Zai Lab Collaboration Studies), but later elects to share in such funding under clause (d)

of Section 3.11.2 (Zai Lab Collaboration Studies), then Zai Lab will invoice INCY for its share of funding activities that have occurred before INCY made such election, and if the Zai Lab Collaboration Study is not yet completed, Zai Lab will invoice INCY for INCY's share of funding Zai Lab Collaboration Studies under clause (d) of Section 3.11.2 (Zai Lab Collaboration Studies) on a quarterly basis w ithin [***] days after the end of each Calendar Quarter in which any of such study activities took place. Zai Lab will invoice INCY for INCY's share of funding INCY Collaboration Studies under clause (d) of Section 3.11.2 (Zai Lab Collaboration Study) promptly after Zai Lab's election to receive access and Right of Reference to the Data arising from such Zai Lab Collaboration Studies. Zai Lab will invoice INCY quarterly for INCY's share of funding Zai Lab Collaboration Studies under clause (e) of Section 3.11.2 (Zai Lab Collaboration Study) promptly after INCY's election to receive access and Right of Reference to the Data arising from such Zai Lab Collaboration Studies. Each such invoice will be accompanied by an accounting showing in reasonable detail all [***] actually incurred in connection with the subject Zai Lab Collaboration Study. Payment of each invoice is due within [***] days of date of invoice.

7.6 Commercial Reversion Right Purchase Price . If INCY exercises its reversion right under Section 4.7 (Commercial Diligence Buy-Back Rights), Zai Lab will promptly provide to INCY an invoice for the amount due. Each such invoice will be accompanied by an accounting showing (a) in reasonable detail the calculation of Net Sales of the relevant Licensed Product(s) during the applicable [***] Period, (b) the applicable [***] determined pursuant to Section 4.7.2 ([***] for Commercial Reversion Right) and the rationale for such selection, and (c) the total purchase price due from INCY.

7.7 Manner of Payments; Payments by Affiliates of Zai Lab . All payments to be made hereunder will be made in U.S. Dollars by wire transfer of immediately available funds to such bank account as will be designated by the recipient. Except as otherwise provided in this Agreement, all payments to be made under this Agreement will be due within [***] days from the date of invoice (if applicable). Late payments will bear interest at the rate provided in Section 7.15 (Interest on Late Payment). From time to time, Zai Lab may request INCY to have one or more of the payments due from Zai Lab hereunder made by an Affiliate of Zai Lab on behalf of or otherwise in satisfaction of an amount due from Zai Lab. If so requested by Zai Lab, INCY will not unreasonably withhold consent to such request so long as (a) Zai Lab and its designated Affiliate confirm in writing at such time that the payment(s) that is/are the subject of such request is/are subject to Section 7.14 (Taxes) as if the Affiliate were the "Payor" therein and (b) Zai Lab will be responsible for any higher withholding or direct tax that is applicable because of such arrangement (including taxes resulting therefrom), notwithstanding anything in this Agreement to the contrary.

7.8 Milestone Payment Timeline . Zai Lab will notify INCY within [***] Business Days following the first achievement of each of the Development Milestones and the Sales-Based Milestones in accordance with Section 7.2 (Milestone Payments). Within [***] days after INCY's receipt of such notice, INCY will issue an invoice to Zai Lab for

the corresponding milestone payment. Zai Lab must pay the amount of such invoice within [***] days of Zai Lab's achievement of such Development Milestone or Sales-Based Milestone, as applicable .

7.9 Royalty Reports and Royalty Payments .

7.9.1 Invoice for Estimated Royalties and Payment . Zai Lab will provide a good faith estimate of the royalties that it will owe for a Calendar Quarter based upon the Net Sales estimated at such time within [***] . After the receipt of such estimate from Zai Lab, INCY will issue an invoice for an estimated amount of royalties due. The estimated royalties will be paid within [***] days after receipt of the invoice.

7.9.2 Royalty Report . Within [***] days following the end of each Calendar Quarter in which Net Sales occurred, Zai Lab will calculate and report to INCY the actual amount of royalties accrued for the subject Calendar Quarter. Each such report (" ***Quarterly Royalty Report*** ") will state on a Licensed Product-by-Licensed Product and Region-by-Region basis: (a) [***] , (b) [***] , and (c) [***] .

7.9.3 Royalty Floor Notice . If a Quarterly Royalty Report shows that the amount of royalties to be paid by Zai Lab (before withholding or deducting any taxes) for the subject Calendar Quarter are less than the minimum amount due pursuant to Section 7.3.5 (Royalty Floor) for such Calendar Quarter, then INCY will notify Zai Lab of such shortfall within [***] days after INCY's receipt of the Quarterly Royalty Report. Such notice will include (a) [***] and (b) [***] .

7.9.4 Royalty True Up Payments .

(a) If the royalty amount reported by Zai Lab in the Quarterly Royalty Report is different than the amount previously invoiced by INCY for such Calendar Quarter based upon Zai Lab's estimate pursuant to Section 7.9.1 (Invoice for Estimated Royalties) or if there is a shortfall pursuant to Section 7.9.3 (Royalty Floor Notice) for such Calendar Quarter, then INCY will issue an invoice for the amount(s) due. Zai Lab will pay the amount of such invoice within [***] days after receipt of the invoice. If Zai Lab overestimated the amount of royalties due pursuant to Section 7.9.1 (Invoice for Estimated Royalties) and as a result overpays the amount of royalties due for the Calendar Quarter, the amount of such excess will be applied as a credit towards future payment(s), if applicable.

(b) INCY will issue Zai Lab an invoice after the end of each Calendar Year if the amount of royalties actually paid to INCY under this Agreement in such Calendar Year were less than the amount due under Section 7.3.5 (Royalty Floor) for such Calendar Year. Zai Lab will pay the amount of such invoice within [***] days after receipt of the invoice.

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7.9.5 Books and Records; Zai Lab's Audit rights . INCY will maintain complete and accurate records in accordance with Section 7.10 (Financial Records and Calculation) and Zai Lab will have the rights to audit such books and records maintained by INCY in accordance with Section 7.11 (Financial Audit).

7.10 Financial Records and Calculations . Zai Lab will maintain books, records and accounts that accurately and fairly reflect the transactions of Zai Lab under this Agreement and , in accordance with this Agreement, as are required to determine gross revenues, Net Sales, royalties or other amounts due under this Agreement. For any Calendar Quarter for which INCY issued to Zai Lab an invoice under clause (a) of Section 7.9.4 (Royalty True Up Payments), INCY will maintain records as are required to show the highest royalty rate paid by INCY to Partner under the Partner License Agreement for such Calendar Quarter. For any Calendar Year for which INCY issued to Zai Lab an invoice under clause (b) of Section 7.9.4 (Royalty True Up Payments), INCY will maintain records as are required to show the highest royalty rate paid by INCY to Partner under the Partner License Agreement for such Calendar Year. For any Calendar Quarter for which Licensed Product is supplied by or on behalf of INCY to Zai Lab, INCY will maintain records as are required to show [***] of such Licensed Product. The Party required to maintain such records will maintain such records until the later of (a) [***] years after the end of the period to which such records pertain, (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or (c) such longer period as may be required by Applicable Law. Each amount to be calculated or reported or paid under this Agreement will be determined from the books and records of [***] , its Affiliates or Sublicensee, and each determination of the highest royalty rate paid by [***] to Partner under the Partner License Agreement will be determined from the books and records of INCY, its Affiliates, licensees, or sublicensees, in each case, that are maintained in accordance with US GAAP, IFRS or other accounting standard applicable to such entity as consistently applied.

7.11 Financial Audit . On [***] days prior written notice, each Party (" ***Auditing Party*** ") will have the right to have an independent certified public accountant inspect the financial records of the other Party and its Affiliates (" ***Audited Party*** ") relating to the records of the Audited Party required to be kept pursuant to Section 7.10 (Financial Records and Calculations). Each such audit must be conducted during usual business hours, at a time and a place mutually agreed to, for the sole purpose of verifying the completeness and accuracy of Net Sales and royalties due under this Agreement or the Partner License Agreement, as applicable, for the period of time [***] years preceding the date of the notice. The notice must identify the period of time subject to inspection. R ecords from a period of time already subject to an inspection pursuant to this Section 7.11 (Financial Audit) may not be inspected again. Such accountant must have agreed in writing to maintain the confidentiality of all information learned in confidence, except as necessary to disclose any discrepancy to the Parties. The Auditing Party will pay for each such inspection and audit, unless such inspection and audit discloses for the period examined that there is an underpayment to the Auditing Party (or in the event INCY is the Audited Party, an overpayment to the Audited Party pursuant to Section 7.9 (Royalty Reports and Royalty Payments)) of greater than [***]

of the amounts actually due in any given Calendar Year, in which case the Audited Party will be responsible for the payment of the reasonable cost of such inspection and audit. The Auditing Party and its independent accounting firm agree that all information concerning such payments and reports will be Confidential Information of the Audited Party, as provided for in this Agreement. The Audited Party will pay to the Auditing Party within [***] days following its receipt of the report any underpayment (or in the event such Audited Party is INCY, any overpayment) identified pursuant to this Section 7.11 (Financial Audit) . The Auditing Party may not conduct inspections or audits more often than once in any [***] month period.

7.12 Payments under Upstream Licenses . As between the Parties, INCY shall be solely responsible for any and all payments payable by INCY to the licensor under the Upstream Licenses, including to the Partner under the Partner License Agreement.

7.13 Currency Exchange . With respect to Net Sales invoiced in a currency other than U.S. Dollars, the Net Sales will be expressed in the domestic currency of Zai Lab and converted to U.S. Dollars using the weighted average based on sales of the daily foreign exchange rates as published by *The Wall Street Journal, Eastern Edition* for the Calendar Quarter in which the Net Sales occurred .

7.14 Taxes .

7.14.1 Withholding . In the event that Applicable Law requires a Party making a payment under this Agreement (" ***Payor*** ") to deduct or withhold taxes, including those on incomes and VAT or any VAT-related miscellaneous taxes (such as local surcharges and stamp duty), with respect to any payment to be made pursuant to this Agreement to the other Party (" ***Payee*** "), Payor will notify Payee of such requirement prior to making the payment to Payee and provide such assistance to Payee, including the provision of such documentation as may be required by a governmental authority, as may be reasonably necessary in Payee's efforts to claim an exemption from or reduction of such taxes. Payor will, in accordance with Applicable Law, deduct and withhold such taxes from the amount due to Payee, remit such taxes to the appropriate governmental authority when due, and furnish Payee with proof of payment of such taxes within [***] days following the payment, and [***] .

7.14.2 Additional Tax . Notwithstanding Section 7.14.1 , to the extent that Payor is required by Applicable Law to withhold, or Payee is required by Applicable Law to pay, any taxes imposed by governmental authorities in the Zai Lab Territory from or in respect of any amount payable under this Agreement other than taxes imposed by governmental authorities outside the Zai Lab Territory (" ***Additional Tax*** "), then [***] .

7.14.3 VAT . If Regulatory Approval has been granted for a Licensed Product in the Zai Lab Territory, in the case of any Additional Tax that is a value-added tax, sales tax, consumption tax, surcharge, and other similar tax (for clarity, excluding

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withholding tax) (" ***VAT*** "), then each amount payable under this Agreement will be increased to take into account such VAT so that, after making all required withholdings or direct tax payments (including taxes on the additional amounts payable), Payee receives amounts equal to the net amounts set forth in this ARTICLE 7 , less [***] .

7.14.4 Recovery of Taxes . Subject to 7.14.3 (VAT), to the extent permitted by Applicable Law, the Parties will use Commercially Reasonable Efforts to recover the Additional Tax, and the Party that actually recovers the Additional Tax will refund to the other Party such amounts of Additional Tax recovered from any governmental authority as necessary to achieve the sharing of Additional Tax set forth in Section 7.14.2 (Additional Tax). The Parties will cooperate with respect to all documentation required by any governmental authority or reasonably required by either Party to secure a reduction in the rate of applicable taxes.

7.15 Interest on Late Payment . Interest will be payable on any payments that are not paid on or before the date [***] days after the date such payments are due under this Agreement at the per-annum rate of prime (as reported in The Wall Street Journal (U.S., Eastern Edition) as of such due date), plus two percentage points or the maximum rate allowable by applicable Law, whichever is less.

8. CONFIDENTIALITY

8.1 Nondisclosure and Non-Use . Each Party agrees that, for so long as this Agreement is in effect and for a period of [***] years thereafter, a Party (the " ***Receiving Party*** ") receiving or possessing Confidential Information of the other Party (the " ***Disclosing Party*** ") will, and will cause its Affiliates and Sublicensees, and its and their respective employees, consultants, contractors, agents and other representatives (" ***Representatives*** "), to, (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary industrial information of similar kind and value (but no less than reasonable care), (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement, including in connection with exercising its rights or fulfilling its obligations under this Agreement (it being understood that this clause (c) will not create or imply any rights or licenses not expressly granted under ARTICLE 6 (LICENSES) hereof). Each Receiving Party will be responsible for any breach of these obligations by any of its Representatives to which it discloses or provides access to any Confidential Information of the Disclosing Party. Each Receiving Party will take all reasonable action under Applicable Law to enforce the confidentiality obligations hereunder against any of its Representatives to which it discloses or provides access to any Confidential Information of the Disclosing Party.

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8.2 Exceptions . The obligations in Section 8.1 (Nondisclosure and Non-Use) will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent proof:

8.2.1 Known . was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party; or

8.2.2 Already Public . was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; or

8.2.3 Became Public . became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or

8.2.4 Disclosures to Third Parties . is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use; or

8.2.5 Independently Developed . has been independently developed by employees or contractors of the Receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the Disclosing Party, as demonstrated by documented evidence prepared contemporaneously with such independent development.

8.3 Authorized Disclosures . The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

8.3.1 Prosecution; Regulatory . preparing, filing or prosecuting Patents; preparing, filing or prosecuting Regulatory Materials with respect to obtaining and maintaining Regulatory Approval of the Licensed Product(s); and prosecuting or defending litigation;

8.3.2 Compliance . (a) in accordance with the compliance addendum attached hereto as **Schedule 10.3 (Compliance)** or (b) subject to Section 8.5 (Securities Filings), complying with Applicable Law (including the rules and regulations of any national securities exchange, regulations of the State Administration of Foreign Exchange of the People's Republic of China, and the State Intellectual Property Office of the People's Republic of China) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; *provided that* the Receiving Party will promptly notify the other Party of such required disclosure so that the Disclosing Party can seek a protective order or other appropriate remedies and, at the Disclosing Party's request and expense, reasonably assist the Disclosing Party in seeking such protective order or other reasonable remedies; and

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8.3.3 Representatives; Acquirers; Partners . disclosure (a) in connection with the performance of this Agreement and solely on a "need to know basis", to Representatives ; or (b) solely on a "need to know basis" to potential or actual investment bankers, consultants, advisors, investors, partners, Subcontractors , lenders, or acquirers; each of whom in the case of clause (a) or (b) prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this ARTICLE 8 (Confidentiality).

8.4 Terms of this Agreement . The Parties acknowledge that the terms of this Agreement will be treated as Confidential Information of both Parties; *provided, however, that,* notwithstanding anything to the contrary herein, INCY may disclose the terms of this Agreement to Partner to the extent INCY deems necessary to comply with the Partner License Agreement.

8.5 Securities Filings . In the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state, country, province or other jurisdiction a registration statement or any other disclosure document which describes or refers to this Agreement under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other Applicable Law, such Party will notify the other Party of such intention and will provide such other Party with a copy of relevant portions of the proposed filing not less than [***] Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto relating to this Agreement, and will use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that such other Party requests be kept confidential, and will only disclose Confidential Information of the Disclosing Party which it is advised by counsel is legally required to be disclosed. No such notice will be required under this Section 8.5 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by the other Party hereunder or otherwise approved by the other Party.

