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, 2018

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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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	Name of each exchange on which registered
American depositary shares, each representing one ordinary share, par value $0.00006 per share	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:

58,355,903 ordinary shares were issued and outstanding as of December 31, 2018

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 再鼎医药. 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 preclinical studies and clinical trials, and our research and development programs;
- the ability of our drug candidates to be granted or maintain Category 1 designation with the State Drug Administration, or SDA (formerly known as the CFDA, China Food and Drug Administration), and to receive a faster development, review or approval process;
- 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, 2018, 2017 and 2016 and the selected balance sheet data as of December 31, 2018 and 2017 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,		
	2018	2017	2016
	(in thousands, except share and per share data)		
Revenue	129	—	—
Cost of sales	(43)	—	—
Gross profit	86	—	—
Research and development expenses	$ (120,278)	$ (39,342)	$ (32,149)
Selling, general and administrative expenses	(21,576)	(12,049)	(6,380)
Loss from operations	(141,768)	(51,391)	(38,529)
Interest income	3,261	527	403
Interest expense	(40)	—	—
Changes in fair value of warrants	—	200	(1,920)
Other income	1,968	933	2,534
Other expense	(1,909)	(403)	—
Loss before income taxes and share of loss from equity method investment	$ (138,488)	$ (50,134)	$ (37,512)
Income tax expense	—	—	—
Share of loss from equity method investment	(587)	(250)	—
Net loss	$ (139,075)	$ (50,384)	$ (37,512)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted (1)	52,609,810	21,752,757	9,439,028
Net loss per share, basic and diluted (1)	(2.64)	(2.32)	(3.97)

(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,	
	2018	2017
	(in thousands)	
Consolidated balance sheet data:		
Cash and cash equivalents	$ 62,952	$ 229,660
Short-term investments (1)	$ 200,350	—
Total assets	$ 301,987	$ 249,634
Total shareholders' equity	$ 251,082	$ 235,171
Total current liabilities	$ 48,841	$ 12,069
Total non-current liabilities	$ 2,064	$ 2,394

(1) The short-term investment primarily comprises 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. The China National Medical Products Administration, or NMPA, also accepted our New Drug Application, or NDA, for ZEJULA in December 2018. In December 2018, we also announced the launch of Optune (Tumor Treating Fields, or TTFields) for the treatment of glioblastoma multiforme, or GBM, in Hong Kong. Although we have launched ZEJULA and Optune in Hong Kong, 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 a follow-on offering in September 2018. For the year ended December 31, 2018, we had generated revenue of $0.1 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 2014. For the two years ended December 31, 2018 and 2017, we reported a net loss of $139.1 million and $50.4 million, respectively.

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

- continue our development and commence clinical trials of our drug candidates;
- maintain and expand regulatory approvals for our products and drug candidates that successfully complete clinical trials;
- commercialize ZEJULA, Optune and any other products for which we may obtain regulatory approval;
- maintain our manufacturing facilities;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- maintain and expand sales, marketing and commercialization infrastructure for ZEJULA, Optune and any other products for which we may obtain regulatory approval;

- 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 completing preclinical testing and clinical trials of our clinical and pre-clinical stage drug candidates, obtaining marketing approval for these drug candidates, manufacturing, marketing and selling approved products, such as ZEJULA, Optune and other products for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never 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 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 our follow-on offering in September 2018. Through December 31, 2018, we have raised $462.6 million in equity financing, including $157.7 million in net proceeds from our initial public offering and $140.3 million in net proceeds from our subsequent follow-on offering in September 2018. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $97.5 million and $32.4 million for the years ended December 31, 2018 and 2017, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue our commercialization efforts of ZEJULA and Optune, advance the clinical development of our eight clinical-stage drug candidates, continue research and development of our preclinical-stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. 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 as a U.S. public company. 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, 2018 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 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;

- 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 commercial sales of ZEJULA, Optune and any other products for which we receive regulatory approval;
- 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 after obtaining 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, your 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 American depositary shares, or 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 and Optune in Hong Kong, we may never obtain approval of or commercialize ZEJULA or Optune outside of Hong Kong, which would limit our ability to realize its full market potential.

In December 2018, we launched ZEJULA and Optune in Hong Kong and the NMPA accepted our NDA for ZEJULA. 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 approval of ZEJULA and Optune for commercialization in Hong Kong and the NMPA's acceptance of our NDA for ZEJULA does not mean that the NMPA will approve ZEJULA. 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 and Optune in China and Hong Kong.

A substantial portion of our time, resources and effort are focused on the commercialization of our approved products in Hong Kong, ZEJULA and Optune. Our ability to generate product revenues will depend heavily on the successful commercialization of ZEJULA and Optune in China and Hong Kong. We have never, as an organization, commercialized a product, and there is no guarantee that we will be able to do so successfully with ZEJULA or Optune for their respective approved indications. 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; and
- manage our growth and spending as costs and expenses increase due to commercialization.

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; and
- the actual market-size for ZEJULA and Optune, which may be larger or smaller than expected.

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 early-stage companies in rapidly evolving fields as we transition to a company with 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.

Eight 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.

Eight 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 their receipt of regulatory approval and successfully commercializing 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 dependent upon our ability to develop, maintain and expand regulatory approval for and commercialize our products and clinical-stage drug candidates, including ZEJULA and Optune. We have initiated commercialization efforts for ZEJULA and Optune. For ZL-2401, we have completed the technology transfer with Paratek for aspects such as manufacturing know-how and IV and oral formulations and engaged in discussions with the NMPA and key opinion leaders on our planned China development strategy in preparation for our NDA filing with the NMPA. We initiated a Phase II trial in advanced HCC patients in China to investigate ZL-2301's optimal treatment schedule and dosage as a second-line treatment in the second quarter of 2017. The recruitment for the Phase II study has been completed and the study is ongoing. Due to the change of competitive landscape, we decided to develop ZL-2301 and PD-1 combo treatment in advanced HCC instead of mono-therapy. The FPI is expected in second half of 2019. As a result, our business is substantially dependent on our ability to complete the development of, maintain, expand or obtain regulatory approval for, and successfully commercialize ZEJULA, Optune, ZL-2401, margetuximab and, to a lesser extent, our other products or 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 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 ZEJULA and Optune were both approved for commercialization in Hong Kong, the United States and the European Union and although the NMPA accepted our NDA for ZEJULA, we cannot provide any assurance that we will ever obtain regulatory approval for ZEJULA or 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 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 contract research organizations, or 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.

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, which acquired Tesaro, Inc. in 2018, 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 and/or any other of our products or drug candidates 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.

We face substantial competition, which may result in our competitors discovering, developing or commercializing drugs before or more successfully than we do, or develop 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, ZL-2301 failed to meet its primary endpoint of overall survival, or OS, noninferiority for ZL-2301 versus sorafenib in Phase III trials in patients with HCC conducted by Bristol-Myers Squibb Company, or Bristol-Myers Squibb, before we licensed the development rights from them. In addition, ZL-2301 showed no difference when compared to placebo in the primary efficacy endpoint. Although we believe that 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 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, 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; and
- the proximity and availability of clinical trial sites for prospective patients.