8.6 Technical Publication .

8.6.1 Publishing for Clinical Trials . As between the Parties, only the sponsor of a Clinical Trial under this Agreement and involving any Licensed Product(s) in the Zai Lab Territory (" ***Sponsor*** ") will have the right to publish, or permit publishing of, the results of the portion of such Clinical Trial conducted in the Zai Lab Territory; *provided that* upon mutual agreement, the other Party may also publish, or permit publishing of, the results of the portion of such Clinical Trial conducted in the Zai Lab Territory. Subject to the first sentence in this Section 8.6.1 , (a) the publishing Party may not publish peer-reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, of or containing any of the results of such Clinical Trials, without the opportunity for prior review by the other Party, except to the extent such publication is required by Applicable Law; (b) the publishing Party will provide the other Party the

opportunity to review and comment on any proposed publication at least [***] days prior to its intended submission for publication; (c) t he other Party will use reasonable efforts to provide the publishing party with comments in writing, if any, within [***] days after receipt of such proposed publication; (d) t he publishing Party will consider in good faith any comments thereto provided by the other Party and will comply with the other Party's request to remove any and all of such other Party's Confidential Information from the proposed publication; (e) the publishing Party will delay the submission for a period up to [***] days in the event that the other Party can demonstrate reasonable need for such delay, including for the preparation and filing of a patent application; and (f) t he publishing Party will provide the other Party a copy of the publication at the time of the submission for publication. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications as scientifically appropriate.

8.6.2 Zai Lab Publications . If Zai Lab desires to publish (including to advisory boards or any other Third Party that is not bound by a duty of confidentiality under terms at least as strict as those contained in this ARTICLE 8) any Data (including Data generated by Zai Lab), abstracts, papers, presentations, posters and other data related to any of the Licensed Molecule or Licensed Product(s), other than Data resulting from Clinical Trials, then Zai Lab will provide INCY the opportunity to review and comment on such proposed publication at least [***] days prior to its intended submission for publication. INCY will use reasonable efforts to provide Zai Lab with comments in writing, if any, within [***] days after receipt of such proposed publication. Zai Lab will consider in good faith any comments thereto provided by INCY, will comply with INCY's request to remove any of such Data or any of INCY's Confidential Information from the proposed publication, and will not publish or submit the publication for publication without the advance, written consent of INCY, which consent will not be unreasonably withheld, conditioned or delayed. Zai Lab will provide INCY a copy of the publication at the time of the submission for publication. Zai Lab will acknowledge the contributions of INCY and its employees in all such publications as scientifically appropriate.

8.7 Publicity . The Parties may issue mutually agreed upon press releases from time-to-time related to this Agreement. Each Party will issue the joint press release attached hereto as **Schedule 8.7 (Joint Press Release)** promptly after the execution and delivery of this Agreement by both Parties at a time mutually agreed.

8.8 Personal Data . Within [***] days of the Effective Date, and prior to collection, use, transfer, disclosure or any other Processing of Personal Data in the performance of this Agreement, the Parties will enter into a supplemental agreement that establishes each Party's respective obligations, including, but not limited to the collection, use, transfer, and disclosure of Personal Data (hereinafter, the " ***Data Processing Agreement*** "). Such Data Processing Agreement shall be incorporated herein by reference.

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9. TERM AND TERMINATION

9.1 Term .

9.1.1 Product Terms . The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with the terms hereof or by mutual written consent, will continue, on a Region-by-Region and Licensed Product-by-Licensed Product basis, until the expiration of the Royalty Term for such Licensed Product in such Region. Survival of the licenses granted to Zai Lab with respect to Licensed Product(s) in a Region is subject to the terms and conditions set forth in Section 7.3.2 (Royalty Term) and Section 9.3 (Effects of Termination).

9.1.2 Agreement Term . The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in its entirety in accordance with Section 9.2 (Early Termination) or by mutual written consent, will continue in effect until the expiration of the last possible Royalty Term under this Agreement. The time between the Effective Date and termination of this Agreement in its entirety for any reason is the " ***Term*** ".

9.1.3 Option to Obtain Supply after Expiration . For any particular Licensed Product, at least [***] years prior to the anticipated date of expiration of the Royalty Term for such Licensed Product in a Region, Zai Lab may notify INCY in writing that it desires INCY to continue to supply such Licensed Product to Zai Lab solely for Zai Lab's continued Commercialization of the Licensed Product in such Region in the Zai Lab Territory after its Royalty Term (such notification, " ***Supply Notice*** "). If Zai Lab delivers such Supply Notice to INCY, then INCY will, in its sole discretion, either (a) supply to Zai Lab such Licensed Product for Commercialization in such Region after the expiration of the Royalty Term at a price equal to [***] , or (b) [***] , in each case of (a) and (b), in accordance with Section 9.3.1 (Licenses upon Termination). If INCY elects to supply to Zai Lab such Licensed Product after the expiration of the Royalty Term in accordance with clause (a) of this Section 9.1.3 , such supply of Licensed Product(s) by or on behalf of INCY to Zai Lab will be exclusive on a Region-by-Region basis for Licensed Products in the Field during such time, if any, as the Commercialization portion of the Surviving License for such Licensed Product(s) in such Region is exclusive in accordance with clause (c) of Section 9.3.1 (Licenses Upon Termination).

9.2 Early Termination .

9.2.1 Termination for Material Breach . Each Party will have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party is in material breach of this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within [***] days from the date of such notice, *provided that* , if such other Party dispute such alleged breach in good faith, such termination will not become effective unless and

until such dispute has been resolved in favor of the Party providing notice of such termination and such other Party has not cured such material breach within [***] days after such resolution . Notwithstanding anything to the contrary, if INCY materially breach's this Agreement and Zai Lab has the right to terminate this Agreement in accordance with Section 9.2.1 (Termination for Material Breach) as a result of a dispute escalated and resolved subject to the dispute resolution procedures set forth in ARTICLE 12 (Dispute Resolution), then Zai Lab, in its sole discretion and upon written notice to INCY, will have the right to elect to either (a) terminate this Agreement with an immediate effect, or (b) not to terminate this Agreement; *provided* if Zai Lab elects to not terminate this Agreement, the Parties agree that, in addition to and without prejudice to any damages or remedies (including any equitable relief) that Zai Lab may have under this Agreement or otherwise, any and all payments payable by Zai Lab as of date of such election and during the remainder of the Term shall be reduced by [***] .

9.2.2 Termination for Convenience . At any time, Zai Lab may terminate this Agreement in its entirety by providing written notice of termination to INCY, which notice includes an effective date of termination at least [***] days after the date of the notice.

9.2.3 Termination for Development or Commercial Diligence Failures . INCY may terminate this Agreement according to Section 3.10 (Development Diligence Reversion Right) and Section 4.7 (Commercial Diligence Buy-Back Rights) above; *provided that* if Zai Lab, within [***] days of INCY's notice of reversion of rights and termination pursuant to Section 3.10 (Development Diligence Reversion Right) or Section 4.7 (Commercial Diligence Buy-Back Rights) above, in good faith disputes (a) whether INCY has the right to revert all rights to the Licensed Molecule under this Agreement to INCY in accordance with Section 3.10 (Development Diligence Reversion Right) or (b) whether INCY has the right to revert all rights to the Licensed Molecule and all Licensed Products of Zai Lab under this Agreement in accordance with Section 4.7 (Commercial Diligence Buy-Back Rights) , then (y) such dispute shall be escalated and subject to the dispute resolution procedures set forth in ARTICLE 12 (Dispute Resolution) and (z) this Agreement will remain in full effect unless and until INCY is found to have such right following such dispute resolution procedures.

9.2.4 Termination for Bankruptcy . If either Party makes a general assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not dismissed, discharged, bonded or stayed within [***] days after the filing thereof, the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party. All rights and licenses granted under or pursuant to this Agreement by Zai Lab or INCY are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code , licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the terminating Party, insofar that it is a licensee

under this Agreement will retain and may fully exercise all of its rights and elections as a licensee under the U.S. Bankruptcy Code and any foreign counterparts thereto .

9.2.5 Termination for Patent Challenge . If a Party or any of its Affiliates or Sublicensees, individually or in association with any other person or entity, challenges in a legal action or an administrative proceeding the validity, enforceability or patentability of any Patent that is licensed to the other Party under this Agreement, the Party who Controls such Patent may upon [***] days' advance notice, terminate this Agreement in its entirety unless during such [***] period the subject challenge is permanently dismissed or withdrawn and is not thereafter reinstituted or continued; *provided that* in the event a Party's Sublicensee initiates such challenge, the other Party who Controls such Patent many not terminate this Agreement if (a) such Party successfully causes such Sublicensee to abort such challenge within such [***] period, or (b) such Party (i) provides the other Party written notice of its intent to terminate its sublicense with such Sublicensee within such [***] period, and (ii) successfully terminates such sublicense within [***] days after the delivery of such notice. For clarity , a good faith contractual dispute brought by Zai Lab under this Agreement solely with respect to whether or not a particular INCY Patent Covers a Licensed Product, or its manufacture or use, in a Region for purposes of determining when the Royalty Term with respect to such Licensed Product in such Region has ended or a royalty-rate reduction occurs pursuant to Section 7.3.4 (Royalty Reduction) shall not be deemed a "challenge" so long as such dispute with respect to such INCY Patent is limited to such purpose and to determination of (y) the scope of such INCY Patent for purposes of determining whether such INCY Patent Covers such Licensed Product and (z) non-infringement of such Licensed Product of such INCY Patent, and Zai Lab does not dispute or challenge the validity, patentability, priority, inventorship, ownership or enforceability of such INCY Patent.

9.3 Effects of Termination .

9.3.1 Licenses upon Termination .

(a) Upon the expiration of a Royalty Term with respect to a Licensed Product in a Region(s), all licenses granted by INCY to Zai Lab for such Licensed Product in such Region(s) for which Zai Lab has paid all royalties and milestone payments due under this Agreement will be deemed fully paid up and irrevocable, but on a non-exclusive basis, except as provided under clauses (b) and (c) of this Section 9.3.1 (each a " ***Surviving License*** ").

(b) If INCY [***] , the Commercialization portion only of the Surviving License for such Licensed Product in such Region(s) shall remain an exclusive license for a payment of the higher of: (i) an amount equal to [***] (as defined in this Agreement, but for Licensed Product manufactured by [***] taking the place of INCY in such definition, *mutatis mutandis*) of Licensed Product sold and counted in Net Sales by Zai Lab after expiration of such Royalty Term; or (ii) [***] of Net Sales of such Licensed

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Product in such Region(s) after expiration of such Royalty Term . Such Surviving License for Commercialization will remain exclusive until [***] days after any of such payments to INCY has become due but is not paid subject to a [***] days' curing period (at the expiration of such curing period, where the payment has not been cured, such license automatically converts to non-exclusive).

(c) If INCY elects to supply to Zai Lab such Licensed Product for Commercialization in such Region(s) after the expiration of a Royalty Term for a Licensed Product in a Region(s) in accordance with Section 9.1.3 (Option to Obtain Supply After Expiration), upon and after the expiration of such Royalty Term pursuant to Section 7.3.2 (Royalty Term), the Commercialization portion only of the Surviving License for such Licensed Product in such Region(s) shall remain an exclusive license for a payment of the higher of: (i) an amount equal to [***] of Licensed Product supplied by INCY under Section 9.1.3 (Option to Obtain Supply after Expiration) after expiration of such Royalty Term; or (ii) [***] of Net Sales of such Licensed Product in such Region(s) after expiration of such Royalty Term, in each case of clause (i) and (ii), above, minus the amount paid to INCY under clause (a) of Section 9.1.3 (Option to Obtain Supply after Expiration). Such Surviving License for Commercialization will remain exclusive until [***] days after any of such payments to INCY has become due but is not paid subject to a [***] days' curing period (at the expiration of such curing period, where the payment has not been cured, such license automatically converts to non-exclusive).

(d) For clarity, while any Surviving License remains exclusive, INCY will not, and will cause its Affiliates to not, directly or indirectly, through Third Party(ies), (i) Commercialize the subject Licensed Product(s) in the Field in the applicable Region(s), (ii) supply the subject Licensed Product(s) to any Third Party(ies) in the Field in the applicable Region(s) for Commercialization of the subject Licensed Product(s) in the Field in the applicable Region(s), or (iii) grant a license to any Third Party(ies) for the Commercialization of the subject Licensed Product in the Field in the applicable Region(s).

(e) Upon the termination of this Agreement in its entirety pursuant to Section 9.2 (Early Termination): (i) all Surviving Licenses will be deemed fully paid up and irrevocable, but on a non-exclusive basis, except as provided under clauses (b) and (c) of this Section 9.3.1 ; and (ii) all other licenses granted by INCY to Zai Lab will terminate and their corresponding rights under the INCY Patents and INCY Technology will revert to INCY. Upon the effective date of such termination, except as provided under clause (a), (b) and (c) of this Section 9.3.1 , the licenses granted from INCY to Zai Lab under Section 6.1 (License to Zai Lab) will convert to non-exclusive and remain in effect for the limited duration of, and to the limited extent necessary to complete, the post-termination transition activities contemplated by this Section 9.3 (Effects of Termination).

9.3.2 **Transition** . Upon the effective date of the termination of this Agreement, Zai Lab will:

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(a) if INCY terminates this Agreement in accordance with Section 9.2.1 (Termination for Material Breach), Section 9.2.3 (Termination for Development or Commercial Diligence Failures), Section 9.2.4 (Termination for Bankruptcy), Section 9.2.5 (Termination for Patent Challenge) or Zai Lab terminates this Agreement in accordance with Section 9.2.2 (Termination for Convenience), then Zai Lab will assign to INCY all rights, title and interest in Zai Lab Trademarks related to the Licensed Molecule and the Licensed Product(s) that are the subject of the termination and transfer to INCY all associated books and records.

(b) to the extent permitted under Applicable Law, assign all rights, title and interest and transfer to INCY, at INCY's business premises, all Data and Regulatory Materials related to the Licensed Molecule and the Licensed Product(s) that are the subject of the termination: (i) if INCY terminates this Agreement in accordance with Section 9.2.1 (Termination for Material Breach), Section 9.2.3 (Termination for Development or Commercial Diligence Failures), Section 9.2.4 (Termination for Bankruptcy), Section 9.2.5 (Termination for Patent Challenge) or Zai Lab terminates this Agreement in accordance with Section 9.2.2 (Termination for Convenience); and (ii) only if commercially feasible, if this Agreement is terminated for any other reason.

(c) with respect to any ongoing Clinical Trials of Licensed Product(s) that are being conducted by or on behalf of Zai Lab at the time of termination, INCY will notify Zai Lab within [***] days after the effective date of termination which of such trials, if any, that INCY desires to continue. To the extent INCY notifies Zai Lab in accordance with the preceding sentence of one or more trials INCY desires to continue and (i) any of such Clinical Trials designated by INCY and any associated clinical trial, contract research and other agreements necessary to conduct them are in fact transferable to INCY or its Affiliate under Applicable Law and the terms of such agreements and (ii) it is commercially feasible to transfer such Clinical Trials to INCY or its Affiliate, then Zai Lab will cooperate with INCY to facilitate the prompt and orderly transfer to INCY of the conduct of such Clinical Trials , including by assignment of any applicable agreements desired by INCY (any Clinical Trials capable and commercially feasible of being so transferred , " ***INCY Post-Termination Clinical Trials*** "). As between the Parties, (1) INCY will be responsible for [***] , (2) Zai Lab will be responsible for [***] , and (3) the Parties will indemnify each other in accordance with ARTICLE 11 (Indemnity), if and as applicable. With respect to all other such ongoing Clinical Trials, Zai Lab will wind-down and stop them as soon as reasonably possible in accordance with all Applicable Laws, and, as between the Parties, [***] will remain responsible for all associated costs and expenses associated with all of such Clinical Trials and their associated agreements and wind down.

(d) if INCY terminates this Agreement in accordance with Section 9.2.1 (Termination for Material Breach), Section 9.2.3 (Termination for Development or Commercial Diligence Failures), Section 9.2.4 (Termination for Bankruptcy), Section 9.2.5 (Termination for Patent Challenge) or Zai Lab terminates this Agreement in accordance with Section 9.2.2 (Termination for Convenience), then with

respect to any Licensed Product(s) that, at the effective date of such termination is the subject of a Regulatory Approval in the Zai Lab Territory, INCY or Zai Lab, as applicable, will continue to add additional/secondary packaging and labelling to the Licensed Product(s) and Zai Lab will continue to accept and fulfill orders through Zai Lab's existing distribution network, in each case, in accordance with its then-current practices and the terms and conditions of this Agreement until the later of: (i) INCY's written notice to Zai Lab to stop such activities, which must be given on at least [***] weeks' advance notice of the date INCY desires to stop such activities, and (ii) [***] months after the effective date of such termination . During such period, Zai Lab will be entitled to continue to book the revenues from such sales (subject to the terms of ARTICLE 7 (FINANCIAL TERMS)), *provided, however,* that if this Agreement was terminated by Zai Lab under Section 9.2.1 (Termination for Material Breach), the royalties payable under Section 7.3 (Royalties) will be reduced by [***] of the amount that would be otherwise due thereunder.

(e) Without limiting the foregoing, each Party will cooperate with the other Party to effect a smooth and orderly transition with respect to the Licensed Product(s) that were the subject of the termination in a prompt and expeditious manner.

9.3.3 Accrued Rights; Remedies . Termination, relinquishment or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination, relinquishment or expiration, including the payment obligations under ARTICLE 7 (FINANCIAL TERMS) hereof, and any and all damages or remedies (whether in law or in equity) arising from any breach hereunder. Such termination, relinquishment or expiration will not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement. Except as otherwise expressly set forth in this Agreement, the termination provisions of this ARTICLE 9 (TERM AND TERMINATION) are in addition to any other relief and remedies available to either Party under this Agreement and Applicable Law.

9.3.4 Survival . The rights and obligations of the Parties set forth in the following provisions will survive the expiration or termination of this Agreement for any reason, in addition to those other terms and conditions that are expressly stated to survive termination or expiration of this Agreement: ARTICLE 1 (DEFINITIONS), Section 3.16 (Remedial Action) (with respect to Licensed Product(s) distributed under this Agreement), Section 4.11 (Export and Import Restrictions), Section 5.1 (Ownership) through Section 5.3 (Patent Prosecution and Maintenance), Section 5.4.4 (Enforcement and Defense of Joint Patents), Section 5.4.5 (Cooperation) (with respect to actions brought under Section 5.4.4 (Enforcement and Defense of Joint Patents) only), Section 5.5 (Defense of Claims Brought by Third Parties), Section 5.6.1 (Zai Lab Trademarks) (only in the event of expiration and not early termination), Section 5.6.2 (No License to INCY Trademarks), Section 5.6.3 (INCY Trademarks in the Zai Lab Territory) (regarding Trademarks), Section 6.4 (License to INCY), Section 6.5 (Right of Reference), Section 6.6 (Reservation of Rights), the last sentence of Section 7.3.2 (Royalty Term), Section 7.9 (Royalty Reports and Royalty Payments) through Section 7.11 (Financial Audits) (with respect to payments

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payable and Net Sales realized prior to the termination effective date of this Agreement and payments payable and Net Sales realized pursuant to each exclusive license that is the subject of Section 9.3.1(b) or Section 9.3.1(c)), Section 7.13 (Currency Exchange) through Section 7.15 (Interest on Late Payment), ARTICLE 8 (CONFIDENTIALITY), Section 9.1.3 (Option to Obtain Supply after Expiration) (only in the event of expiration and not early termination), Section 9.3 (Effects of Termination), ARTICLE 11 (INDEMNITY), ARTICLE 12 (DISPUTE RESOLUTION) and ARTICLE 13 (MISCELLANEOUS) (other than Section 13.4 (Anti-Corruption)).

10. REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties . Each Party represents and warrants to the other Party that:

10.1.1 Organization . It is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated;

10.1.2 Authority . It has all requisite corporate power and authority to enter into this Agreement, and to perform its obligations under this Agreement;

10.1.3 Authorization . The execution of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized;

10.1.4 Enforceable . This Agreement is legally binding and enforceable on such Party in accordance with its terms; and

10.1.5 No Breach . The performance of this Agreement by it does not create a material breach or material default under any other agreement to which it is a Party.

10.2 INCY Representations, Warranties and Covenants . INCY represents , warrants or covenants, as applicable, to Zai Lab that:

10.2.1 Sufficiency . as of the Effective Date, (a) INCY has the rights to grant the license granted herein, and it has not granted any license or other right under the INCY Patents and INCY Technology inconsistent with this Agreement, and (b) all employees, officers, contractors, agents and consultants of INCY who are or were involved in the creation of any INCY Patents or INCY Technology have executed an assignment of inven tions agreement that vests in INCY or its Affiliates exclusive ownership of all right, title and interest in and to such Patents or Technology, to the extent not already provided by law.

10.2.2 INCY Patents and INCY Technology . (a) **Schedule 1.38 (INCY Patents as of the Effective Date)** contains a complete and accurate list of all INCY Patents issued in the Zai Lab Territory as of the Effective Date and, to INCY's knowledge, all such INCY Patents are valid and enforceable, (b) **Schedule 3.1 (INCY Technology)** contains a

list of all Technology that exists as of the Effective Date and that INCY believes constitutes a complete summary of the INCY Technology;

10.2.3 **No Litigation** . as of the Effective Date, there is no pending litigation, nor has INCY received any written notice from any Third Party, (a) asserting or alleging the Development, manufacture, or Commercialization of any Licensed Molecule or Licensed Product(s) prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (b) seeking to invalidate any INCY Patent;

10.2.4 **No Violation** . INCY (a) to INCY's knowledge as of the Effective Date, has not violated or (b) will not violate any Applicable Law in connection with the Development, manufacture or Commercialization of any of the Licensed Molecule or Licensed Product(s) in any manner that would adversely affect Zai Lab's ability to exploit the rights granted to Zai Lab under this Agreement in any material way.

10.2.5 **No Infringement** . to INCY's knowledge as of the Effective Date, there is no infringement or misappropriation of any of INCY IP in the Field in the Zai Lab Territory or use of any of the INCY IP in derogation of the rights granted to Zai Lab in this Agreement;

10.2.6 **No Investigation** . to INCY's knowledge as of the Effective Date, there are no investigations, inquiries, actions or other proceedings that were initiated by any Third Party or governmental authority and that are pending before any Regulatory Authority or other government agency with respect to any Licensed Product(s), and INCY has not received at its corporate offices any written notice addressed to senior management threatening any such investigation, inquiry, action or other proceeding;

10.2.7 **Upstream Licenses** . as of the Effective Date, (a) **Schedule 1.86 (Upstream Licenses)** contains a complete and accurate list of all Upstream Licenses, (b) INCY and its permitted Affiliates (i) have been in compliance with all material terms and conditions of the Upstream Licenses and all Upstream Licenses are in full force and effect, (c) INCY has not received any written notice that alleges breach or default by INCY of , requests a material amendment of, termination of any Upstream License, and (d) INCY is not aware of any material breach or facts or circumstances likely to result in a material breach of any Upstream License or that would result in any reduction or loss of any rights to Zai Lab;

10.2.8 **Compliance with Upstream Licenses** . INCY and its Affiliates (a) will remain in material compliance with all terms and conditions of each Upstream License; (b) will ensure that the Upstream Licenses are in full force and effect for so long as any INCY IP licensed to INCY under such Upstream Licenses are necessary for the Development or Commercialization of Licensed Products in the Field and in the Zai Lab Territory; (c) will provide prompt notice to Zai Lab of its receipt of any written notice that alleges material breach by INCY or termination of any Upstream License; and (d) will not, without the prior

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written consent of Zai Lab, amend an Upstream License in any way that negatively effects the rights sublicensed to Zai Lab hereunder;

10.2.9 Disclosures Before the Effective Date . as of the Effective Date, INCY has disclosed to Zai Lab and made available to Zai Lab for review all material clinical data for the Licensed Molecule and Licensed Products and all material correspondence with Regulatory Authorities relating to the Licensed Molecule and Licensed Products, in each case that (a) is Controlled by INCY as of the Effective Date and (b) would be material for Zai Lab to assess the safety and efficacy of the Licensed Molecule and Licensed Products; and

10.2.10 Protection . INCY, as of the Effective Date, (a) has taken and will continue to take commercially reasonable efforts to protect the confidentiality of information in the INCY Technology that INCY desires to remain confidential or is required to keep confidential pursuant to the terms of an Upstream License and (b) has executed valid, written agreements with all of its past and present employees, contractors and consultants pursuant to which such employees, contractors and consultants have agreed to hold all trade secrets and other Confidential Information of INCY, its Affiliates, and Third Parties who have entrusted INCY with their trade secrets and other Confidential Information within the INCY Technology, in confidence both during and after their engagement and/or employment.

10.3 Zai Lab Representations and Warranties . Zai Lab represents and warrants to INCY that it has obtained all necessary internal approvals and consents for entering into and implementing this Agreement. To the extent Zai Lab is required to obtain any Regulatory Approvals or make any regulatory filings or recordals for performance of its obligations hereunder after signing of this Agreement, Zai Lab warrants that it will obtain such approvals and complete such filings or recordals as required by Applicable Law. Zai Lab further represents and warrants as set forth on **Schedule 10.3 (Compliance)** .

10.4 Disclaimer . EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY PATENTS, CONFIDENTIAL INFORMATION OR KNOW-HOW OF SUCH PARTY OR ANY LICENSE GRANTED BY SUCH PARTY HEREUNDER, OR WITH RESPECT TO ANY COMPOUNDS, INCLUDING, BUT NOT LIMITED TO, THE MATERIALS TRANSFERRED FROM ONE PARTY TO THE OTHER.

11. INDEMNITY

11.1 Indemnification by Zai Lab . Zai Lab will indemnify, defend and hold harmless INCY, its Affiliates, and its and their respective directors, officers, employees and agents from and against any and all actual or threatened claims, suits, or proceedings of

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Third Parties (collectively " ***Third Party Claims*** ") and all associated damages, awards, fines, expenses, liabilities, or losses, including, without limitation, reasonable legal expenses and attorneys' fees, to the extent resulting from or arising out of: (a) the [***] or breach of this Agreement by Zai Lab, including any [***] ; or (b) the Development or Commercialization of the Licensed Product(s) by on behalf of Zai Lab, its Affiliates or its sublicensees in the Zai Lab Territory, except in each case to the extent such Third Party Claims result from or arise out of any activities set forth in Section 11.2 (Indemnification by INCY) for which INCY is obligated to indemnify.

11.2 Indemnification by INCY . INCY will indemnify, defend and hold harmless Zai Lab, its Affiliates, and its and their respective directors, officers, employees and agents from and against any and all Third Party Claims and all associated damages, awards, fines, expenses, liabilities, or losses, including reasonable legal expenses and attorneys' fees, to the extent resulting from or arising out of: (a) the [***] or breach of this Agreement by INCY, including any [***] ; (b) the Development, manufacture or Commercialization of Licensed Molecule or Licensed Product(s) by or on behalf of INCY or its sublicensees outside the Field or outside of the Zai Lab Territory; (c) Zai Lab's conduct of any Clinical Trials on behalf of INCY pursuant to Section 9.3.2(b) ; (d) INCY's Development or Commercialization of any INCY Pipeline Combination Regime n in the Zai Lab Territory, except the Licensed Product(s) portion thereof; (e) INCY's co-promotion activities pursuant to Section 4.8 (INCY Co-Promotion Option); or (f) Zai Lab's or its Affiliates' activities in relation to maintaining or transferring the INCY Post-Termination Clinical Trials in accordance with Section 9.3.2(c) after INCY's notification to Zai Lab pursuant to Section 9.3.2(c) ; except in each case to the extent such Third Party Claims result from or arise out of any activities set forth in Section 11.1 (Indemnification by Zai Lab) for which Zai Lab is obligated to indemnify INCY.

11.3 Indemnification Procedure . The indemnified Party will provide the indemnifying Party with prompt notice of the claim giving rise to the indemnification obligation pursuant to this ARTICLE 11 and the exclusive ability to defend (with the reasonable cooperation of the indemnified Party) or settle any such claim; *provided however* , that the indemnifying Party will not enter into any settlement for damages other than monetary damages without the indemnified Party's written consent, such consent not to be unreasonably withheld. The indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party. If the Parties cannot agree as to the application of Sections 11.1 (Indemnification by Zai Lab) and 11.2 (Indemnification by INCY) to any particular Third Party Claim, the Parties may conduct separate defenses of such claim and reserve the right to claim indemnity from the other in accordance with Sections 11.1 (Indemnification by Zai Lab) and 11.2 (Indemnification by INCY) above upon resolution of the underlying claim, notwithstanding the provisions of this Section 11.3 (Indemnification Procedure) requiring the indemnified Party to tender to the indemnifying Party the exclusive ability to defend such claim or suit.

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11.4 Mitigation of Loss . Each indemnified Party will take and will procure that its Affiliates, agents, directors, officers and employees take all such reasonable steps and action as are reasonably necessary or as the indemnifying Party may reasonably require in order to mitigate any Third Party Claims (or potential losses or damages) under this ARTICLE 11 . Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

11.5 Limitation of Liability . IN NO EVENT WILL ANY PARTY BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE, SUFFERED BY A PARTY OR ANY OF ITS RESPECTIVE REPRESENTATIVES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.5 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 (INDEMNIFICATION BY ZAI LAB) OR 11.2 (INDEMNIFICATION BY INCY), DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 8 (CONFIDENTIALITY), OR DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE OR INTENTIONAL AND WILLFUL BREACH IN BAD FAITH OF ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT CONTAINED IN THIS AGREEMENT BY THE OTHER PARTY.

12. DISPUTE RESOLUTION

12.1 Choice of Law . This Agreement will be governed by, enforced, and will be construed in accordance with the laws of the State of New York, U.S., without regard to its conflicts of law provisions.

12.2 Internal Resolution . Other than disputes subject to the final resolution by the JSC or Executive Officers pursuant to Section 2.5 (Decision-making of JSC) or determinations made by certified accountants as provided in Section 7.11 (Financial Audit), in the event of any dispute between the Parties relating to or arising out of this Agreement, the formation, construction, breach or termination hereof, or the rights, duties or liabilities of either Party hereunder, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves . In the event that such dispute is not resolved on an informal basis within [***] days, either Party may, by written notice to the other Party, refer the dispute to the Executive Officers for attempted resolution by good faith negotiation within [***] days after such notice is received.

12.3 Binding Arbitration . If the Executive Officers are not able to resolve such disputed matter within [***] days and any Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim will be finally resolved by binding arbitration administered by the International Chamber of Commerce (" ***ICC*** ")

pursuant its arbitration rules, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The Parties agree that:

12.3.1 **Venue** . The arbitration will be conducted by a single arbitrator appointed by the ICC, who will be experienced in the pharmaceutical business in the relevant country. The place of arbitration will be [***] , and all proceedings and communications will be in English, unless otherwise agreed by all Parties involved in such dispute.

12.3.2 **Injunctive Relief** . Any Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Any Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award.

12.3.3 **No Punitive Damages** . The arbitrator will have no authority to award punitive or any other type of damages not measured by a Party's compensatory damage. Each Party will bear its own costs and expenses and attorneys' fees, and an equal share of the arbitrator's fees and any administrative fees of arbitration regardless of the outcome of such arbitration.

12.3.4 **Confidentiality of Arbitration** . Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of all Parties. In no event will an arbitration be initiated after the date when commencement of a legal or equitable proceeding, based on the dispute, controversy or claim, would have been barred by the applicable statute of limitations.

12.4 **Excluded Claim** . As used in Section 12.3 (Binding Arbitration), the term " ***Excluded Claim*** " will mean a dispute, controversy or claim that concerns the scope, validity, enforceability, inventorship or infringement of an Intellectual Property Right. Any Excluded Claim will be submitted to a court of competent jurisdiction.