Enrollment delays in our clinical trials 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 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. While we believe that the superior selectivity of ZEJULA has the potential to significantly improve the unfavorable adverse off-target toxicity issues, if patients were to experience off-target toxicity, we may not be able to achieve an effective dosage level (especially in combination therapies), receive or maintain approval to market in additional jurisdictions, or achieve the commercial success we anticipate with respect to, any of our products and drug candidates, which could prevent us from ever generating revenue or achieving profitability. 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 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 ETX2514 are imported drug products, they will be subject to Category 5 status if they are approved by the NMPA. Our CTAs for ZEJULA, ZL-2301, ZL-2302 and ZL-2401 were approved as Category 1 drugs by the NMPA. Other than FPA144, all of our other clinical stage drug candidates are eligible for Category 1 designation. 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 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 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 (SMRA), which merges and undertakes the responsibilities previously held by the China Food and Drug Administration, the State Administration for Industry and Commerce (SAIC), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), price supervision and antitrust enforcement responsibilities previously held by the National Development and Reform Commission (NDRC), the antitrust enforcement responsibilities previously held by the Ministry of Commerce (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 (CAC), and the Standardization Administration of China (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 2018, the reorganization will continue at the provincial and local levels through the first quarter of 2019. This massive restructuring exercise could result in the delay of key decision-making in various sectors, including the pharmaceutical and medical device industry. In addition, there could be delays in the NMPA's implementation of the new reform initiatives and disruption in the NMPA's routine operations due to personnel reshuffling during this process.

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 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 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, the United States or other countries 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 18 oncology drugs in October 2018, which resulted in a price reduction by over 50%. NHSA, together with other government authorities, review the inclusion or removal of drugs from the PRC's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursable Drug List, 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. The NHSA included 17 of the 18 oncology drugs on the NRDL after the price negotiation.

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 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 either China or the United States 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.

Within the United States, significant uncertainty exists regarding the coverage and reimbursement status of drug products approved by the FDA. Sales of approved drugs and devices depend, in part, on the availability of coverage and the adequacy of reimbursement from third-party payors. Third-party payors include government authorities or government healthcare programs, such as Medicare and Medicaid, and private health insurance, including managed care plans. Coverage and reimbursement may vary from payor to payor. Net prices for drugs or devices may be reduced by discounts or rebates required by U.S. government healthcare programs or requested by private payors and by any future relaxation of laws that presently restrict imports of drugs and devices from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both governmental and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

In the United States, federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Healthcare Reform Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty established under Healthcare Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Healthcare Reform Act has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the Healthcare Reform Act is still operational in all respects.

There have also been efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products and devices, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug and medical device costs, which generally have focused on increasing transparency around drug and medical device costs or limiting drug and medical device prices.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates and devices if approved for sale in the United States. We cannot, however, predict the ultimate content, timing or effect of any other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

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 and GMP certificate 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) and good supply practice, or GSP, certificate from the NMPA and its relevant branches; and
- renew the manufacturing permits, the distribution permits (or record-filing), marketing authorizations, GMP certificates and GSP certificates 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. The PRC 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, 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 we have licensed and sublicensed from third parties including ZEJULA from Tesaro (now GSK), Optune (TTFields) from Novocure Limited, or Novocure, ZL-2301 from Bristol-Myers Squibb, ZL-2401 from Paratek, FPA144 from Five Prime, ETX2514 from Entasis and margetuximab, MGD013 and a pre-clinical multi-specific TRIDENT molecule from MacroGenics Inc. Because our license from Paratek was granted to us by a subsidiary of Paratek, our license may not encumber all intellectual property rights owned or controlled by the affiliate of Paratek and relevant to our drug candidates. If we have not obtained a license to all intellectual property rights owned or controlled by such affiliates of our licensors that are relevant to our products and drug candidates, 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 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 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, under our agreements relating to ZEJULA and ZL-2301, we are required to use commercially reasonable efforts to conduct the necessary pre-clinical, clinical, regulatory and other activities necessary to develop and commercialize such drug candidates in the licensed territories. We are also obligated to use commercially reasonable efforts to develop and commercialize Optune, margetuximab, MGD013, a pre-clinical multi-specific TRIDENT molecule, ZL-2401, ZL-2302, FPA144 and ETX2514 in certain of their respective licensed territories, in each case, under their respective license agreements.

If we fail to meet any of our obligations under our license and 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. For example, if our agreement with Sanofi for ZL-2302 terminates for any reason, we are required to grant Sanofi an exclusive license with respect to certain of our owned patents and know-how that are necessary to exploit ZL-2302 in the field of oncology in the regions where the license is terminated. 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, MGD013 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, MGD013 and a pre-clinical multi-specific TRIDENT molecule in China, Hong Kong, Macau and Taiwan to an exclusive license. 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 license 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 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, and MacroGenics 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 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 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 or sublicensed 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.

Existing PRC laws and regulations do not require us to have, nor do we currently, maintain liability insurance to cover product liability claims. We do not have business liability, or in particular, product liability insurance for each of our products and drug candidates. 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), this insurance may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the 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. We currently have no drug candidates beyond pre-clinical trials under our internal discovery programs. Each of our drug candidates will require additional clinical and preclinical development, management of clinical, preclinical 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 preclinical 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 early 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 is 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. In addition, 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 for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. 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.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical 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 preclinical and clinical programs. We rely on these parties for execution of our preclinical 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 preclinical 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 you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with ICH-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 preclinical 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 preclinical 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 preclinical 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 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 GMP certificates 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, MGD013, and a pre-clinical multi-specific TRIDENT molecule, and Novocure to manufacture and supply Optune pursuant to our license agreements with MacroGenics and Novocure.

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, ZL-2401 from Paratek, ZL-2301 from Bristol-Myers Squibb, ZL-2302 from Sanofi, FPA144 from Five Prime, ETX2514 from Entasis, and margetuximab, MGD013 and a pre-clinical multi-specific TRIDENT molecule from MacroGenics. 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 these patents and patent applications 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 Bristol-Myers Squibb for ZL-2301, Bristol-Myers Squibb has the first right to enforce the licensed patents in China, Hong Kong and Macau, subject to certain exceptions. 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 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 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. Similarly, 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 the PRC, 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, the PRC 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.

The PRC'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. 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 the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, 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 the PRC 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 the PRC 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 the PRC, 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 will be effective as of January 1, 2020. Foreign-invested entities will enjoy national treatment in industry sectors that are not prohibited or restricted from foreign investment. The 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 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 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 expands, the applicability of the FCPA and other anti-bribery laws to our operations will 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 Lenders, 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.

Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We received approximately $1.3 million and $0.2 million in financial incentives from local governments in China relating to our business operations in 2018 and 2017, respectively. We also received approximately nil and $0.7 million in financial incentives from local governments in Australia as part of its tax incentive program in 2018 and 2017. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives

at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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.

The PRC Enterprise Income Tax Law, or the EIT Law, and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008, 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 enterprise income tax purposes, that entity would be subject to a 25% enterprise income tax 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 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, in October 2018 CFIUS launched a new "pilot program" that authorizes it to review transactions that include certain non-controlling investments in companies that deal in "critical technology." 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 and Macau. We do not own or exclusively license any issued patents covering Optune in Hong Kong, Macau or Taiwan. We do not own or exclusively license any issued patents covering margetuximab, MGD013 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 and 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. Additionally, we do not own or exclusively license any issued patents covering ZL-2302 in the PRC, but we do in-license a pending patent application relating to ZL-2302 in the PRC. However, we cannot predict whether such patent application 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, and Bristol-Myers Squibb for ZL-2301, our licenses are limited to China, Hong Kong, and Macau. In the case of our agreements with Novocure for Optune, Paratek for ZL-2401, Five Prime for FPA144, and MacroGenics for margetuximab, MGD013 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 ETX2514, 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.

Patents may be invalidated and patent applications, including our in-licensed patent application relating to FP144, Optune, margetuximab, MGD013, or a pre-clinical multi-specific TRIDENT molecule, 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 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, 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 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 may become involved in patent litigation against third parties to enforce our 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 our owned or in-licensed patents 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 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. 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.

We are eligible to be treated as an "emerging growth company," as defined in the Securities Act of 1933, as amended (the "Securities Act), and we cannot be certain if the reduced disclosure requirements applicable to us as an "emerging growth company" will make our ADSs less attractive to investors.

We are eligible to be treated as an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. As a result, our shareholders may not have access to certain information that they may deem important. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if our total annual gross revenue exceeds $1.07 billion, if we issue more than $1.0 billion in non-convertible debt securities during any three-year period, or if the market value of our ordinary shares held by non-affiliates exceeds $700.0 million. We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our stock price may be more volatile.

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 will be 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. However, while we remain an emerging growth company, we will not be required to include 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 are unable 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 may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are 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, 2019. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the U.S. and we fail to meet additional requirements necessary to maintain our foreign private issuer status. 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, 2020, 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 the PRC, 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 announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or CSRC, and the Ministry of Finance, which establishes 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 continues to be in discussions with the CSRC and the Ministry of Finance to permit joint inspections in the PRC of audit firms that are registered with PCAOB and audit Chinese companies that trade on U.S. exchanges.

This lack of PCAOB inspections in China prevents the PCAOB from regularly 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. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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 March 15, 2019, the closing price of our ADSs ranged from a high of $34.09 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 October 2018, the exchanges in 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, the PRC 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, China's People's Bank of China, or PBOC, announced that the PRC 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 PRC 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 year ended December 31, 2018 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 the PRC 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 the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC 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 the PRC Civil Procedures Law, the PRC 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.

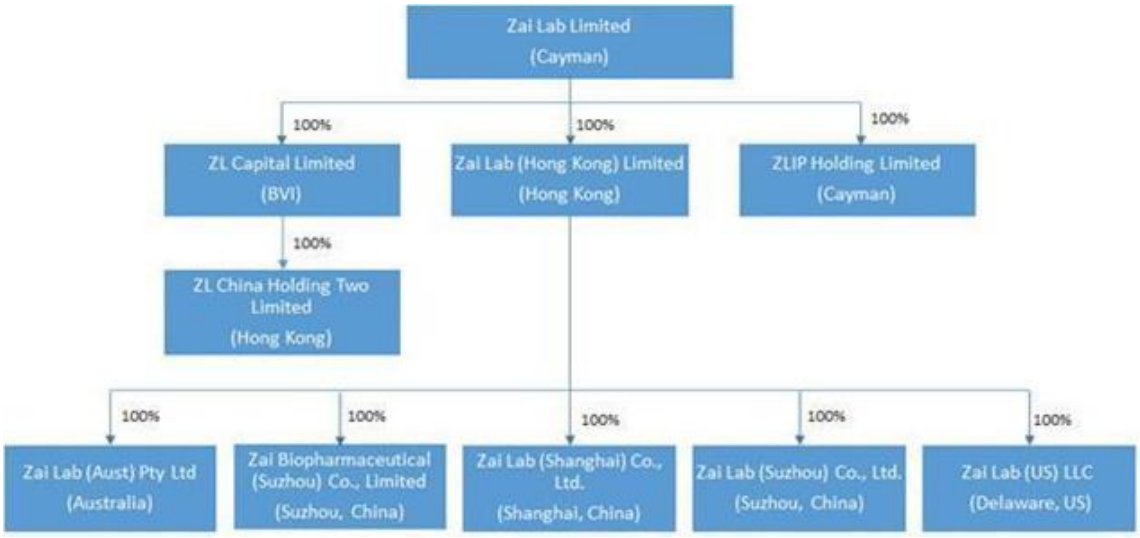
ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs 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 February 28, 2019.



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 addition, we have received government grants totaling approximately $5.4 million since our inception.

We currently have eight 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 Asia, through partnerships with GSK, Bristol-Myers Squibb, Paratek, Five Prime, Entasis, Novocure and MacroGenics. To date, we have made upfront, milestone and clinical cost reimbursement payments totaling approximately $101.4 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 based in China and the United States 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 first in China and, potentially, the rest of the world. Our mission is to leverage our expertise and insight to address the expanding needs of Chinese patients in order to transform their lives and eventually utilize our China-based competencies to impact human health 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 China-based, innovation-focused companies.

We have a broad and validated innovative pipeline currently consisting of eight clinical-stage drug candidates with potentially differentiated profiles, in addition to other assets, through partnerships with global biopharmaceutical companies. Our clinical-stage portfolio includes seven late-stage assets targeting large, fast growing segments of China’s pharmaceutical market. Across our broader portfolio, we currently have over 20 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 eight 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 Asia. Our clinical trial applications, or CTAs, for four of these drug candidates have been accepted as Category 1 drugs by the NMPA. This classification provides us with a competitive advantage as Category 1 drugs benefit from an expedited review of CTAs and NDAs, as well as commercial benefits.

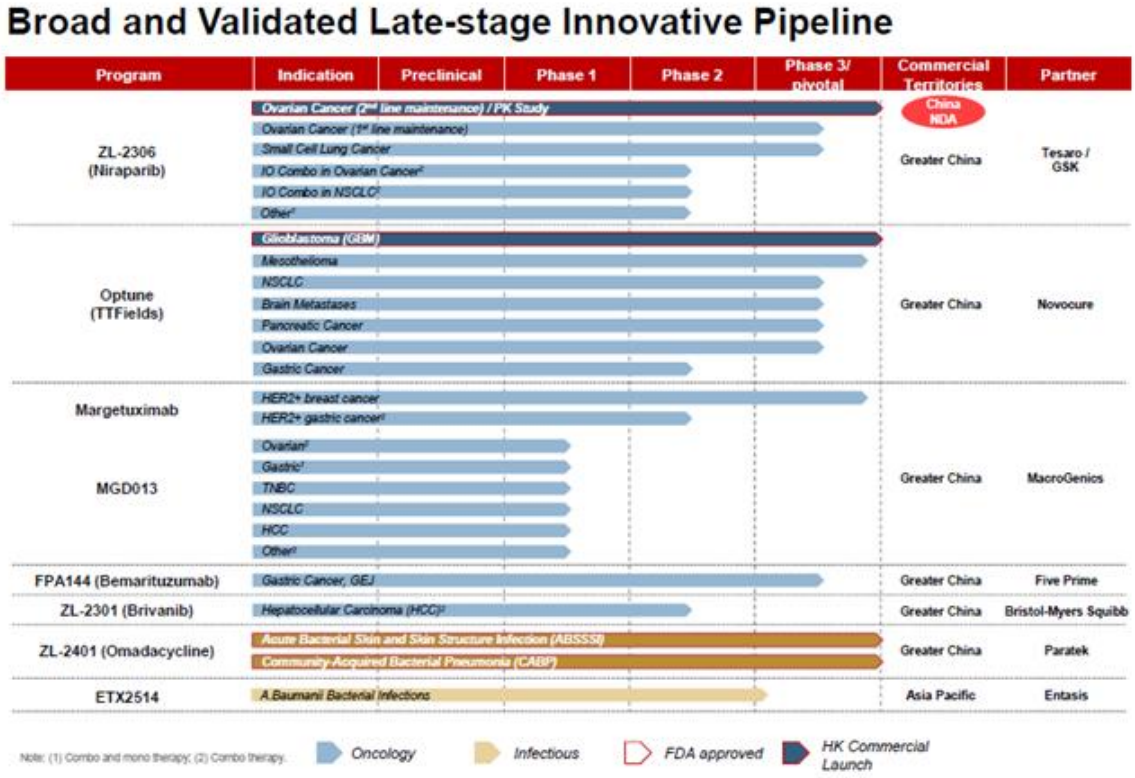
Our lead drug candidate ZL-2306, or ZEJULA, is an oral, once-daily small molecule PARP 1/2 inhibitor being developed and commercialized outside of China, Hong Kong and Macau by our partner, TESARO, Inc. (recently acquired by GSK). ZEJULA has the potential to be a differentiated drug for treatment across multiple solid tumor types in China, including ovarian and certain other types of cancer. In March 2017, ZEJULA received U.S. Food and Drug Administration, or FDA, marketing approval and in November 2017, it received European Commission European Medicines Agency, or EMA, marketing approval as a maintenance treatment for recurrent platinum-sensitive epithelial ovarian cancer. In April 2017, TESARO (now 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 China, our CTA for ZEJULA has been approved as a Category 1 drug by the NMPA across all indications that we aim to pursue. 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.