13. MISCELLANEOUS

13.1 **Severability** . If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties hereto will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably

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assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

13.2 **Notices** . Any notice required or permitted to be given by this Agreement will be in writing and will be delivered by express international courier with tracking capabilities or via email with confirmation by the preceding method and addressed as set forth below unless changed by notice so given:

If to Zai Lab:

Zai Lab (Shanghai) Co., Ltd.
4560 Jinke Rd, Bldg. 1, 4/F
Pudong, Shanghai, China, 201210
Attention: Jonathan Wang
Fax: +86 21 6163 2570

with a copy to :

Ropes & Gray LLP
36F Park Place
1601 Nanjing Road West
Shanghai, China 200040
Attention: Arthur Mok and Geoffrey Lin
Email: Arthur.Mok@ropesgray.com ; and Geoffrey.Lin@ropesgray.com

If to INCY:

Incyte Corporation
1815 Augustine Cut-Off
Wilmington, DE 19802 USA
Attention: General Counsel

with a copy to :

Jones Day
4655 Executive Drive, Suite 1500
San Diego, CA 92130 USA
[***]

Any such notice will be deemed given on the date received, except any notice received after 5:30 p.m. (in the time zone of the receiving party) on a Business Day or received on a non-Business Day will be deemed to have been received on the next Business Day. A Party may add, delete, or change the person or address to which notices

should be sent at any time upon written notice delivered to the other Party in accordance with this Section 13.2 (Notices).

13.3 **Force Majeure** . Neither Party will be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of God, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, civil unrest, intervention of any governmental authority or material changes in Applicable Law (" ***Force Majeure*** "); *provided however* , that the affected Party promptly notifies the other Party and further *provided* that the affected Party will use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and will continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties will negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

13.4 **Anti-Corruption** . Each Party will, and will cause its Affiliates and Sublicensees, and its and their Representatives to, (a) comply with the requirements of the U.S. Foreign Corrupt Practices Act of 1977, as amended; the UK Bribery Act 2010; and other applicable anti-corruption laws in connection with this Agreement; and (b), without limiting the generality of clause (a) of this Section 13.4 , not make, offer, or promise to make or offer any improper payment or transfer of anything of value, directly or indirectly, to any (i) official or employee of a government or any department, agency, or instrumentality thereof, or official or employee of a public international organization, (ii) political party or political party official, (iii) candidate for political office, in each case of (i) through (iii), above, for (1) the purpose of corruptly obtaining, retaining, or directing business in relation to this Agreement, or (2) an improper financial or other advantage or the improper performance of the recipient's relevant function or activity in relation to this Agreement.

13.5 **Export Control** . The Parties understand and acknowledge that any goods, services or Technology furnished directly or indirectly, in writing or otherwise, by INCY made available under this Agreement, and the direct products thereof, are subject to the U.S. Export Administration Regulations and U.S. trade sanctions, including those administered by the U.S. Departments of Treasury, State and Commerce. The Parties will adhere to the U.S. Export Administration Regulations and U.S. trade sanctions, and will not export or re-export any Technology or direct product or service of such Technology to any proscribed country or end-user listed in the U.S. Export Administration Regulations, including those countries and end-users specified in the Entity List and Unverified List maintained by the U.S. Department of Commerce, or otherwise listed on or subject to the restrictions of any other U.S. government restricted list, including without limitation the Specially Designated Nationals (SDN) list, unless properly authorized by the U.S. Government, if such authorization is required. If, and to the extent that any such performance is prohibited by or contrary to any applicable U.S. export regulation or trade

sanction, it would be deemed a Force Majeure event and the Parties will not be obligated to perform any obligations hereunder pursuant to Section 13.3 (Force Majeure) above.

13.6 Equitable Relief . Each Party acknowledges and agrees that a breach of Section 2.6 (Limitations on Authority of JSC), ARTICLE 3 (DEVELOPMENT), Section 4.7 (Commercial Diligence Buy-Back Rights), ARTICLE 5 (INTELLECTUAL PROPERTY), ARTICLE 6 (LICENSES) and ARTICLE 8 (CONFIDENTIALITY) of this Agreement cannot reasonably or adequately be compensated in damages in an action at law and that such a breach will cause the other Party irreparable injury and damage. By reason thereof, the Parties agree that each Party will be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any breach of such obligations, without the posting of bond or other security. The Parties further agree not to raise as a defense or objection to the request or granting of such relief that any breach of this Agreement is or would be compensable by an award of money damages.

13.7 Assignment . Neither Party may assign this Agreement to any Person without the prior written consent of the other Party, except as provided in this Section 13.7 .

13.7.1 By INCY . INCY, without the prior written consent of Zai Lab, may assign INCY's rights and obligations under this Agreement in whole or in part to (a) an Affiliate of INCY for as long as such Affiliate remains as an Affiliate of INCY or (b) a Third Party that acquires (whether by merger, reorganization, acquisition, sale, exclusive license or otherwise) all or substantially all of the business or assets of INCY to which this Agreement relates at such time and in each case of (a) and (b), agrees in writing to be bound by the terms of this Agreement. INCY may otherwise assign its rights and obligations under this Agreement in whole or in part only with the written consent of Zai Lab, which consent may not be unreasonably withheld, delayed or conditioned.

13.7.2 By Zai Lab . Zai Lab may assign this Agreement, in whole or in part, only with the advance written consent of INCY; *provided, however* , that INCY will not unreasonably withhold, delay or condition such consent if Zai Lab requests to assign its entire interest under this Agreement to an Affiliate; *provided, that* such consent shall apply for as long as such Affiliate remains as an Affiliate of Zai Lab, or to a Third Party purchaser of all of or substantially all of the assets of Zai Lab.

13.7.3 Any successor or assignee of rights or obligations of a Party permitted hereunder shall, in writing delivered to the other Party within [***] days of such assignment, expressly assume performance of such rights or obligations and agree to be bound by the terms of this Agreement. This Agreement will inure to the benefit of and be binding on the Parties' successors and permitted assigns. Any assignment in violation of this Section 13.6 will be null and void and wholly invalid, the assignee in any such assignment will acquire no rights hereunder whatsoever, and the non-assigning Party will not recognize, nor will it be required to recognize, such assignment. Notwithstanding anything in this

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Agreement to the contrary, if an assignment of this Agreement, in whole or in part, by either Party causes a higher withholding or direct tax rate than would be applicable without such assignment, such taxes will be borne and indemnified by the assigning Party, including taxes resulting therefrom.

13.8 Further Assurances . Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may deem advisable in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

13.9 Waivers . Any term or condition of this Agreement may be waived at any time by the Party or Parties that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party or Parties waiving such term or condition. Neither the waiver by any Party of any term or condition of this Agreement nor the failure on the part of any Party, in one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, will be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be a limitation of any other remedy, right, undertaking, obligation or agreement.

13.10 Independent Contractor . The relationship between the Parties is that of independent contractors. Such Parties are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties. Such Parties' obligations and rights in connection with the subject matter of this Agreement are solely and specifically as set forth in this Agreement, and such Parties acknowledge and agree that neither such Party owes the other any fiduciary or similar duties or obligations by virtue of the relationship created by this Agreement .

13.11 Third Party Beneficiaries . None of the provisions of this Agreement will be for the benefit of or enforceable by any Third Party, including any creditor of a Party. No Third Party will obtain any right under any provision of this Agreement or will by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against a Party.

13.12 Waiver of Jury Trial . EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED WITH [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 13.12 (WAIVER OF JURY TRIAL).

13.13 Entire Agreement; Amendments . This Agreement (including all Schedules attached hereto, which are incorporated herein by reference) (a) sets forth all of the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof, (b) constitutes and contains the complete, final and exclusive understanding and agreement of the Parties with respect to the subject matter hereof, and (c) cancels, supersedes and terminates all prior agreements and understanding between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings with respect to the subject hereof, whether oral or written, between the Parties other than as set forth herein. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

13.14 Counterparts . This Agreement may be executed in counter-parts with the same effect as if both Parties had signed the same document. All such counterparts will be deemed an original, will be construed together and will constitute one and the same instrument.

13.15 Registration . If required by Applicable Law, Zai Lab will be responsible for the registration of this Agreement with all applicable Regulatory Authorities in the Zai Lab Territory. INCY will reasonably cooperate with Zai Lab in obtaining any such registrations, including providing relevant documents required by the applicable Regulatory Authorities in the Zai Lab Territory. Upon successful registration of this Agreement with each applicable Regulatory Authority in the Zai Lab Territory, Zai Lab will promptly forward to INCY copies of any registration certificates as well as any other documentation received by Zai Lab.

13.16 Construction .

13.16.1 Representation by Counsel . Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party hereto as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party,

irrespective of which Party may be deemed to have authored the ambiguous provision. The English language version of this Agreement will control any interpretations of the provisions of this Agreement.

13.16.2 Interpretation . Headings and captions are for convenience only and are not be used in the interpretation of this Agreement. The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation” whether or not such phrase is included. The word “will” will be construed to have the same meaning and effect as the word “shall”. The word “any” will mean “any and all” unless otherwise clearly indicated by context. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Law herein will be construed as referring to such Applicable Law as from time to time enacted, repealed or amended, (c) any reference herein to any person will be construed to include the person’s successors and assigns, (d) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) all references herein to Articles, Sections or Schedules, unless otherwise specifically provided, will be construed to refer to Articles, Sections and Schedules of this Agreement, (f) the word “or” is used in the inclusive sense (and/or), and (g) any payment amounts, including those designated by the sign “$” are stated in and must be paid in U.S. Dollars.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers to be effective as of the Effective Date.

INCYTE CORPORATION	**ZAI LAB (SHANGHAI) CO., LTD**
By: _____	By: _____
Name: Hervé Hoppenot	Name: Samantha Du
Title: Chief Executive Officer	Title: Chief Executive Officer
Date:	Date:

Schedule 1

Definitions

1.1 " ***Affiliate*** " means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means (a) direct or indirect ownership of fifty percent (50%) or more of the voting securities or other voting interest of any Person (including attribution from related parties), or (b) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of voting securities, by contract, as a general partner, as a manager, or otherwise.

1.2 " ***Ancillary Study*** " means, (a) with respect to a Monotherapy Licensed Product, (i) any Phase I Clinical Trials, and (ii) any pre-clinical bioequivalence studies or similar studies conducted prior to a Phase I Clinical Trial that in each case (1) are conducted for such Licensed Product in the Field in any jurisdiction and (2) are not, in whole or in part, an expansion study Phase II Clinical Trials, Phase III Clinical Trials, a Pivotal Trial or Clinical Trials conducted after Regulatory Approval of such Licensed Product, or (b) with respect to a Licensed Product that is being studied in combination with a chemotherapy product, whether or not in fixed dosage form, any pharmacokinetic studies or bioequivalence studies or dose escalation studies of the Licensed Product from a Phase I Clinical Trial that is not in whole or in part an expansion study, Phase II Clinical Trial, Phase III Clinical Trial, Pivotal Trial, or Clinical Trial conducted after Regulatory Approval of such Licensed Product.

1.3 " ***Applicable Law*** " means all laws, statutes, rules, orders, regulations, by-laws, ordinances, subordinate legislation, judgments, decisions, decrees, and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, to the extent any of the foregoing is applicable to a Party, Affiliate or other Person in any jurisdiction in connection with its activities under this Agreement .

1.4 " ***Biologics License Application*** " or " ***BLA*** " means a "biologic license application" as defined by the FDA, or any equivalent application recognized by the NMPA or any other equivalent governmental authority or agency anywhere in the world.

1.5 " ***Biosimilar Product*** " means, with respect to a Licensed Product that has received Regulatory Approval in a Region, (a) a biologic therapeutic containing the same amino acid polymer as such Licensed Product, (b) a biologic therapeutic containing an amino acid polymer that is highly similar, or similar enough to one contained in a reference Licensed Product, notwithstanding minor differences in clinically inactive components, to permit an applicant for Regulatory Approval for such

biologic therapeutic to refer to and rely on clinical and other scientific information regarding the safety, purity, potency and/or efficacy of the reference Licensed Product in order to allow such biologic therapeutic to receive Regulatory Approval in such Region through an abbreviated regulatory pathway, or (c) a biologic therapeutic containing an amino acid polymer that is highly similar, or similar enough to one contained in a reference Licensed Product notwithstanding minor differences in clinically inactive components, to permit such biologic therapeutic to be marketed in such Region as generic-equivalent, functionally equivalent, biosimilar, biogeneric, biobetter, interchangeable, or by using any other description referring to the reference Licensed Product (and/or such Licensed Product's clinical and other scientific information) for support for safety, purity, potency and/or efficacy claims for such biologic therapeutic.

1.6 " ***Business Day*** " means a day other than Saturday, Sunday or any day on which commercial banks located in Shanghai, China or New York City, New York, U.S. (as applicable) are authorized or obligated by Applicable Law to close.

1.7 " ***Calendar Quarter*** " means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on the last day of March, June, September, or December, respectively; *provided that* , the final Calendar Quarter will end on the last day of the Term.

1.8 " ***Calendar Year*** " means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) consecutive calendar months beginning on January 1 and ending on December 31; *provided that* , the final Calendar Year will end on the last day of the Term.

1.9 " ***Change of Control*** " means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which would result in shareholders or equity holders of such Party immediately prior to such transaction, no longer owning at least 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions. Notwithstanding the foregoing clauses (a) and (b), if any investment transaction described therein is conducted by or with venture capital or other financial investors not engaged in the pharmaceutical or biotechnology business and not otherwise affiliated with a pharmaceutical or biotechnology company and for the sole purpose of raising

capital for a Party , such transaction shall not be deemed to be a Change of Control for purposes of this Agreement so long as the investment transaction does not also contemplate or require a change in any of the senior management of the Party upon or within one year after closing of the transaction .

1.10 " ***Clinical Trials*** " means any clinical trial or any other test or study in human subjects, whether sponsor or principal investigator initiated, intended to determine the safety, tolerability, pharmacokinetics, efficacy, pharmacodynamics or benefit/risk analysis of a Licensed Product(s) in human subjects as may be required by Applicable Law or recommended by a Regulatory Authority to obtain or maintain Regulatory Approval for a Licensed Product(s).

1.11 " ***Commercialization*** " means any and all activities directed to the launch, marketing, Detailing, promotion and securing of pricing and reimbursement of any Licensed Product(s), whether before or after Regulatory Approval has been obtained, including (a) pre-launch marketing research, preparation of sales force, and preparation of marketing materials and labels for finished goods, (b) post-launch marketing, promoting, Detailing, research, customer service, administering and commercially selling Licensed Product(s) after Regulatory Approval, (c) importing, building inventory, warehousing, distributing, and transporting Licensed Product(s) for commercial sale, (d) activities required to perform the foregoing in accordance with all Applicable Law and Regulatory Approvals, and (e) interacting with Regulatory Authorities regarding any of the foregoing. " ***Commercialize*** " means the performance of any of the foregoing Commercialization activities.

1.12 " ***Commercially Reasonable Efforts*** " means, with respect to either Party in relation to this Agreement, Licensed Molecule, Licensed Product(s) or activity, such efforts that are consistent with the level of efforts and resources used by such Party in connection with its other small molecule compounds (whether internally developed or licensed in from a Third Party), but in any event no less than those used by biopharmaceutical companies of similar size and market capitalization in the exercise of its commercially reasonable business practices with respect to a small molecule compound or product, as applicable, at a similar stage in its development or commercial life as the relevant compound or product and that has commercial and market potential similar to the relevant compound or product, taking into account [***] .

1.13 " ***Confidential Information*** " means, with respect to a Party, all non-public, confidential and proprietary information and materials, including Technology, marketing plans, strategies, and customer lists, in each case, that are disclosed by such Party to the other Party or generated by or on behalf of a Party in connection with the activities conducted under this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other Party by the disclosing Party in oral, written, visual, graphic or electronic form.

1.14 " ***Control*** ", " ***Controlled*** " or " ***Controls*** " means, with respect to any Intellectual Property Rights, Technology or Confidential Information, the ability of a Party,

itself or through an Affiliate, whether through ownership or license (other than a license granted in this Agreement) to grant to the other Party or its Affiliates, as applicable, the licenses or sublicenses upon the terms and conditions specified in this Agreement or to otherwise disclose the subject matter of Intellectual Property Rights, Technology or Confidential Information to the other Party without violating the terms of any then-existing agreement with any Third Party or misappropriating such Technology or Confidential Information.