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 have collaborations with academic institutions in China, including Tsinghua University, Shanghai Institute of Materia Medica and Shanghai Institute of Organic Chemistry, the Chinese Academy of Sciences, or CAS, to expand our in-house research projects. 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 180 employees as of March 1, 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 products, clinical-stage drug candidates and programs.



Our Late-Stage Clinical Pipeline

Our eight clinical stage products consist of seven late-stage drug candidates with China rights focus on oncology and infectious diseases, two therapeutic areas where there is a large unmet need and lack of innovative treatment options in China. These drug candidates are:

- **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, which in March 2017 received FDA marketing approval and in November 2017, received EMA marketing approval as 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 in the United States in April 2017. We commercialized ZEJULA in Hong Kong in the fourth quarter of 2018. In China, our IND for ZEJULA has been approved as a Category 1 drug by the NMPA. 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 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 July 2018, we also initiated a Phase III study in patients with platinum-responsive small cell lung cancer as maintenance therapy. In August 2018, we completed our PK study for Chinese patients with platinum-sensitive ovarian cancer, which demonstrated a comparable PK profile to studies in non-Chinese patients. We continue to explore ZEJULA in patients with small cell lung cancer and other tumors with defects in their DNA repair mechanism. In August 2018, we enrolled the first patient in our Phase III registration trial of ZEJULA as a first-line maintenance therapy in small cell lung cancer in China. This will be the first clinical trial of ZEJULA in this type of cancer. We are also exploring the combination potential of ZEJULA with immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

- **Optune (TTFields)** is a new treatment modality known as tumor-treating fields (TTFields) which has demonstrated overall survival benefit in patients with newly diagnosed glioblastoma multiforme, or GMB, in a large randomized controlled clinical trial. TTFields 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 U.S., EU and Japan for the first line and reoccurring treatment of glioblastoma and has demonstrated clinical proof of concept in multiple other tumor types such as mesothelioma, lung cancer and pancreatic cancer. Novocure currently has global Phase III studies in brain metastases, non-small cell lung cancer, or NSCLC, and ovarian cancer, which are large commercial opportunities in China. In September 2018, Zai Lab announced a global strategic development collaboration with Novocure. Zai Lab obtained an exclusive license to develop and commercialize TTFields in Greater China and will also support enrollment of Chinese patients to accelerate clinical trial enrollment for additional indications. In December, within three months of signing the partnership deal with Novocure, Zai Lab launched Optune in Hong Kong and treated its first patient with newly diagnosed glioblastoma multiforme.

- **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 second half of 2019. Zai Lab has exclusive rights to margetuximab in Greater China from MacroGenics.

- **MGD013** is a first-in-class bispecific DART molecule designed to provide coordinate blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies. We have exclusive rights to MGD013 in Greater China from MacroGenics. MGD013 is anticipated to be used for the treatment of a wide range of cancers, including both solid tumors and hematological malignancies and MGD013 has demonstrated a favorable preclinical safety and toxicological profile and is currently being evaluated in a Phase I dose escalation study.

- **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 FPA144, or Bemarituzumab, from Five Prime as part of a global strategic collaboration. In clinical studies conducted by Five Prime, FPA144 has demonstrated good tolerability and efficacy profiles in late-line gastric patients as a monotherapy. The randomized, controlled Phase III portion of the trial evaluating FPA144 in combination with a chemotherapy regimen 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 FPA144 global registrational study. We will manage the China portion of this global Phase III study and plans to contribute a significant number of patients from China to this Phase III study.

- **Brivanib (ZL-2301)** is an oral, small molecule dual target tyrosine kinase inhibitor, or TKI, that blocks both vascular endothelial growth factor receptor, or VEGFR, and fibroblast growth factor receptor, or FGFR. ZL-2301, or brivanib, was studied by our partner Bristol-Myers Squibb mainly for the treatment of hepatocellular carcinoma, or HCC, the most common type of liver cancer. In those trials, brivanib demonstrated anti-tumor activity and a generally well-established safety profile in HCC patients. In 2012, Bristol-Myers Squibb terminated its development program of brivanib after it missed the primary endpoints in two Phase III trials with advanced HCC patients. Based on our review of the results from Bristol-Myers Squibb's development program for brivanib, our understanding of the etiology and current standard of care of HCC in Chinese patients and our ongoing research, we believe that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical trials. The NMPA has approved our CTA for ZL-2301 as a Category 1 drug, and in the second quarter of 2017 we initiated a Phase II trial of ZL-2301 as a second-line treatment for advanced HCC patients in China. The recruitment for the Phase II study has been completed and the preliminary data were presented at the Chinese Society of Clinical Oncology (CSCO) in September 2018. Preliminary anti-tumor activity has been observed with second-line HCC patients treated with ZL-2301. The safety profile to date appears to be tolerable and manageable in general. Given the rapidly changing landscape in the management of HCC, Zai Lab has decided to conduct a trial of brivanib in combination with a PD1 antibody and the trial is planned to initiate in China and Hong Kong in the second half of 2019.

- **Omadacycline (ZL-2401)** is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. We have licensed ZL-2401, or omadacycline, from Paratek, which in October 2018 received FDA marketing approval. ZL-2401 is primarily being developed for acute bacterial skin and skin structure infection (ABSSSI), community-acquired bacterial pneumonia (CABP), and urinary tract infections (UTI). ZL-2401 is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. Drugs competing with ZL-2401 in the same class are only available in IV formulation, in contrast, ZL-2401 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 with Paratek for aspects such as manufacturing know-how of the IV and oral formulations and engaged in discussions with the NMPA and key opinion leaders on our planned China development strategy in preparation for our NDA filing in China. In July 2018, we received CTA approval from the NMPA. In December 2018, Zai Lab initiated the abbreviated bridging program previously agreed to with the NMPA, which is expected to allow us to accelerate NDA preparation and submission timeline by up to two years.

- **ETX2514 (ZL-2402)** is a novel beta-lactamase inhibitor. We have licensed ETX2514 from Entasis Therapeutics, or Entasis, as part of a global strategic collaboration. ETX2514 restores activity of beta-lactams against Class A, C, and D beta-lactamases. Entasis is developing ETX2514 as ETX2514SUL, a fixed combination of ETX2514 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, or MDR, and has become extremely difficult to treat. The microbiologic efficacy of the combined ETX2514 and sulbactam was demonstrated in large studies of well-characterized MDR Acinetobacter isolates from diverse regions, including Asia. The FDA has granted ETX2514SUL Qualified Infectious Disease Product, or 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 plans to initiate a pivotal Phase III study in MDR Acinetobacter pneumonia and bloodstream infections by mid-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 ETX2514 for MDR Acinetobacter pneumonia and bloodstream infections in late 2019.

For our late-stage oncology drug candidates with Greater China rights, our near-term development plan focuses on specific patient segments. These segments have an estimated annual incidence of over 1.3 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, ZL-2401 and ZL-2402 (ETX2514), will address significant unmet patient and market needs.

With ZL-2401, 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 ZL-2401 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.

With ZL-2402, 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. 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 multidrug-resistant infections, 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 therapeutics in the areas of oncology and autoimmune diseases, with a focus on large market opportunities with unmet clinical needs in both China and the U.S. market. Our aim is to produce up to two global INDs per year starting in 2020. We have collaborations with leading academic institutions in China, including Tsinghua University, Shanghai Institute of Materia Medica and Shanghai Institute of Organic Chemistry, the CAS, to expand our in-house research capabilities. We believe our discovery effort 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 targets in our focus areas that we are moving into preclinical 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 large molecule therapeutics and creating a proprietary, best-in-class human 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-chemo therapy 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. If approved by the SDA, ZEJULA may potentially be the first Category 1 PARP inhibitor on the China market approved for second-line maintenance treatment in all recurrent platinum-sensitive ovarian cancer patients.

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 China, our CTA for ZEJULA has been approved as a Category 1 drug by the NMPA. 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 July 2018, we also initiated a Phase III study in patients with platinum-responsive small cell lung cancer as maintenance therapy. 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 small cell lung cancer and gBRCA+ and triple negative breast cancer and squamous-type non-small cell lung cancer in China. In August 2018, we enrolled the first patient in our Phase III registration trial of ZEJULA as a first-line maintenance therapy in small cell lung cancer in China. This will be the first clinical trial of ZEJULA in this type of 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. We intend to explore ZEJULA's efficacy in patients with squamous-type non-small cell lung cancer and small cell 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. Based on an assumption of 80% share of non-small cell lung cancer and 30% of cancers being squamous, we estimate a potential target patient population of 176,000 patients with squamous-type non-small cell lung cancer and 147,000 in small cell lung cancer in China.

The standard of care for advanced small cell lung cancer and non-small cell lung cancer in China is platinum-based chemotherapy. For EGFR mutation positive patients, geftinib (Iressa) and erlotinib (Tarceva) are recommended as first-line therapies for patients in the advanced/metastatic stage of non-small cell lung cancer who are EGFR mutation positive. For non-small cell lung cancer patients with unclear EGFR mutation status, as well as for small cell lung cancer, chemotherapy is the standard of care in China.

We believe ZEJULA has first-in-class potential in both indications in China, representing an attractive addition to the current standard of care in small cell lung cancer and. Given the relatively limited therapy options for Chinese physicians and patients we believe that a small molecule PARP inhibitor will offer an attractive addition to the standard of care with an attractive price level relative to large molecule drugs.

In addition to ZEJULA monotherapy in the potential indications stated above, we also intend to explore the combination of ZEJULA with other potential therapies such as immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

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.

Our second Phase III study is expected to evaluate ZEJULA as a first-line maintenance therapy in patients with platinum-responsive ovarian cancer. The study design of this clinical trial has been discussed and agreed with the NMPA and the trial was initiated in the June 2018. Tesaro (now GSK) is also evaluating ZEJULA in the PRIMA trial, a Phase III clinical trial in the first-line maintenance setting in platinum responsive ovarian cancer patients.

Lung Cancer

We initiated a Phase III study in patients with platinum responsive small cell lung cancer as maintenance therapy in August 2018. The study design has been discussed and agreed with the NMPA.

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, 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.

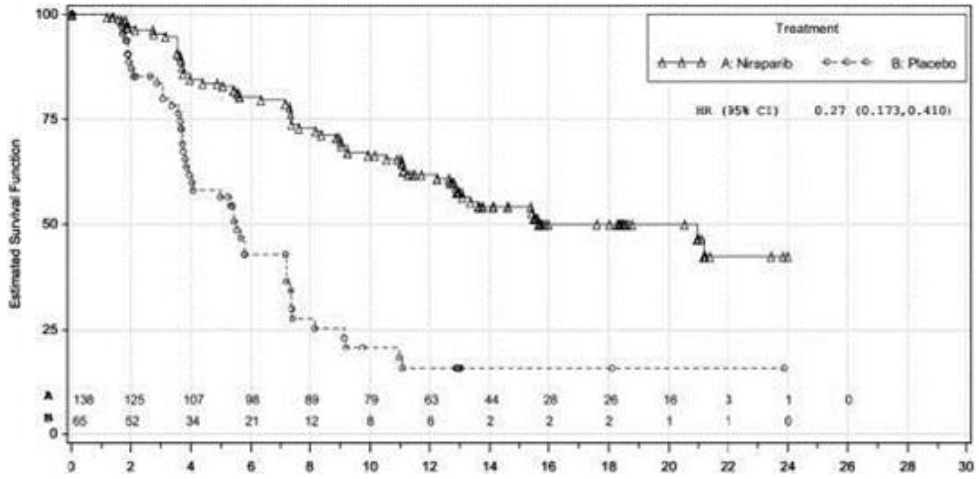
Figure 1: Progression free survival was significantly longer for patients who received ZEJULA compared to those who received placebo for all primary efficacy populations.

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 <0.0001	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 <0.0001	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 <0.0001	36%	14%	12%

Source: Tesaro.

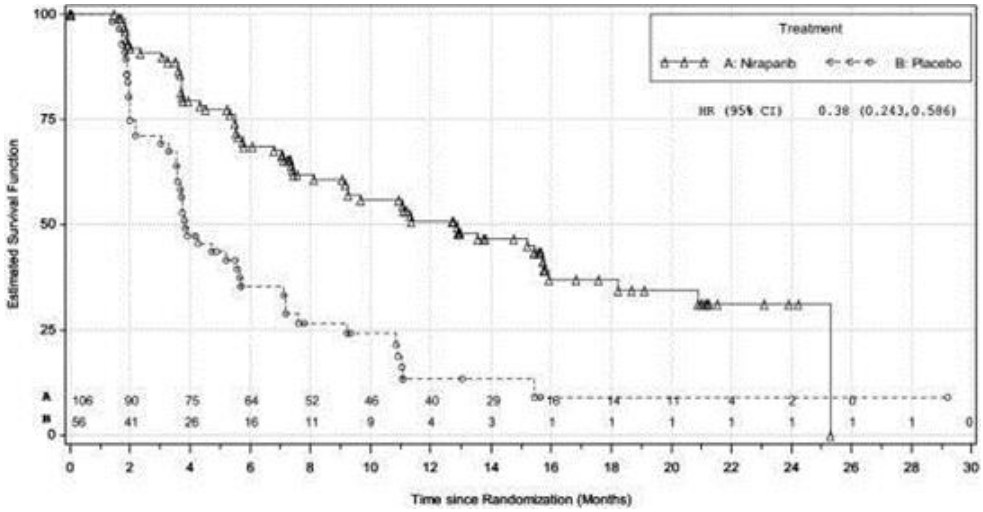
Notes: gBRCAmut = gBRCA mutation positive; non-gBRCA mut = gBRCA mutation negative

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



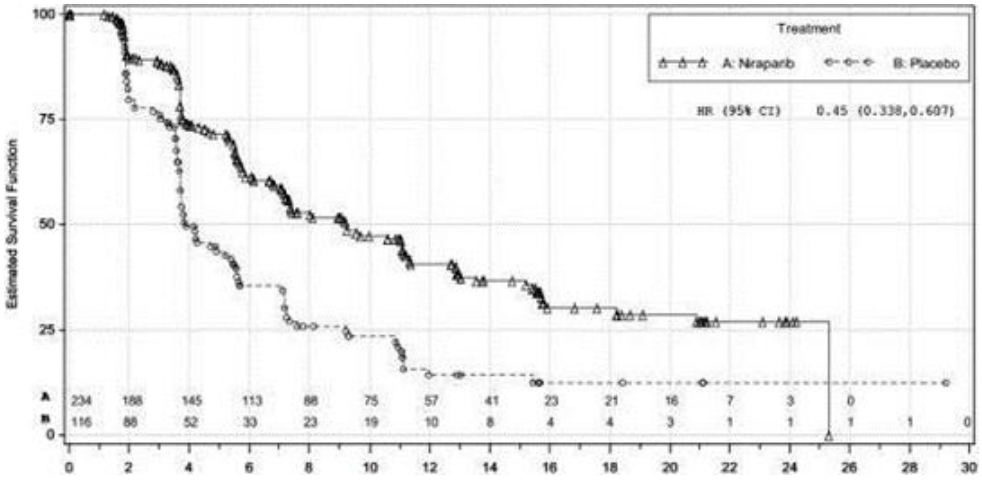
Source: Tesaro.