1.15 " ***Cover*** ," " ***Covered*** " or " ***Covering*** " means, with reference to a Patent and a product, composition, article of manufacture, or method, that the manufacture, practice, use, offer for sale, sale or importation of the product, composition , article of manufacture, or method, would infringe a Valid Claim of such Patent, or with respect to a Valid Claim of a pending application for Patent, would infringe such Valid Claim if it were issued in the form pending, in each case in the country in which such activity occurs without a license thereto (or ownership thereof) .

1.16 " ***Data*** " means pre-clinical, clinical (including interim clinical study reports (CSRs)), chemical and associated analytical data and any other data and information generated or resulted from the Development or Commercialization of the Licensed Molecule or Licensed Product(s) anywhere in the Zai Lab Territory or INCY Territory.

1.17 " ***Detail*** " means a face-to-face meeting in an individual or group practice setting (or other method of individual contact if mutually agreed by the Parties), including a hospital setting, between a professional sales representative of the applicable Party, and a health care professional licensed or authorized to prescribe drugs, during which a presentation of a Licensed Product(s)'s attributes is presented in a manner consistent with Applicable Law and industry standards and with the quality of similar presentations made by a Party's sales representatives for such Party's other products, if applicable. A Detail does not include a reminder or sample drop made by a sales representative or contacts made at conventions, exhibit booths or speaker meetings. " ***Detailing*** " will mean the act of presenting a Detail.

1.18 " ***Defense*** " means the defense against any actions to challenge the patentability, validity or enforceability of a Patent, whether as part of a lawsuit, reexaminations, *inter partes* reviews or post-grant reviews, but excluding typical pre-grant, *ex-parte* prosecution examination activities by the Patent owner with the relevant patent authority, and " ***Defend*** " means to conduct any of the foregoing.

1.19 " ***Development*** " means, with respect to Zai Lab, clinical drug or biologic product development activities with respect to a Licensed Product(s) for use in Clinical Trials in the Field in the Zai Lab Territory and associated test method development and stability testing, toxicology, qualification and validation, Clinical Trials (including Clinical Trials commenced after Regulatory Approval), statistical analysis and report writing, the preparation and submission of INDs, BLAs and Regulatory Materials, regulatory affairs with respect to the foregoing, post-marketing approval commitments and all other activities necessary or useful or

otherwise requested or required by a Regulatory Authority or as a condition or in support of obtaining or maintaining a Regulatory Approval. " ***Development*** " means, with respect to INCY, all of the foregoing plus manufacturing scale-up and process development and manufacturing of products for use in Clinical Trials. " ***Develop*** " means the performance of any of the foregoing activities.

1.20 " ***Development Costs*** " means [***] .

1.21 " ***Dollar(s)*** " or " ***$*** " means the legal tender of the United States.

1.22 " ***Domestic Drug Registration Pathway*** " means registration of a Licensed Product(s) as a domestic drug with NMPA.

1.23 " ***Executive Officer*** " means, (a) in the case of INCY, the Chief Medical Officer of INCY, and (b) in the case of Zai Lab, the Chief Executive Officer of Zai Lab.

1.24 " ***FDA*** " means the U.S. Food and Drug Administration, or any successor agency of the U.S. government with a similar scope of responsibility regarding the regulation of human pharmaceutical products.

1.25 " ***Field*** " means the treatment, palliation, diagnosis or prevention of diseases in any the following fields: Hematology Field or Oncology Field in humans.

1.26 " ***First Commercial Sale*** " means , with respect to each Licensed Product, the first sale of such Licensed Product(s) by Zai Lab, its Affiliates or its Sublicensees to an unrelated Third Party in the Zai Lab Territory after Regulatory Approval of such Licensed Product(s) has been granted in the Zai Lab Territory.

1.27 " ***Foreign Marketing Approval*** " means the Regulatory Approval, certificate of pharmaceutical product, or equivalent certification for a Licensed Product outside the PRC that is required of an applicant for Regulatory Approval of the Licensed Product in the PRC under the Import Drug Registration Pathway.

1.28 " ***FTE*** " means the equivalent of the work of [***] full time for one (1) Calendar Year (consisting of at least a total of [***] hours per Calendar Year). In no event may the same person to be deemed to have worked more than [***] hours in any one Calendar Year or [***] hours in any one Calendar Month.

1.29 " ***FTE Rate*** " means, (a) with respect to Detailing activities, the applicable rate per FTE for Detailing activities conducted by employees or contractors of INCY, which rate will be determined by the Parties at the time INCY exercises its option to co-promote under Section 4.8 (INCY Co-Promotion Option) and which rate will be a reasonable approximation of the [***] , (b) with respect to determining Fully Burdened Cost, the applicable rate per FTE for [***] , and (c) for Development activities, the rate of [***] per FTE for employees of INCY and [***] per FTE for employees of Zai Lab. Once set, the FTE Rate for employees of INCY may be adjusted by [***] per Calendar Year to reflect changes in such costs, including those caused by inflation or otherwise. Once set, the FTE Rate for employees of

Zai Lab may be adjusted by [***] per Calendar Year to reflect changes in such costs, including those caused by inflation or otherwise.

1.30 " ***Fully Burdened Cost*** " means, with respect to any Licensed Product(s) supplied by or on behalf of INCY to Zai Lab hereunder: (a) if such Licensed Product(s) (or any precursor or intermediate thereof) is manufactured by a Third Party manufacturer (i) [***] , and (ii) [***] ; and (b) if such Licensed Product(s) (or any precursor or intermediate thereof) is manufactured by INCY or its Affiliate, [***] . Such fully burdened costs will be calculated in accordance with US GAAP, consistently applied and will be evidenced by invoices or other written documentation.

1.31 " ***GCP*** " means the Good Clinical Practice for Drugs (i.e. □□□□□□□□□□□□) promulgated by NMPA effective as of September 1, 2003, together with any guidelines or implementation rules issued by NMPA in connection thereto, in each case as amended from time to time.

1.32 " ***Generic Competition*** " means on a Region-by-Region basis, to the extent a Licensed Product is sold in such Region in the Zai Lab Territory in which one (1) or more Third Parties is selling or has previously sold one or more Biosimilar Products, and such Biosimilar Products, collectively, have achieved a [***] or more market share of the aggregate market share of such Licensed Product and such Biosimilar Products (based on data provided by an independent Third Party market analysis company mutually agreed by the Parties) as measured on a units sold basis in any Calendar Quarter, or if such data is not available, such other methodology for estimating the percentage of unit sales based market share of such Biosimilar Products in such Region as agreed upon by the Parties.

1.33 " ***Hematology Field*** " means the treatment, control, mitigation, prevention, cure, or diagnosis of all hematologic Indications as defined as of the Effective Date in subsections D50-D89 (Diseases of the blood and blood-forming organs) of ICD10.

1.34 " ***ICD10*** " means version 10 of the International Classification of Diseases as published by the World Health Organization as such version exists on the Effective Date.

1.35 " ***ICH Requirements*** " means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Licensed Molecule and Licensed Product(s).

1.36 " ***Import Drug Registration Pathway*** " means registration the Licensed Product(s) as an import drug with NMPA.

1.37 " ***INCY IP*** " means INCY Technology and INCY Patents.

1.38 " ***INCY Patent*** " means each Patent that is Controlled by INCY or its Affiliates as of the Effective Date or at any time during the Term, that is pending or issued in the Zai Lab Territory, and that is necessary for the Development or Commercialization of the Licensed Products in the Field in the Zai Lab Territory. INCY Patents include INCY's joint interest in any Joint Patents and any applicable Partner Patents. **Schedule 1.38 (INCY Patents as of the Effective Date)** contains a list of all INCY Patents as of the Effective Date.

1.39 " ***INCY Pipeline Assets*** " means all pharmaceutical compounds Controlled by INCY or any of its Affiliates as of the Effective Date or at any time during the Term or that are otherwise Covered by any Patent Controlled by INCY, in each case, that are not a Licensed Molecule.

1.40 " ***INCY Pipeline Combination Regimen Detailing*** " means an interactive face-to-face meeting that relates to an INCY Pipeline Combination Regimen between a sales representative acting on behalf of Zai Lab and a health care professional having prescribing authority within the target audience and that occurs after Regulatory Approval of a Licensed Product as part of an INCY Pipeline Combination Regimen in the Zai Lab Territory.

1.41 " ***INCY Pipeline Combination Study*** " means any Clinical Trials involving administration of an INCY Pipeline Combination Regimen.

1.42 " ***INCY Technology*** " means all Technology that is Controlled by INCY or its Affiliates (a) as of the Effective Date and that is reasonably necessary for the Development or Commercialization of the Licensed Product(s) in the Zai Lab Territory, including Technology disclosed by INCY or any of its Affiliates to Zai Lab pursuant to Section 3.1 (Transfer of Technology) , (b) after the Effective Date and developed in a INCY Collaboration Study, Joint Collaboration Study or Joint [***] Collaboration Study for which Zai Lab has paid its share of Development Costs in accordance with Section 3.11.1 (INCY Collaboration Studies), Section 3.11.3 (Joint Collaboration Study), Section 3.11.4 (Joint [***] Collaboration Study), respectively, (c) as of or after the Effective Date that INCY is required to disclose pursuant to Section 3.12 (Ancillary Studies), (d) INCY voluntarily discloses to Zai Lab pursuant to Section 3.1.2 (Additional Disclosures), or (e) constitutes INCY's right and interest in and to any Joint Inventions and any applicable Partner Technology. **Schedule 1.42 (INCY Technology as of the Effective Date)** contains a list of all INCY Technology as of the Effective Date.

1.43 " ***INCY Territory*** " means all the world except for the Zai Lab Territory.

1.44 " ***IND*** " means an Investigational New Drug Application filed with the FDA, a Clinical Trial Application (" ***CTA*** ") filed with the NMPA, or an analogous application or filing with any analogous Regulatory Authority outside of the USA under any analogous foreign law for the purposes of obtaining permission to conduct human clinical trials in such jurisdiction.

1.45 " ***Indication*** " means any disease or condition, or sign or symptom of a disease or condition .

1.46 " ***Intellectual Property Rights*** " means any intellectual or industrial property right recognized under the Applicable Law of any jurisdiction anywhere in the world, including all rights in: (a) Patents, (b) Trademarks, (c) trade secrets and other rights in Technology, (d) copyrights, including rights in databases and data collections, and (e) Internet domain names.

1.47 " ***Licensed Molecule*** " means the monoclonal antibody designated internally by INCY as of the Effective Date as "INCMGA012", which is an anti-PD-1 monoclonal antibody that is the subject of the Partner License Agreement, the structure of which is illustrated on **Schedule 1.47 (Structure of Licensed Molecule)** .

1.48 " ***Licensed Product(s)*** " means any pharmaceutical preparation containing (a) the Licensed Molecule without any other active ingredient (" ***Monotherapy Licensed Product*** ") or (b) a combination of the Licensed Molecule, together with another active ingredient that is not an INCY Pipeline Asset or otherwise Covered by any Intellectual Property Rights of INCY, whether or not in fixed dosage form (" ***Zai Lab Combination Licensed Product*** "); in each case (a) or (b), whether offered for sale by prescription, over-the-counter or any other method . For the avoidance of doubt, Licensed Product(s) do not include any pharmaceutical preparation that is (x) a combination of the Licensed Molecule together with any active ingredient that is an INCY Pipeline Asset or otherwise Covered by any Intellectual Property Rights of INCY (an " ***INCY Pipeline Combination Regimen*** "), except the portion of an INCY Pipeline Combination Regimen corresponding to a Licensed Molecule.

1.49 " ***Net Price Floor*** " means, with respect to any Licensed Product(s), an amount equal to [***] less than the PD-1 Antibody Price Benchmark calculated over an applicable period.

1.50 " ***Net Sales*** " means, with respect to a Licensed Product(s) in the Zai Lab Territory, and subject to Section 7.3.3 (Royalty Conditions) , the gross amounts invoiced by Zai Lab or any of its Affiliates or Sublicensees for sales of such Licensed Product to unaffiliated Third Party purchasers in arms-length transactions (" ***Gross Sales*** ") , less the following deductions calculated in accordance with US GAAP, to the extent actually taken, paid, accrued and allowed (" ***Net Sales Deductions*** ") :

(a) cash, trade or quantity discounts, retroactive price reductions, coupons, charge-back payments, and rebates granted (in each case, whether in cash or in kind) to trade customers, hospitals, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, and national, state, or local governments;

(b) credits, rebates or allowances allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Licensed Product,

including in connection with recalls and withdrawals, and the amount of any write-offs for bad debt (provided, that an amount written off as bad debt but subsequently recovered will be treated as Net Sales);

(c) outbound freight, shipment and insurance costs, to the extent included in the price and separately itemized on the invoice price;

(d) taxes (other than taxes addressed in Section 7.14 (Taxes)), duties, tariffs, mandated contribution or other governmental charges levied on the sale of such Licensed Product, including value added tax (excluding VAT paid on any payment to INCY under this Agreement), customs duties, healthcare taxes, excise taxes, use taxes, and sales taxes (collectively " ***Trade Taxes*** ");

(e) compulsory payments and cash rebates related to sales of such Licensed Product payable to a governmental authority (or agent thereof) pursuant to Applicable Law by reason of any national or local health insurance program or similar program that Zai Lab, its Affiliates or Sublicensees, as applicable, allocate to sales of the Licensed Product(s) in accordance with Zai Lab's, its Affiliates' or Sublicensees' standard policies and procedures consistently applied across its products, as applicable; and

(f) any other similar and customary deductions (e.g., currently, co-pay cards) that are consistent with US GAAP and Zai Lab's actual practice (or its Affiliates' or Sublicensees') at the time in calculating and reporting its actual product net sales throughout its businesses (in the particular country, if applicable), provided that no item shall be deducted pursuant to this clause (f) if included in any another deduction provided for under this definition (for example, Zai Lab shall not deduct an allowance for bad debts pursuant to this clause (f), as actual bad debts are subject to deduction pursuant to clause (b)),

All of the aforementioned deductions shall be determined, on a Region-by-Region basis, as incurred in the ordinary course of business in type and amount consistent with Zai Lab's or its applicable Affiliate's or Sublicensee's (as the case may be) business practices consistently applied across its product lines and accounting standards, as applicable. All such deductions shall be fairly and equitably allocated to such Licensed Product(s) and other products of Zai Lab and its Affiliates and Sublicensees.

In the event a Licensed Product is sold as part of a combination product containing the Licensed Molecule and one or more other therapeutic ingredient(s) (whether co-formulated or co-packaged) that is/are not a Licensed Molecule, the Net Sales from such combination product shall be determined by [***]. The Parties shall seek to determine such fair market values by mutual agreement and, in the absence of such mutual agreement, the Parties shall engage an independent valuation firm [***] to determine such fair market values.

Notwithstanding the foregoing, amounts invoiced by Zai Lab, its Affiliates, or its Sublicensees for the sale of a Licensed Product(s) among Zai Lab, its Affiliates or its Sublicensees for resale shall not be included in the computation of Net Sales hereunder unless such Affiliate or such Sublicensee is the end user of such Licensed Product(s) and as long as such Licensed Product(s) is subsequently resold by Zai Lab, its Affiliates or its Sublicensees, as applicable, and considered Net Sales. Net Sales shall exclude reasonable and customary quantities (e.g., samples) of the Licensed Product(s) transferred, disposed of or sold at no cost or at or below cost (i) for promotional or educational purposes, (ii) for Clinical Trial purposes, (iii) for early access programs (such as to provide patients with a Licensed Product(s) prior to Regulatory Approval pursuant to treatment INDs (or equivalents thereto) or protocols, named patient programs or compassionate use programs), (iv) for patient assistance programs or (v) for any similar uses.

1.51 " ***Niche Indication*** " means [***] .

1.52 " ***NMPA*** " means the National Medical Products Administration, or any successor agency with a similar scope of responsibility regarding the regulation of human pharmaceutical products in China.

1.53 " ***Oncology Field*** " means the treatment, control, mitigation, prevention, cure, or diagnosis of any oncology Indications as defined as of the Effective Date in subsections C00-D49 of ICD10 (Neoplasms), including all hematologic malignancies, solid tumors and myeloproliferative diseases (including Myelofibrosis , Polycythemia Vera and Essential Thrombocythemia).