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<0.0001). As shown in the chart above, ZEJULA's treatment effect started very early during treatment as seen by the two curves being separated at first efficacy assessment. Progression free survival was also significantly longer with ZEJULA in the HRDpos group of the gBRCA mutation negative cohort (median, 12.9 months versus 3.8 months; hazard ratio=0.38; p<0.0001) and in the overall gBRCA mutation negative cohort (median, 9.3 months versus 3.9 months; hazard ratio = 0.45; p<0.0001). Additionally, in an exploratory pooled analysis that evaluated all patients in both cohorts combined, progression free survival was longer with ZEJULA (median 11.3 months versus 4.7 months, hazard ratio = 0.38, 95% confidence interval: 0.303, 0.488; p<0.0001).

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.

ZEJULA Preclinical Development

As discussed below, Merck and our partner Tesaro (now GSK) have completed various preclinical trials to evaluate the pharmacodynamics, pharmacokinetics and toxicology profile of ZEJULA.

Pharmacodynamics. In preclinical 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 preclinical 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 (TTFields)

Overview of TTFields

Tumor treating fields (or TTFields) were invented in 2000 by Professor Emeritus Yoram Palti of the Technion Institute of Technology in Israel, who founded Novocure (Israel) in 2000, conducted preclinical studies of TTFields, developed a medical device capable of delivering TTFields to patients, and finally brought TTFields into clinical use through clinical testing in patients with recurrent glioblastoma. Today, after more than 15 years of preclinical research, it is known that TTFields 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, TTFields 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. TTFields cannot stimulate nerves or muscles, nor do they lead to heating of the tumor or surrounding tissues. Since TTFields 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 TTFields.

The efficacy of TTFields is frequency dependent on specific cell types. The anti-mitotic effect of TTFields 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 TTFields in a variety of solid tumors are ongoing. PANOVA-3 is TTFields combined with chemotherapy for newly-dagnosed pancreatic cancer. LUNAR is targeting advanced NSCLC, to evaluate TTFields 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).

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 TTFields to the patient's shaved head by means of electrically insulated surface transducer arrays. It has been FDA approved for the treatment of recurrent Glioblastoma multiforme (GBM) and has received CE mark for the treatment of both recurrent and newly diagnosed GBM. The device has been available commercially in the E.U. and in the U.S. since October 2011. Optune was approved in Japan for the treatment of recurrent GBM in March 2015. The indication of Optune was expanded to include treatment of adult patients with newly diagnosed GBM in combination with temozolomide in October 2015 in the U.S. It was also commercially launched 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 temozolomide, or 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 TTFields 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 temozolomide 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<0.001). Median overall survival from randomization was 20.9 months versus 16 months for the Optune /TMZ and TMZ alone, respectively, with a hazard ratio of 0.63 (95% CI 0.53–0.76), p<0.001. The most common adverse events in the Optune /TMZ arm, defined as occurring in ≥10% of patients, were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression. Grade 3 to 4 adverse events were well balanced between the 2 treatment arms. None of the systemic grade 3 to 4 adverse events were considered related to Optune by any of the investigators. Mild to moderate skin toxicity underneath the transducer arrays occurred in 52% of patients who received Optune-temozolomide vs no patients who received temozolomide alone.

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 TTFields in the China Market

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

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 caners 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 (Fcg receptor IIIA or FcgRIIIA) 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. Details of the study design are being worked on. Data from the positive SOPHIA study and the bridging study data will be used to support potential regulatory filing for approval in China. In additional, Zai Lab plans to participate in the upcoming global studies of margetuximab in combination with a PD-1 antibody 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 Preclinical 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.

Margetuximab has been evaluated in several ongoing or completed studies. Study CP-MGAH22-04 (SOPHIA) is a Phase III randomized, comparator-controlled study of margetuximab plus chemotherapy for the treatment of patients with HER2+ metastatic breast cancer who have received at least 2 prior lines of anti-HER2 directed therapy in the metastatic setting, or in case of having received (neo)adjuvant pertuzumab, at least 1 prior line of anti-HER2 directed therapy in the metastatic setting, and who have received at least 1, and no more than 3, lines of therapy overall in the metastatic setting. Eligible patients are randomized 1:1 to receive either margetuximab (15.0 mg/kg IV Q3W) or trastuzumab (8 mg/kg loading dose, 6 mg/kg subsequent doses, IV Q3W) to be administered in combination with chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine) of the investigator's choice and as allowable per local regulations. Patients will receive treatment until disease progression, death, withdrawal of consent, or request by the treating physician to discontinue treatment. Following completion of (or discontinuation from) treatment, patients will be followed for survival. The study enrolled 536 subjects and the trial met the primary endpoint of prolongation of progression-free survival (PFS) in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy. Patients in the margetuximab arm experienced a 24% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.76, p=0.033), and approximately 85% of patients in the study were carriers of the CD16A (FcγRIIIa) 158F allele, which has been previously associated with diminished clinical response to Herceptin and other antibodies. In this pre-specified subpopulation, patients in the margetuximab arm experienced a 32% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.68, p=0.005).

Study CP-MGAH22-05 is a Phase Ib/2, open-label, dose escalation and cohort expansion study designed to characterize the safety, tolerability, pharmacokinetics (PK), pharmacodynamics, immunogenicity, and preliminary anti-tumor activity of margetuximab administered IV every 3 weeks in combination with pembrolizumab (Keytruda) administered IV every 3 weeks in patients with relapsed/refractory unresectable locally advanced or metastatic HER2+ gastroesophageal junction or gastric cancer. The study consists of a dose escalation phase to determine maximum tolerated dose (MTD, or maximum administered dose, if no MTD is defined). Margetuximab was evaluated in 2 sequential escalating doses, 10 mg/kg and 15 mg/kg, in combination with 200 mg pembrolizumab in cohorts of 3 to 6 patients each. Subsequently a cohort expansion phase enrolled 60 patients (30 each in North America and Asia) to define safety and initial efficacy of the combination with the dose defined in the first phase (15 mg/kg).

Margetuximab also has an Expanded Access Program (EAP) program that provides margetuximab for the treatment of HER2+ metastatic breast cancer in single, individually approved single-patient INDs is ongoing.

Two studies of margetuximab have been completed. Study CP-MGAH22-01 was a Phase I, open-label, single-arm, multicenter dose-escalation study to define the toxicity profile, maximum tolerated dose (MTD), immunogenicity, PK, and potential antitumor activity of margetuximab in patients with refractory HER2+ breast cancers and patients with other carcinomas that overexpress HER2 for whom no standard therapy is available. A total of 66 patients received treatment with margetuximab in this study. Margetuximab doses of 0.1 mg/kg (n=3), 0.3 mg/kg (n=3), 1.0 mg/kg (n=3), 3.0 mg/kg (n=6), and 6.0 mg/kg (n=4) per week were evaluated in a sequential manner in the dose escalation segment of the study. Dose-limiting toxicity (DLT) was reported in only one patient treated at 3.0 mg/kg who experienced Grade 3 infusion related reaction (also a SAE) associated with the first dose of margetuximab. The cohort was expanded and the margetuximab dose subsequently escalated to 6.0 mg/kg with no further DLTs observed. When margetuximab was dosed weekly, the MTD was not reached. Margetuximab was tolerated at the highest dose evaluated, 6.0 mg/kg, and this cohort was subsequently expanded to enroll an additional 15 patients. Overall, 34 patients were enrolled in the weekly dosing cohorts. Margetuximab was well tolerated at doses of 0.1 to 0.6 mg/kg once weekly or 10.0 to 18.0 mg/kg once Q3W. An MTD was not reached for either regimen evaluated. Adverse events were generally mild to moderate in severity and no cardiotoxicity was observed. The safety data evaluated in this Phase I clinical trial demonstrated an acceptable safety profile for margetuximab. Overall, the results of this Phase I study indicated that single-agent margetuximab was well-tolerated and demonstrated encouraging initial antitumor activity in heavily pretreated patients with refractory HER2-expressing tumors, including patients with metastatic HER2+ breast cancer.

Study CP-MGAH22-02 was a single-arm, open-label, Phase II study of margetuximab in patients with relapsed or refractory breast cancer whose tumors express HER2 at a 2+ level by IHC and lack evidence of HER2 gene amplification by FISH. No partial response (PR) or complete response (CR) among 22 response-evaluable patients was observed in response to such treatment. As a result, the study was discontinued early because it did not meet the criteria to continue as specified in the protocol.

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.

FPA144, 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 FPA144 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 FPA144 plus chemotherapy was initiated in the second half of 2018 and Zai Lab enrolled the 1st 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 FPA144 both within and outside of China.

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

As FPA144 is a targeted biologic, the clinical development of FPA144 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 (FPA144-004) study is designed to evaluate the efficacy, safety, and PK of FPA144 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 FPA144 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. The global Phase III data will support the NDA submissions both in China and outside China.

FPA144 Mechanism of Action

FPA144 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. FPA144 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). FPA144 inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation in cell culture in FGFR2b overexpressing gastric and breast cancer cell lines. FPA144 also inhibits tumor growth in FGFR2b overexpressing gastric and breast xenograft models. The 3 potential mechanisms of action of FPA144 thus include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and enhancing ADCC.

FPA144 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, FPA144 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 FPA144 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), FPA144 does not inhibit FGF23 signaling. FGF23 is a ligand involved in calcium/phosphate metabolism. Thus, treatment with FPA144 is not expected to cause the dose-limiting hyperphosphatemia associated with the FGFR TKIs.

FPA144 Preclinical and Clinical Background

Nonclinical Pharmacology

The nonclinical pharmacology program for FPA144 has been designed to assess the *in vitro* and *in vivo* pharmacologic action of FPA144 with particular focus on efficacy and safety. *In vitro* pharmacodynamic (PD) studies have been performed to characterize the binding affinity of FPA144 to FGFR2b *in vitro*, as well as to assess the ability of FPA144 to inhibit FGFR2b ligand binding, downstream signaling, and cell proliferation. In addition, the ability of FPA144 to induce ADCC has been determined *in vitro*. The *in vivo* pharmacology of FPA144 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. FPA144 inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation of FGFR2b-overexpressing gastric and breast cancer cell lines. FPA144 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 FPA144 mediates ADCC in cells expressing FGFR2b.

Nonclinical Pharmacokinetics

The PK characteristics of FPA144 were investigated as a part of both nonclinical TK and PK studies in rat and cynomolgus monkey. Single-dose and repeat-dose studies evaluated FPA144 doses of 1–150 mg/kg. In those studies, FPA144 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 FPA144 and anti-FPA144 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, FPA144 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 FPA144 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). FPA144 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 $\geq$ 10 mg/kg for single doses and doses $\geq$ 5 mg/kg following repeat doses, marked by dose-proportional increases in exposure at doses exceeding this level when dosed at weekly intervals. Since FPA144 binds equivalently to rat, monkey, and human FGFR2b, the nonclinical data provide a solid foundation to understanding the profile in clinical studies with FPA144.

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 FPA144: 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.

FPA144 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 FPA144 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.

FPA144 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 FPA144 were corneal epithelium thinning and a unilateral cataract in one high-dose animal.

FPA144 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. FPA144-related but non-adverse microscopic findings were also noted in the mammary gland of animals in all dose groups. With the exception of FPA144-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.

FPA144 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. FPA144-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 FPA144-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 FPA144 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 FPA144 to date.

FPA144 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 FPA144 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.

FPA144 is a recombinant, afucosylated, humanized immunoglobulin G1 (IgG1) kappa monoclonal antibody directed against FGFR2b. FPA144 is glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). Preclinically, FPA144 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* preclinical studies have shown that FPA144 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 FPA144 include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and ADCC.

FPA144 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, FPA144-001, entitled "A Phase I Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 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 FPA144 in patients with FGFR2b-selected tumors. Based on an August 7, 2017 data cut, treatment with FPA144 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 FPA144, 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 FPA144-004 (FIGHT), a double-blind, randomized, controlled, global Phase III study of FPA144 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 FPA144 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 FPA144 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 FPA144 for the treatment of gastric cancer includes FPA144-002, a Phase I pharmacokinetic (PK) safety study in Japan. This dose escalation study is designed to assess the PK and safety of single agent FPA144 and will identify the RD for single agent FPA144 in Japanese patients. The first cohort of three patients treated on FPA144-002 had no DLTs reported at doses of 10 mg/kg administered every two weeks.

Omadacycline (ZL-2401)

ZL-2401 is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. ZL-2401 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. ZL-2401 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, ZL-2401 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 ZL-2401 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 ZL-2401 compared to moxifloxacin. In July 2017, Paratek also announced positive top-line results from a Phase III study comparing oral-only administration of ZL-2401 in ABSSSI compared to oral-only linezolid, which met all of its primary endpoints.

Omadacycline / NUZYRA was launched in the United States in February 2019 as a once-daily oral and intravenous antibiotic for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute skin and skin structure infections (ABSSSI). The European Marketing Authorization Application for oral and IV omadacycline was submitted in October 2018 and the review has been initiated.

In addition to its Phase III program for ZL-2401, Paratek initiated a Phase Ib study in UTIs in May 2016 and positive top-line PK proof-of-principle data was reported in November 2016.

We obtained the exclusive license to develop, manufacture and commercialize ZL-2401 in the field of all human therapeutic and preventative uses (other than biodefense) in China, Hong Kong, Macau, and Taiwan in April 2017.

Our Clinical Trial Designs and Strategy for ZL-2401 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 SDA interactions. We have submitted documents and filed for an IND with Chinese Health Authorities in January 2018. Zai is actively engaged in discussions with the SDA and key opinion leaders on our planned China development strategy in preparation for our NDA filing.

We have completed a microbiology study investigating the activity of ZL-2401 against pathogens obtained from Chinese/Asian patients. In this pilot trial of 3,832 isolates, ZL-2401 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 European Union). Our data have recently been published.

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 also initiated a PK study in Chinese which will provide exposure data for both the IV and oral formulation. We have enrolled the first ABSSSI patient in our clinical efficacy study and these studies are part of our bridging plan for regulatory approval in China.

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.

ZL-2401 – 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.

ZL-2401 Clinical Results

Phase III Pivotal Trial—ABSSSI / OASIS—ABSI 1108

ZL-2401 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 ZL-2401 for 4.4 days, and oral ZL-2401 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 ZL-2401 against skin pathogens including MRSA.