1.54 " ***Out-of-Pocket Costs*** " means with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for the applicable Licensed Product(s), and for the avoidance of doubt will include, for any applicable period, pre-paid amounts paid on or after the Effective Date to the extent amortized in such applicable period by means of amortizing such amounts over the time period in which the applicable activities as to which such pre-paid amounts relate are to be performed.

1.55 " ***Partner License Agreement*** " means that Global Collaboration and License Agreement between Macrogenics, Inc. (" ***Partner*** ") and INCY dated October 24, 2017 pursuant to which Partner grants to INCY certain Intellectual Property Rights with respect to the Licensed Molecule.

1.56 " ***Partner Patent*** " means any Patent that is licensed to INCY pursuant to the Partner License Agreement. Partner Patents in the Zai Lab Territory as of the Effective Date include any counterpart granted in a Region claiming priority to [***] .

1.57 " ***Partner Technology*** " means any Technology that is licensed to INCY pursuant to the Partner License Agreement.

1.58 " ***Patents*** " means (a) all patents and patent applications in any country or supranational jurisdiction worldwide, (b) any substitutions, divisionals, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents and patent applications, and (c) any foreign counterparts of any of the foregoing.

1.59 " ***Patient Population*** " means the specific group of patients (by histologic or genetic subtype or line of therapy) suffering from an Indication. Such group in the context of Clinical Trials is the specific group of patients that could possibly serve as the population for studying the effects of a Licensed Product(s) targeting the Indication during a Clinical Trial. For the sake of clarity, treatment of different subpopulations within an Indication will be deemed separate Patient Populations for purposes of this Agreement (e.g., front-line treatment, relapsed refractory treatment and maintenance treatment of a given Indication will be considered different Patient Populations and [***] and biomarker-positive [***] will be considered different Patient Populations).

1.60 " ***PD-1*** " means programmed cell death protein 1.

1.61 " ***PD-1 Antibody Price Benchmark*** " means the average [***] of the three approved branded PD-1 monoclonal antibodies (or the average [***] of all approved branded PD-1 monoclonal antibodies listed on the [***] if there are less than three such branded PD-1 monoclonal antibodies) that have the highest market share by volume in the ZAI Lab Territory (excluding (a) the Licensed Product(s) from such approved branded PD-1 monoclonal antibodies and (b) molecules that are not Covered by a Valid Claim of a Patent Covering a composition of matter, formulations or method of treatment or use of such molecule(s) in the Zai Lab Territory), as updated on the first Business Day of each Calendar Quarter during the term of this Agreement. As of the Effective Date, the approved PD-1 monoclonal antibodies are pembrolizumab, nivolumab, sintilimab and toripalimab.

1.62 " ***Person*** " means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.63 " ***Personal Data*** " has the same meaning as set forth in any applicable Privacy Law.

1.64 " ***Phase I Clinical Trial*** " means a Clinical Trial of a Licensed Product(s) in a small group of human patients focusing on preliminary clinical pharmacology and human safety evaluation tests to observe the tolerance and pharmacokinetics of the Licensed Product(s) to the human body, to provide a basis for formulation of the drug delivery program, as further defined in the Provisions for Drug Registration (□□□□□□□□) in China, as amended from time to time, or the corresponding foreign regulations.

1.65 " ***Phase II Clinical Trial*** " means a Clinical Trial of a Licensed Product(s) in human patients to preliminarily evaluate the therapeutic effect of the Licensed Product(s) for the purpose of preliminarily evaluating the Licensed Product(s)'s therapeutic effect and safety on eligible patients with target indication(s), including providing support for the design and recommended dose for Phase III Clinical Trial, as further defined in the Provisions for Drug Registration (□□□□□ □□□) in China, as amended from time to time , or the corresponding foreign regulations.

1.66 " ***Phase III Clinical Trial*** " means a Clinical Trial of a Licensed Product(s) in human patients to further verify drug therapeutic efficacy and safety on eligible patients with target indication(s), to evaluate overall risk benefit relationship of the drug, and to ultimately provide sufficient evidence for the review of application for market approval of the drug, as further defined in the Provisions for Drug Registration (□□□□□□□□) in China or a foreign equivalence, as amended from time to time, or the corresponding foreign regulations.

1.67 " ***Pivotal Trial*** " means a Clinical Trial of a Licensed Product designed to demonstrate statistically significant clinical efficacy and safety in human patients (in conjunction with performance of a therapeutic procedure) pursuant to a clinical study agreed with the NMPA or another Regulatory Approval, which the NMPA or such other Regulatory Approval accepts as a pivotal clinical trial necessary for Regulatory Approval of such Licensed Product. Pivotal Trial for the purposes of this Agreement includes Phase II Clinical Trials and Phase III Clinical Trials.

1.68 " ***PRC*** " or " ***China*** " means the People's Republic of China, which for the purpose of this Agreement excludes Hong Kong, Macau, and Taiwan.

1.69 " ***Privacy Laws*** " means to the extent applicable, all data protection requirements including to those specified in the United Stated Health Insurance Portability and Accountability Act of 1996, as amended from time to time including the amendments in Subtitle D of the Health Information Technology for Economic and Clinical Health Act (HIPAA); the General Data Protection Regulation 2016/679 of the European Parliament and of the Council (GDPR); the Swiss data protection legislation; the Personal Data (Privacy) Ordinance of Hong Kong (Cap. 486); the PRC Cybersecurity Law; Personal Data Protection Act (Taiwan); Macau Personal Data Protection Law no. 8/2005, and any other applicable data protection privacy legislation in force as amended, extended or replaced from time to time and including any regulations and codes of practice.

1.70 " ***Province*** " means a region, municipality, province in the PRC.

1.71 " ***Processing*** " with respect to Personal Data has the same meaning as set forth in any applicable Privacy Law.

1.72 " ***Region*** " means each of the following administrative regions: (a) the PRC; (b) the Special Administrative Region of Hong Kong ; (c) the Special Administrative Region of Macau; and (d) Taiwan.

1.73 " ***Regulatory Approval*** " means the approval, license or authorization of the applicable Regulatory Authority necessary for the marketing and sale of a product for a particular Indication in a country in the world (including, with respect to Zai Lab Territory, separate pricing or reimbursement approvals whether or not legally required in order to sell the product in such country), and including the approval by the applicable Regulatory Authority of any expansion or modification of the label for such Indication.

1.74 " ***Regulatory Authority*** " means any federal, national, supranational, state, provincial or local regulatory agency, department, bureau or other governmental authority, including, without limitation, the FDA and the NMPA, that has authority over the manufacture, Development, Commercialization or other use or exploitation (including the granting of Regulatory Approval) of any Licensed Product(s) in any applicable regulatory jurisdiction.

1.75 " ***Regulatory Exclusivity Period*** " means, with respect to each Licensed Product in any Region, the period of exclusivity (other than patent exclusivity) granted or afforded by Applicable Law or by any Regulatory Authority within the Region within the Zai Lab Territory that confers exclusive marketing rights with respect to such Licensed Product in such Region or prohibits the use or reference for purposes of obtaining Regulatory Approval of a pharmaceutical or biologic product, without the consent of the holder of the Regulatory Materials, to the clinical and other data that is contained in such materials, and that is not published or publicly available outside of such submission.

1.76 " ***Regulatory Materials*** " means any (a) materials that are/were developed or compiled in for meetings with any Regulatory Authority or for or in support of any applications for Regulatory Approval (at any stage and for any pathway), including all INDs, BLAs, and related submissions, dossiers, and notifications, but excluding the internal notes and memoranda of a Party (b) Regulatory Approvals or other registrations or approvals granted or issued by a Regulatory Authority; in all cases related to the Development, manufacture, market, sale or Commercialization of any Licensed Product(s) in a particular regulatory jurisdiction.

1.77 " ***Right of Reference*** " means the right to allow a Regulatory Authority or a Party to rely upon the Data and other information from Clinical Trials or other Development activities that are in the possession of a Regulatory Authority for the purpose of seeking, obtaining or maintaining Regulatory Approval, including the ability to allow such Regulatory Authority to review the underlying raw data as part of an investigation by such Regulatory Authority, if necessary.

1.78 " ***Segregate*** " means, with respect to any two (2) programs: (a) to restrict and prevent all program-related contacts and communications between personnel (whether employees, consultants, Third Party contractors or otherwise and whether or not located within the Zai Lab Territory (for the purposes of this definition, " ***Personnel*** ")) working on or involved with the development or commercialization of the first program and Personnel working on or involved with the development or

commercialization of the second program; (b) to ensure that Personnel that are working on the first program will not simultaneously work on the second program and vice versa; (c) to ensure that confidential information relating to the first program is not shared with or accessed by Personnel that are working on the second program and vice versa; and (d) from time-to-time, upon the reasonable request of the other Party, to provide information requested relating to the foregoing items (a) through (c), and to reasonably cooperate to enable the other Party to verify that such restrictions are in place and suffi cient to achieve the foregoing . For clarity, the foregoing restrictions will not prevent employees of either Party that are at or above the vice president level from providing high-level oversight of both programs, provided, however, that such employees do not perform day-to-day responsibilities for either program and that such Party ensures such employees understand and comply with their obligations of confidentiality and non-use as set forth herein.

1.79 " ***Subcontractor*** " means a Third Party engaged by Zai Lab for the purpose of conducting clinical Development for Licensed Product(s), contract manufacturing, toxicology testing and other related Development activities, solely at the direction, and on behalf of, Zai Lab and within the scope of the rights licensed to Zai Lab under this Agreement and otherwise in connection with activities of Zai Lab permitted by this Agreement.

1.80 " ***Sublicensee*** " means any Person to which Zai Lab grants a sublicense, directly or indirectly through its Affiliate, under any of the rights granted to Zai Lab under Section 6.1 (License to Zai Lab) in the INCY Technology or INCY Patents.

1.81 " ***Technology*** " means all information, data and knowledge of a technical, scientific, business and other nature, including know-how, inventions, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, specifications, results, Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, quality control data and information, including all information and data related to Clinical Trial designs and protocols, materials, reagents (e.g., plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

1.82 " ***Third Party*** " means any Person other than Zai Lab, INCY, or their respective Affiliates.

1.83 " ***Trademark*** " means any trademark, service mark, trade name, business name, brand name, corporate name, commercial name, logo, slogan or other thing used to identify or distinguish the source or origin of goods or services, including any common law rights, registrations and applications for registration of the foregoing, and any translation, adaptation, derivation and combination of the foregoing.

1.84 " ***Two-Invoice Policy*** " means the policy described in "the Opinion on the Implementation of the ' Two Invoices ' System in the Procurement of Pharmaceutical Products by Public Medical Institutions (trial)" (Guoyigaibanfa [2016] No. 4) , officially released on 9 January 2017 and in any other follow-on, Applicable Law or policies that mandates public hospitals or any other purchaser of drugs in PRC to purchase drugs from the distributor that purchases the drugs directly from the drug manufacturer, limiting the total number of invoices to two.

1.85 " ***United States*** " or " ***U.S.*** " means the United States of America and its territories and possessions (including, without limitation, Puerto Rico).

1.86 " ***Upstream Licenses*** " means all agreements with Third Parties as of the Effective Date pursuant to which INCY has licensed a certain part of the INCY IP from such Third Parties. **Schedule 1.86 (Upstream Licenses)** contains a complete and accurate list of all Upstream Licenses.

1.87 " ***Valid Claim*** " means a claim of (a) an issued patent (in any jurisdiction) that has not expired, lapsed, been permanently cancelled or abandoned, or been dedicated to the public, disclaimed, or held unenforceable, invalid, revoked or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken; or (b) a pending patent application of a patent that has been pending for no more than [***] years since its priority date and has not been finally abandoned or declared unpatentable by an administrative agency of competent jurisdiction (and from which no further appeal can be taken).

1.88 " ***VAT*** " has the meaning set forth in Section 7.14.3 (VAT).

1.89 " ***Zai Lab Patent*** " means each Patent that is Controlled by Zai Lab or its Affiliates as of the Effective Date or at any time during the Term and that Covers (a) the composition of matter, formulation of the Licensed Molecule or the Licensed Product(s); (b) methods or processes directed to the manufacture of the Licensed Molecule or the Licensed Product(s); or (c) methods of use, administration or formulation of a Licensed Molecule or the Licensed Product(s) . Zai Lab Patents include Zai Lab's joint interest in and to any Joint Patents.

1.90 " ***Zai Lab Territory*** " means each of the Regions.

Additional Definitions. The following table identifies the location of definitions set forth in various Sections of the Agreement:

Defined Terms	Section
Acquirer	4.10.1(b)
Additional Amounts	6.7
Additional Tax	7.14.2
After-Acquired IP	6.7
Agreement	Preamble
Agreement Inventions	5.1.1
Agreement Works	5.1.2
Audited Party	7.11

Auditing Party	7.11
Clinical Supply Agreement	3.3
Combination Licensed Product	Definition of Licensed Product
Commercial Supply Agreement	4.3
Common Interest Agreement	5.5
Competing [***]	4.10.1
Competitive Product Infringement	5.4.3(b)
Core Data Sheet	3.15
CS CMO	4.4
CTA	Definition of IND
Data Processing Agreement	8.8
Development Milestone	7.2.1(a)
Development Plan	3.4
Disclosing Party	8.1
Effective Date	Preamble
Excluded Claim	12.4
Force Majeure	13.3
Global Safety Database	3.14
Gross Sales	Definition of Net Sales
ICC	12.3
INCY	Preamble
INCY Collaboration Study	3.11.1
INCY Pipeline Combination Regimen	Definition of Licensed Product(s)
INCY Post-Termination Clinical Trial	9.3.2(c)9.3.2(b)
Joint Collaboration Study	3.11.3
Joint Development Committee or JDC	2.7
Joint Inventions	5.1.1
Joint [***] Collaboration Study	3.11.4
Joint Patents	5.1.1
Joint Steering Committee or JSC	2.1
[***]	Definition of Licensed Product(s)
[***] Period	4.7.1
Net Sales Deductions	Definition of Net Sales
New CMO	4.4.2
Packaging CMO	4.5
Partner	Definition of Partner License Agreement
Party or Parties	Preamble
Payee	7.14.1
Payor	7.14.1
Personnel	Definition of Segregate
Pharmacovigilance Agreement	3.14
Quarterly Royalty Report	7.9.2
Receiving Party	8.1

Remedial Action	3.16
Representatives	8.1
Rolling Forecast	3.3
Royalty Term	7.3.2
Sales-Based Milestone	7.2.2(a)
Sponsor	8.6
Supply Notice	9.1.3
Surviving License	9.3.1(a)
Term	9.1
Third Party Claims	11.1
Trade Taxes	Definition of Net Sales
Zai Lab	Preamble
[***]	Definition of Licensed Product(s)
Zai Lab Collaboration Study	3.11.2
Zai Lab Trademarks	5.6.1

Schedule 1.38

INCY Patents as of the Effective Date

1) [***]

2) [***]

Schedule 1.42

INCY Technology as of the Effective Date

[***]

Schedule 1.47

Structure of Licensed Molecule

[***]

Schedule 1.86

Upstream Licenses

[***]

Schedule 3.1

INCY Technology

[***]

Schedule 3.4

Development Plan

[***]

Schedule 3.11.1

INCY Collaboration Studies Underway

[***]

Schedule 3.11.4

Joint [***] Collaboration Study

[***]

Schedule 4.4.1

Manufacturer Criteria

[***]

Schedule 4.8

Co-Promotion Plan

[***]

Schedule 6.6

Partner Terms and Conditions

[***]

Schedule 8.7

Joint Press Release

See Attachment to **Schedule 8.7 (Joint Press Release)**

Schedule 10.3

Compliance

[***]

Exhibit 10.28

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (" **Agreement** ") is made and entered into as of June 3, 2019 (the " **Effective Date** "), by and between Zai Lab (US) LLC (the " **Company** "), and **Valeria Rosa Fantin** (the " **Employee** ").

RECITALS

The Company and its Affiliates are engaged in the business of researching, developing, manufacturing, commercialization of drug products in the pharmaceutical industry, including without limitation the sales and marketing of both small molecule and large molecule therapeutics (the "Business Of The Group"), and the Employee is qualified to engage in providing services in support of the Business Of The Group as contemplated under this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the promises and the respective covenants and agreements of the parties, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **EMPLOYMENT** . From the Effective Date, the Company agrees to continue the employment of the Employee and the Employee agrees to continue employment with the Company. The period beginning on the Effective Date and ending on the date the Employee's employment under this Agreement is terminated is referred to herein as the " **Employment Period** ".

1.1 Employment by Company . The Company agrees to employ the Employee as the **Chief Scientific Officer** of the Company. In addition, the Employee shall serve as the Chief Scientific Officer of Zai Lab Limited, a limited company incorporated under the laws of the Cayman Islands and the ultimate parent corporation of the Company (the " **Parent Company** ") without further compensation. The Employee agrees to render such services and to perform such duties and responsibilities as are normally associated with and inherent in the aforementioned roles and the capacities in which the Employee is employed, as well as such other duties and responsibilities as shall from time to time be assigned to the Employee by the Chief Executive Officer of the Company or such person's designee.

1.2 Acceptance of Employment . The Employee accepts such employment set out in Section 1.1 and agrees to faithfully perform and render the services required of the Employee under this Agreement. Except for reasonable vacations, absences due to temporary illness, and activities that may be mutually agreed to by the parties, the Employee shall devote his entire time, attention and energies during normal business hours and such evenings and weekends as may be reasonably required for the discharge of his duties to the Business of The Group, and the performance of the Employee's duties and responsibilities under this Agreement.

1.3 Positions with Affiliates . If requested by the Company, the Employee agrees to serve without additional compensation if elected, nominated or appointed as an officer and/or director of the Company, the Parent Company and any of the subsidiaries or affiliates of the Company or the Parent Company (collectively, " Affiliates ") and in one or more executive offices of any of the Affiliates.

1.4 Conflicts of Interest . The Employee has reviewed with the board of directors of Zai Lab Limited (the " **Board** ") the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Employee or his/her associate(s) in all such business organizations or arrangements which may be directly competitive or directly in conflict with the Company or the Parent Company. The Employee agrees to review with the Board any potential directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles with business organizations or arrangements which may be directly competitive or directly in conflict with the Company or the Parent Company. The Employee or his/her associate(s) is precluded from owning an interest (legal and beneficial, direct and indirect) in another company or serving as an employee, director, consultant, advisor or member of such another company that may be directly competitive or directly in conflict with the Company or the Parent Company until such interest is presented to the Board and the Board consents to such interest or employment.

2. **PLACE OF PERFORMANCE** . The Employee shall be based in San Francisco. The Company or the Parent Company may require that the Employee travel in furtherance of the Business of the Group, to the extent necessary and/or substantially consistent with the then present business travel obligations of employees at substantially the same service level as the Employee.

3. **COMPENSATION BENEFITS AND EXPENSE REIMBURSEMENTS** .

3.1 Base Salary . In consideration for the agreement of the Employee to be employed under this Agreement, during the Employment Period, the Employee shall receive from the Company an annual base salary (" **Base Salary** ") of US$380,000. This Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service organization. The Base Salary to be paid to the Employee will be subject to reduction for payroll tax withholdings legally required (if any) or such other reductions properly and reasonably requested by the Employee. The Company (or human resources service organization, as applicable) shall pay such Base Salary in accordance with its standard payroll procedures. The Employee's Base Salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices.

3.2 Equity Incentives .

3.2.1 Stock Options . Subject to the approval of the Board (or the compensation committee thereof), the Employee shall, as soon as practicable following the Employee's commencement of employment with the Company, be granted an option to purchase 200,000 American Depositary Shares (" **ADSs** ") representing ordinary shares of the Parent Company (the " **Option** ") with an exercise price equal to the fair market value of an ADS on the date of grant in accordance with the Zai Lab Limited 2017 Equity Incentive Plan (as it may be amended from

time to time, the " **Plan** "). The Option shall vest in accordance with the standard vesting schedule applicable to options granted by the Parent Company, as determined from time to time, subject to the Employee continuing to provide services to the Company under this Agreement on the date of grant of the Option and through each applicable vesting date and to no notice of termination of employment having been tendered through each applicable date. The Option will be subject to the terms, definitions and provisions of the Plan and the stock option agreement to be entered into by and between the Employee and the Parent Company.

3.2.2 Restricted Share Unit . Subject to the approval of the Board (or the compensation committee thereof), the Employee shall, as soon as practicable following the Employee's commencement of employment with the Company, be granted 50,000 ADSs representing ordinary shares of the Parent Company (the " **Restricted Share Unit** "), which shall vest in accordance with the standard vesting schedule applicable to restricted share units granted by the Parent Company, as determined from time to time, subject to the Employee continuing to provide services to the Company under this Agreement on the date of grant of the Restricted Share Unit and through each applicable vesting date and to no notice of termination of employment having been tendered through each applicable date. The Restricted Share Unit will be subject to the terms, definitions and provisions of the Plan and the restricted share units award agreement to be entered by and between the Employee and the Parent Company.

3.3 Bonuses .

3.3.1 Annual Bonus . At the conclusion of each calendar year during the Employment Period, the Employee may be eligible to receive an annual bonus with a target equal to 35% of the Base Salary (the " **Target Bonus** "), the amount of which shall be determined by the Board or the Compensation Committee in its discretion. Any annual bonus earned hereunder shall be paid not later than March 15th following the end of the calendar year to which it relates and otherwise in accordance with the Company's bonus plan as in effect from time to time. In order to receive any such bonus, the Employee must be employed through the date that such bonus is paid.

3.3.2 Sign-on Bonus . The Employee will be entitled to receive a cash payment of US$80,000 (the " **Sign-On Bonus** ") on the seven-month anniversary of his continuous employment with the Company, provided that the Employee remains employed with the Company on the date of such anniversary. The Company will withhold all applicable income taxes on such amount, and will pay the net amount to the Employee with the regularly scheduled payroll for such month of payment. In the event that the employee's employment is terminated by the Company for cause within the three (3) year period following the Effective Date, the Employee will repay to the Company the full amount of the Sign-On Bonus within thirty (30) days following the date of termination. In the event that the Employee resigns from the Company or the employment is terminated by the Company without cause prior to the third anniversary of the Effective Date, she will repay to the Company a prorated portion of the Sign-On Bonus based on the number of full and partial months remaining in such three (3) year period as of the date of such termination of employment, with such repayment being made on or prior to the employee's last working day with the Company.

3.4 Fringe Benefits . During the Employment Period, the Employee will be eligible to receive the fringe benefits that are made available to employees of the Company and such other benefits as are determined by the Board or the Compensation Committee of the Board, in its respective discretion. Any benefit plan participation will be subject to the terms and conditions of the applicable plan, applicable Company policy and applicable law.

3.5 Reimbursements . During the Employment Period, the Employee will be reimbursed, in accordance with the practice applicable to employees of the Company from time to time, for all reasonable traveling expenses and other disbursements incurred by her for or on behalf of the Company in the performance of her duties hereunder upon presentation by the Employee of appropriate vouchers. The Employee's right to payment or reimbursement for business expenses hereunder shall be subject to the following additional rules: (i) the amount of expenses eligible for payment or reimbursement during any calendar year shall not affect the expenses eligible for payment or reimbursement in any other calendar year, (ii) payment or reimbursement shall be made by the Company as soon as reasonably practicable following the time that the applicable expense is submitted by the Employee to the Company and in no event later than December 31 of the calendar year following the calendar year in which the expense or payment was incurred, and (iii) the right to payment or reimbursement shall not be subject to liquidation or exchange for any other benefit.

3.6 Deductions . Recognizing that the Employee is an employee for all purposes, the Company shall deduct from any compensation payable to the Employee the sums which the Company is required by law to deduct, including, but not limited to, government state withholding taxes, social security taxes and state disability insurance and mandatory provident funds, and the Company shall pay any amounts so deducted to the applicable governmental entities and agents entitled to receive such payments.

4. **INVOLUNTARY TERMINATION** .

4.1 Disability . If the Employee dies, then the Employee's employment by the Company hereunder shall automatically terminate on the date of the Employee's death. If the Employee is incapacitated or disabled by accident, sickness or otherwise so as to render her mentally or physically incapable of performing the services required to be performed by her under this Agreement for a period of ninety (90) consecutive days or longer, or for any ninety (90) days during any six (6) month period (such condition being herein referred to as " **Disability** "), the Company, at its option, may terminate the Employee's employment under this Agreement immediately upon giving her notice to that effect. In the case of a Disability, until the Employee becomes eligible for disability income under the Company's disability income insurance (if any) or until the Company shall have terminated the Employee's service in accordance with the foregoing, whichever shall first occur, to the extent permitted by the terms of the Company's plans, the Employee will be entitled to receive compensation, at the rate and in the manner provided in Section 3 , notwithstanding any such physical or mental disability. Termination pursuant to this Section 4 is hereinafter referred to as an " **Involuntary Termination** ".

4.2 Substitution . The Board or its designee may designate another employee to act in the Employee's place during any period of Disability suffered by the Employee during the Employment Period. Notwithstanding any such designation, the Employee shall continue to receive the Employee's Base Salary and benefits in accordance with Section 3 of this Agreement until the Employee becomes eligible for disability income under the Company's disability income insurance (if any) or until the termination of the Employee's employment, whichever shall first occur.

4.3 Disability Income Payments . While receiving disability income payments under the Company's disability income insurance (if any), the Employee shall not be entitled to receive any Base Salary under Section 3.1 , but shall continue to participate in all other compensation and benefits in accordance with Sections 3.3 until the date of the Employee's termination of employment.

4.4 Verification of Disability . If any question shall arise as to whether during any period the Employee is disabled through any illness, injury, accident or condition of either a physical or psychological nature so as to be unable to perform substantially all of the Employee's duties and responsibilities hereunder, the Employee may, and at the request of the Company shall, submit to a medical examination by a physician selected by the Company to whom the Employee or the Employee's guardian has no reasonable objection to determine whether the Employee is so disabled and such determination shall for the purposes of this Agreement be conclusive of the issue. If such question shall arise and the Employee shall fail to submit to such medical examination, the Company's determination of the issue shall be binding on the Employee.

5. **TERMINATION FOR CAUSE BY THE COMPANY** . The Company may terminate the employment of the Employee hereunder at any time during the Employment Period for "Cause" (such termination being hereinafter referred to as a " **Termination for Cause** ") by giving the Employee notice of such termination, upon the giving of which such termination shall take effect immediately. For the purpose of this Section 5 , " **Cause** " means any one of the following grounds, as determined by the Board in its reasonable judgment:

(i) the Employee's drunkenness or use of illegal drugs which interferes with the performance of the Employee's obligations and duties to the Company or any of its Affiliates;

(ii) the Employee's commission of a felony, or any crime involving fraud, moral turpitude or misrepresentation or violation of applicable securities laws;

(iii) mismanagement by the Employee of the business and affairs of the Company or any Affiliate of the Company which results or could reasonably be expected to result in a material loss to the Company or any of its Affiliates;

(iv) the Employee's violation of any confidentiality, non-competition, non-solicitation, no-hire or other restrictive covenant set forth in this Agreement, the Compliance Agreement (as defined below) or any other agreement between the Employee and the Company or any of its Affiliates or any material policy of the Company or any of its Affiliates; or

(v) the Employee's material failure to perform or substantial negligence in the performance of the Employee's obligations and duties to the Company or any of its Affiliates, or any misconduct, dishonesty or acts of moral turpitude by the Employee which is or could reasonably be expected to be materially detrimental to the interests and well-being of the Company or any of its Affiliates, including, without limitation, harm to its business or reputation.

6. **TERMINATION WITHOUT CAUSE BY THE COMPANY** . The Company may terminate the employment of the Employee hereunder at any time during the Employment Period without "Cause" (such termination being hereinafter called a " **Termination Without Cause** ") by giving the Employee notice of such termination.

7. **TERMINATION BY THE EMPLOYEE** .

7.1 Without Good Reason . The Employee may terminate her services hereunder at any time without Good Reason (as defined below) (such termination being referred to hereinafter as a " **Voluntary Termination** ". A Voluntary Termination will be deemed to be effective following reasonable notice by the Employee of not less than thirty (30) calendar days, provided that the Company may elect to waive all or any portion of such notice period.

7.2 With Good Reason . The Employee may terminate her services hereunder at any time for Good Reason (as defined below) by giving the Company written notice of such termination, provided that such notice specifies: (i) the basis for termination and (ii) the effective date of termination, which shall be no later than thirty (30) days after the date such notice is provided to the Company, provided that the Company may unilaterally select an earlier effective date (such termination being hereinafter referred to as a " **Termination for Good Reason** "). For purposes of this Agreement, the term " **Good Reason** " shall mean (a) any material diminution of the Employee's duties or responsibilities hereunder (except in each case in connection with the Termination for Cause or pursuant to Section 4.1) or the assignment to the Employee of duties or responsibilities that are materially inconsistent with the Employee's then-current position, provided that the Company has not cured such material diminution or materially inconsistent assignment within ten (10) business days after written notice thereof is given to the Company; (b) any material breach of the Agreement by the Company which is not cured within ten (10) business days after written notice thereof is given to the Company; or (c) an unconsented-to relocation of the Employee from the place of initial assignment of the Employee by the Company to a location more than thirty (30) kilometers from such location, other than on a temporary basis not to exceed a period equal to six (6) consecutive calendar months.

8. **EFFECT OF TERMINATION ON SERVICES** .

8.1 Voluntary Termination or a Termination for Cause .

8.1.1 Upon the termination of the Employee's employment hereunder pursuant to a Voluntary Termination or a Termination for Cause, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company or any of its Affiliates under this Agreement except to receive the following (in the aggregate, the " **Final Compensation** "):

(i) the unpaid portion of the Base Salary provided for in Section 3.1 , computed on a *pro rata* basis up to (and including) the effective date of such termination;

(ii) and reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 3.5 , provided that the Employee submits all such expenses and required supporting documentation within sixty (60) days of the effective date of such termination; and

(iii) if required by applicable law or Company policy, pay at the rate of the Base Salary for any accrued by unused vacation time as of the effective date of such termination.

8.1.2 Final Compensation (other than expense reimbursement, which shall be paid within thirty (30) days after such reimbursement is submitted in accordance with subsection (ii) above) will be paid to the Employee within thirty (30) days following the date of termination (or such shorter period required by law).

8.2 Involuntary Termination . Upon the termination of the Employee's employment hereunder pursuant to an Involuntary Termination in accordance with Section 4 hereof, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company, or any of its Affiliates under this Agreement except to receive:

(i) Final Compensation in accordance with Section 8.1 ;

(ii) an aggregate amount equal to one (1) month's Base Salary; and

(iii) an amount equal to one (1) month of the Company's portion of monthly premiums for health, dental and vision insurance benefits as in effect for the Employee immediately prior to the effective date of such termination, payable in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 3.1 and 3.4 hereof, plus any additional compensation as may be expressly required under applicable law.

8.3 Termination Without Cause or Termination for Good Reason .

8.3.1 Upon the termination of the Employee's employment hereunder pursuant to a Termination Without Cause or a Termination for Good Reason, neither the Employee nor her beneficiary or estate will have any further rights or claims against the Company or any of its Affiliates under this Agreement except to receive the following (in the aggregate, the " **Severance Payments** "):

(i) Final Compensation in accordance with Section 8.1 ;

(ii) an aggregate amount equal to the Base Salary (i) for six (6) months if such termination occurs prior to the third (3r d) anniversary of the Effective Date, or (ii) for twelve (12) months if such termination occurs on or following the third (3 r d) anniversary of the Effective Date, (in either case, such six (6) months or twelve (12) months, the " **Severance Period** "), payable from the effective date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 3.1 and 3.4 hereof, plus any additional compensation as may be expressly required under applicable law; and

(iii) an aggregate amount equal to the Company's portion of monthly premiums for health, dental and vision insurance benefits as in effect for the Employee immediately prior to the effective date of such termination (i) for six (6) months if such termination occurs prior to the third (3 rd) anniversary of the Effective Date, or (ii) for twelve (12) months if such termination occurs on or following the third (3 rd) anniversary of the Effective Date, (in either case, such six (6) months or twelve (12) months, the " **Severance Period** "), payable from the effective date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 3.1 and 3.4 hereof, plus any additional compensation as may be expressly required under applicable law.

8.3.2 Subject to Sections 8.5 , 14 and 15 , Severance Payments (other than Final Compensation) will be provided in the form of salary continuation, payable in equal installments in accordance with the Company's normal payroll practices, during the Severance Period, provided that the first such payment will be made on the next regular pay day following the date on which the Release of Claims (as defined below) becomes effective and irrevocable and will be retroactive to effective date of the termination of the Employee's employment.

8.4 Change in Control Termination .

8.4.1 Upon the termination of the Employee's employment hereunder pursuant to a Termination Without Cause or a Termination for Good Reason within twelve (12) months following a Change in Control (such termination being referred to in this Agreement as a " **Change in Control Termination** "), neither the Employee nor her beneficiary or estate will

have any further rights or claims against the Company or any Affiliates under this Agreement except to receive the following (in the aggregate, the " **Enhanced Severance Payments** "):

(i) Final Compensation in accordance with Section 8.1 ;

(ii) an aggregate amount equal to twelve (12) months' Base Salary;

(iii) an aggregate amount equal to twelve (12) months of the Company's portion of monthly premiums for health, dental and vision insurance benefits as in effect for the Employee immediately prior to the effective date of such termination, payable in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 3.1 and 3.4 hereof, plus any additional compensation as may be expressly required under applicable law; and

(iv) a payment equal to pro-rated Target Bonus for the year of such employment termination (determined by multiplying the Target Bonus by a fraction, the numerator of which is the number of days during the fiscal year of termination that Employee is employed by the Company and the denominator of which is three hundred and sixty-five (365)), payable at the same time bonuses for such year are paid to other senior executives of the Company (the " **Pro-rated Bonus** ").

8.4.2 Subject to Section 8.5 , 14 and 15 , Enhanced Severance Payments (other than Final Compensation) will be provided in the form of salary continuation, payable in equal installments in accordance with the Company's normal payroll practices, during the twelve (12) month period following the Change in Control Termination, provided that the first such payment will be made on the next regular pay day following the date on which the Release of Claims becomes effective and irrevocable and will be retroactive to effective date of the termination of the Employee's employment.

8.4.3 Notwithstanding anything to the contrary in any agreement between the Employee and the Company, upon a Change in Control Termination, the Employee will be entitled to one hundred percent (100%) accelerated vesting of any then-outstanding unvested stock options, restricted stock or other equity awards granted to the Employee by the Parent Company, subject to Section 8.5 , 14 and 15 .

8.4.4 For purposes of this Agreement, " **Change in Control** " means the occurrence of any of the following:

(i) any one person, or more than one person acting as a group (" **Person** "), acquires ownership of the stock of the Parent Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Parent Company, except that any change in the ownership of the stock of the Parent Company as a result of a private financing of the Parent Company that is approved by the Board will not be considered a Change in Control;

(ii) a majority of members of the Board is replaced during any twelve- (12-) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election; or

(iii) any Person acquires (or has acquired during the twelve- (12-) month period ending on the date of the most recent acquisition by such person or persons) assets from the Parent Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Parent Company immediately prior to such acquisition or acquisitions. For purposes of this subsection (iii), gross fair market value means the value of the assets of the Parent Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Parent Company. Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to re-domicile the Parent Company in a jurisdiction other than its original jurisdiction of incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the Persons who held the Parent Company's securities immediately before such transaction.

8.4.5 Liquidated Damages . The parties acknowledge and agree that damages which will result to the Employee for a Termination Without Cause or other breach of this Agreement by the Company shall be extremely difficult or impossible to establish or prove, and agree that the Severance Payments and Enhanced Severance Payments shall constitute liquidated damages for any breach of this Agreement by the Company through the date of termination. The Employee agrees that, except for such other payments and benefits to which the Employee may be eligible as expressly provided by the terms of this Agreement or any applicable benefit plan, such liquidated damages shall be in lieu of all other claims that the Employee may make by reason of termination of her/his employment or any such breach of this Agreement and that, as a condition to receiving the Severance Payments and/or Enhanced Severance Payments (as applicable), the Employee will execute the Release of Claims.

8.5 Release . The obligation of the Company to make any payments and benefits (other than Final Compensation) to or on behalf of the Employee under Sections 8.2 , 8.3 and 8.4 is conditioned on the Employee signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the " **Release of Claims** ") and provided that the Release of Claims becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the " **Release Deadline** "). If the Release of Claims does not become effective by the Release Deadline, the Employee will forfeit any rights to severance or benefits (other than Final Compensation) under this Agreement. In no event will Severance Payments, Enhanced Severance Payments or benefits (other than Final Compensation) be paid or provided until the Release of Claims becomes effective and irrevocable.

9. **COMPLIANCE AGREEMENT** . The Employee agrees that the Compliance Agreement (as defined in the Existing Agreement) remains in full force and effect, and the terms and conditions thereof are specifically incorporated herein by reference. The obligation of the Company to make any payments (other than Final Compensation) to or on behalf of the Employee under Section 8.3 or Section 8.4 above, and the Employee's right to retain the same, is expressly conditioned upon the Employee's continued performance of the Employee's obligations under the Compliance Agreement.

10. **STANDARDS OF CONDUCT** . The Employee will conduct herself in an ethical and professional manner at all times and in accordance with any Employee policies or guidelines which the Company may issue from time to time.

11. **REPRESENTATIONS AND WARRANTIES OF THE EMPLOYEE** . The Employee represents and warrants to the Company that: (i) the Employee has the proper skill, training and background so as to be able to perform under the terms of this Agreement in a competent and professional manner; (ii) the Employee will not infringe any intellectual property rights including patent, copyright, trademark, trade secret or other proprietary right of any person; (iii) the Employee will not use any trade secrets or confidential information owned by any third party and (iv) the Employee's signing of this Agreement and the performance of the Employee's obligations under it will not breach or be in conflict with any other agreement to which the Employee is a party or is bound, and the Employee is not now subject to any covenants against competition or similar covenants or any court order that could affect the performance of the Employee's obligations under this Agreement.

12. **ENFORCEMENT** . It is the desire and intent of the parties hereto that the provisions of this Agreement will be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, to the extent that a restriction contained in this Agreement is more restrictive than permitted by the laws of any jurisdiction whose law may be deemed to govern the review and interpretation of this Agreement, the terms of such restriction, for the purpose only of the operation of such restriction in such jurisdiction, will be the maximum restriction allowed by the laws of such jurisdiction and such restriction will be deemed to have been revised accordingly herein. A court having jurisdiction over an action arising out of or seeking enforcement of any restriction contained in this Agreement may modify the terms of such restriction in accordance with this Section 12.

13. **COVENANT AGAINST ASSIGNMENT** . The Employee may not assign any rights or delegate any of the duties of the Employee under this Agreement. As used in this provision, "assignment" and "delegation" shall mean any sale, gift, pledge, hypothecation, encumbrance, or other transfer of all or any portion of the rights, obligations, or liabilities in or arising from this Agreement to any person or entity, whether by operation of law or otherwise, and regardless of the legal form of the transaction in which the attempted transfer occurs.

14. **TIMING OF PAYMENTS AND SECTION 409A** .

14.1 Notwithstanding anything to the contrary in this Agreement, if at the time that the Employee's employment terminates, the Employee is a "specified employee," as defined below, any and all amounts payable under this Agreement on account of such separation from service

that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next business day following the expiration of such six- (6-) month period or, if earlier, upon the Employee's death; except (i) to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury regulation Section 1.409A-1(b) (including without limitation by reason of the safe harbor set forth in Section 1.409A-1(b)(9)(iii), as determined by the Company in its reasonable good faith discretion); (ii) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (iii) other amounts or benefits that are not subject to the requirements of Section 409A (" **Section 409A** ") of the Internal Revenue Code of 1986, as amended (the " **Code** ").

14.2 For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a "separation from service" (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term "specified employee" means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

14.3 Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

14.4 In no event shall the Company or any of its Affiliates have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

15. **LIMITATIONS ON PAYMENTS** . Notwithstanding anything in this Agreement or elsewhere to the contrary, in the event that any payment or benefit received or to be received by the Employee under this Agreement or otherwise (collectively, the " **Payments** ") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section 15 , be subject to the excise tax imposed by Section 4999 of the Code, then the Payments shall be reduced (but not below zero) to the extent, but only to the extent, needed to ensure that no portion of the Payments constitutes a "parachute payment" within the meaning of Section 280G of the Code; provided, that no reduction in the Payments shall be made by reason of this Section 15 unless, on an after-tax basis taking into account the excise tax imposed by Section 4999 of the Code together with all applicable income taxes, the Payments payable to the Employee would be greater than if such reduction had not been made. Any reduction in the Payments required by the immediately preceding sentence shall be applied, first, against any cash severance payments, then against other payments and benefits to which Q&A 24(c) of Section 1.280G-1 of the Treasury Regulations does not apply, and finally against all remaining payments and benefits.

16. **MISCELLANEOUS** .

16.1 Notices . Any notice, request, demand or other communication required or permitted to be given to a party pursuant to the provisions of this Agreement will be in writing and will be effective and deemed given under this Agreement on the earliest of: (i) the date of personal delivery, (ii) the date of transmission by facsimile or e-mail, with confirmed

transmission and receipt, (iii) two (2) days after deposit with an internationally-recognized courier or overnight service such as Federal Express, DHL, or (iv) five (5) days after mailing via certified mail, return receipt requested. All notices not delivered personally or by facsimile will be sent with postage and other charges prepaid and properly addressed to the party to be notified at the address set forth on the signature pages hereto.

16.2 Gender; Time . The parties agree that any use of words in any gender in this Agreement shall also refer to the masculine, feminine or neuter gender, as the case may require. Time is of the essence in performance of the rights and obligations under this Agreement.

16.3 Survival . Provisions of this Agreement shall survive any termination of employment if so provided in this Agreement or if necessary or desirable to accomplish the purposes of other surviving provisions.

16.4 Binding Agreement; Benefit. The provisions of this Agreement will be binding upon and will inure to the benefit of the respective heirs, legal representatives and successors of the parties hereto.

16.5 Governing Law . This Agreement will be governed by, and construed and enforced in accordance with, the laws of California, without giving effect to its principles or rules of conflict laws to the extent such principles or rules would require or permit the application of the laws of another jurisdiction.

16.6 Waiver of Breach . The waiver by either party of a breach of any provision of this Agreement by the other party must be in writing and will not operate or be construed as a waiver of any subsequent breach by such other party.

16.7 Entire Agreement; Amendments . This Agreement, together with the Compliance Agreement, contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements (including the Existing Agreement) or understanding among the parties with respect thereto. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

16.8 Headings . The Section headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

16.9 Severability . Subject to the provisions of Section 12 above, any provision of this Agreement that is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction.

16.10 Assignment . This Agreement is personal in its nature and the parties hereto shall not, without the consent of the other party hereto, assign or transfer this Agreement or any rights or obligations hereunder, provided, however, that the rights and obligations of the Company hereunder shall be assignable and delegable without the Employee's consent to any of its Affiliates or in connection with any subsequent merger, consolidation, sale of all or substantially all of the assets or shares of the Company or similar transaction involving the Company or a successor corporation.

16.11 Confidentiality . The Employee agrees not to disclose this Agreement or its terms to any person or entity, other than the Employee's agents, advisors or representatives, except as consented to by the Company in writing or as may be required by law.

16.12 Further Assurances . The Employee agrees to execute, acknowledge, seal and deliver such further assurances, documents, applications, agreements and instruments, and to take such further actions, as the Company may reasonably request in order to accomplish the purposes of this Agreement.

16.13 Costs . Each of the parties shall pay all costs and expenses incurred or to be incurred by such party in negotiating and preparing this Agreement and in closing and carrying out the transactions contemplated by this Agreement.

16.14 Counterparts . The parties may execute this Agreement in any number of counterparts and, as so delivered, the counterparts shall together constitute one and the same document. The parties agree that each such counterpart is an original and shall be binding upon all of the parties, even though all of the parties are not signatories to the same counterpart.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

COMPANY:

By: /s/ Samantha Du
Print Name: Samantha Du
Title: Chairperson and CEO

Address:

Facsimile:
E-mail:

EMPLOYEE:

/s/ Valeria Rosa Fantin
Valeria Rosa Fantin

Address:

E-mail:

Exhibit 12.1

Certification by the Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Samantha Du, certify that:

1. I have reviewed this annual report on Form 20-F of Zai Lab Limited (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition and results of operations of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I:

(a) are responsible for establishing and maintaining internal controls;

(b) have designed such internal controls to ensure that material information relating to the Company and its consolidated subsidiaries is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(c) have evaluated the effectiveness of the Company internal controls as of a date within 90 days prior to this report; and

(d) have presented in this report our conclusions about the effectiveness of our internal controls based on our evaluation as of that date; and

5. The Company's other certifying officer and I have disclosed to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize, and report financial data and have identified for the Company's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls; and

6. The Company's other certifying officer and I have indicated in this report whether or not there were significant changes in internal controls or in other factors that could significantly

affect internal controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses .

Date: April 29, 2020

By: /s/ Samantha Du
Samantha Du
Chief Executive Officer

Exhibit 12.2

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Billy Cho, certify that:

1. I have reviewed this annual report on Form 20-F of Zai Lab Limited (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition and results of operations of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I:

(a) are responsible for establishing and maintaining internal controls;

(b) have designed such internal controls to ensure that material information relating to the Company and its consolidated subsidiaries is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(c) have evaluated the effectiveness of the Company internal controls as of a date within 90 days prior to this report; and

(d) have presented in this report our conclusions about the effectiveness of our internal controls based on our evaluation as of that date; and

5. The Company's other certifying officer and I have disclosed to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize, and report financial data and have identified for the Company's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls; and

6. The Company's other certifying officer and I have indicated in this report whether or not there were significant changes in internal controls or in other factors that could significantly

affect internal controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses .

Date: April 29, 2020

By: /s/ Billy Cho
Billy Cho
Chief Financial Officer

Exhibit 13.1

Certification by the Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the annual report of Zai Lab Limited (the "Company") on Form 20-F for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2020

By: /s/ Samantha Du
Samantha Du
Chief Executive Officer

Exhibit 13.2

Certification by the Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the annual report of Zai Lab Limited (the "Company") on Form 20-F for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2020

By: /s/ Billy Cho
Billy Cho
Chief Financial Officer

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements No. 333-221616 on Form S-8 of our reports dated April 29, 2020, relating to the financial statements of Zai Lab Limited and the effectiveness of Zai Lab Limited's internal control over financial reporting, appearing in this Annual Report on Form 20-F for the year ended December 31, 2019.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China
April 29, 2020

Exhibit 23.2

中倫律師事務所
ZHONG LUN LAW FIRM
上海市浦东新区世纪大道 8 号国金中心二期 10-11 层 邮政编码：200120
Level 10 & 11, Two IFC, No. 8 Century Avenue, Pudong New Area, Shanghai 200120, PRC
电话/Tel: (8621)6061 3666 传真/Fax: (8621)6061 3555
网址：www.zhonglun.com

CONSENT LETTER

To Zai Lab Limited
4560 Jinke Road, Bldg. 1, Fourth Floor
Pudong, Shanghai 201210
People's Republic of China

April 29, 2020

Dear Sir/Madam:

We hereby consent to the reference of our name under the headings "Item 6.B. Directors, Senior Management and Employees—Compensation—Employment Arrangements with Our Executive Officers—Employment Agreements with Executive Officers at Zai Lab (Shanghai) Co., Ltd." in Zai Lab Limited's Annual Report on Form 20-F for the year ended December 31, 2019 (the " **Annual Report** "), which will be filed with the Securities and Exchange Commission (the " **SEC** ") in the month of April 2019. We also consent to the filing of this consent letter with the SEC as an exhibit to the Annual Report.

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, or under the Securities Exchange Act of 1934, in each case, as amended, or the regulations promulgated thereunder.

Very truly yours,

/s/ Zhong Lun Law Firm

Zhong Lun Law Firm