Figure 5: ZL-2401 vs Linezolid—ABSSSI Trial—Primary Efficacy Outcomes

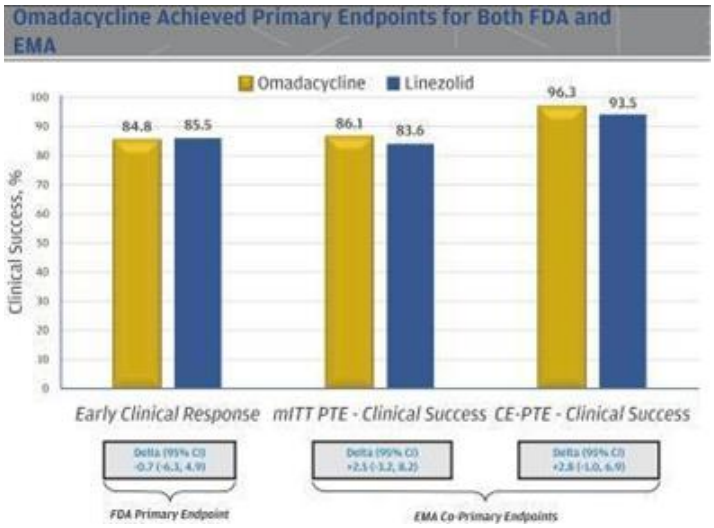
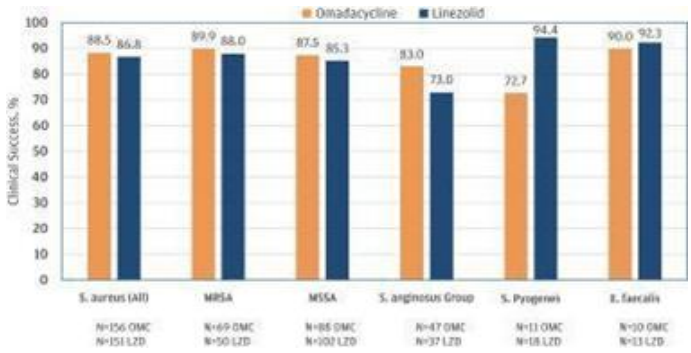


Figure 6: Early Clinical Success by Pathogen—micro-mITT Population



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 ZL-2401 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 7: 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

ZL-2401 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 ZL-2401 and moxifloxacin, a powerful respiratory fluoroquinolone.

Figure 8: CABP Study—OPTIC: Primary Efficacy Results—FDA Analysis

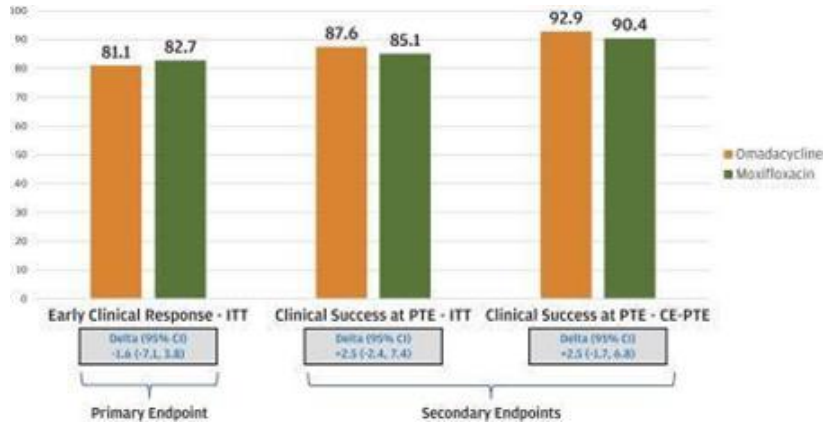


Figure 9: CABP Study—OPTIC: Primary Efficacy Results—EMA Analysis

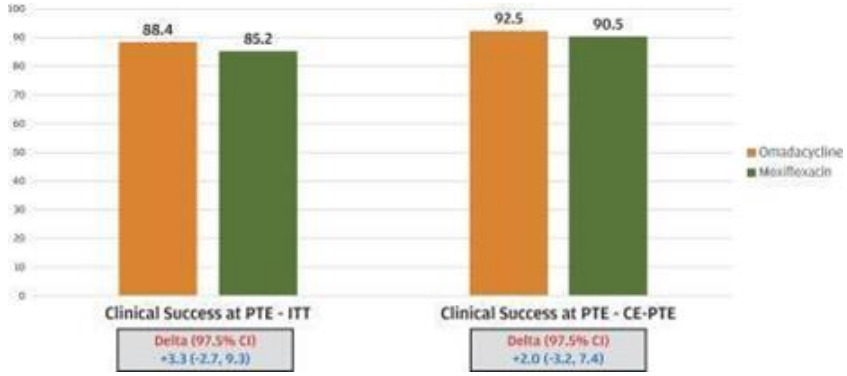


Figure 10: CABP Study—OPTIC: Clinical Success at PTE by Baseline Pathogen

	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 ZL-2401 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 11: 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 ZL-2401 in ABSSSI compared to oral-only linezolid. Oral, once daily ZL-2401 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 ZL-2401 and linezolid treatment arms were 87.5% and 82.5%, respectively. In addition, ZL-2401 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, ZL-2401 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% (ZL-2401) vs. 80.8% (linezolid) and 97.9% (ZL-2401) vs. 95.5% (linezolid), respectively.

The most common TEAEs in ZL-2401-treated patients (occurring in ≥ 3% of patients) were gastrointestinal adverse events of ZL-2401 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 ZL-2401 vs. 3.0% with linezolid), aspartate aminotransferase increases (4.6% with ZL-2401 vs. 3.3 for linezolid) and headache (3.5% with ZL-2401 vs. 2.2% with linezolid). Drug-related TEAEs were 37.8% for ZL-2401 vs. 14.2% for linezolid (including gastrointestinal events). Discontinuation for TEAEs was uncommon, 1.6% for ZL-2401 vs. 0.8% for linezolid. Serious TEAEs occurred in 1.4% of ZL-2401 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 ZL-2401 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 ZL-2401 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

ZL-2401 has been evaluated in more than 20 Phase I studies, including food-effect, age and gender, and renal / hepatic insufficiency studies.

ZL-2401 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 ZL-2401 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.

ZL-2401 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. ZL-2401 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 ZL-2401 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 ZL-2401.

ETX2514 (ZL-2402)

ETX2514 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, ETX2514 reduces the minimum inhibitory concentration, or MIC, against this organism and restores susceptibility to sulbactam. It is being developed by Entasis as ETX2514SUL, a combination of ETX2514 and sulbactam. The microbiologic efficacy of this combination was demonstrated in large studies of well-characterized MDR Acinetobacter isolates from diverse regions, including Asia. ETX2514SUL was bactericidal and active against penem-resistant Acinetobacter organisms. ETX2514SUL was synergistic with imipenem, further lowering MICs on in-vitro testing. The FDA has granted ETX2514SUL QIDP, Fast Track and Priority Review status.

ETX2514 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 ETX2514. Single ascending dose and multiple ascending does studies showed that ETX2514 alone and in combination with sulbactam or imipenem is well tolerated and safe. There were no noticeable drug-drug interactions.

Entasis plans to develop ETX2514SUL for the treatment of severe A. baumannii infections. Entasis anticipates initiating a Phase II cUTI trial starting in 2018 and a pivotal Phase III trial in MDR Acinetobacter infections in 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 are no reports of mcr-1 resistance in Acinetobacter but the risk is high that this mobile resistance plasmid 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 European Union, the incidence of infection is between 80,000 and 120,000 patients per year in each region. The incidence is higher in Asia-Pacific 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.

ETX2514 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, ETX2514 has demonstrated much greater potency against many β-lactamases, especially the Class D OXA enzymes prevalent in Acinetobacter.

Fugan* (*ZL-3101)

Overview

ZL-3101 is a topical botanical product with anti-inflammatory properties. for the treatment of. The active ingredients in ZL-3101, *glycyrrhizae radix et rhizoma* and *sophorae flavescentis*, have a long tradition of use in China for the treatment of mild / moderate forms of eczema and psoriasis. Our management team acquired global rights to this product from GSK in 2016 for development as a potentially steroid-sparing treatment for these conditions.

We started a well-designed placebo-controlled double-blind Phase II study that incorporated two dosing regimens in patients with mild / moderate atopic dermatitis in China in the second quarter of 2017. The primary efficacy endpoint was a change in EASI from baseline to day 21 of treatment compared to placebo. Although the study showed that topical ZL-3101 was safe and well-tolerated, treatment showed no difference compared to placebo in EASI score improvement, the primary efficacy endpoint.

Given the lack of efficacy with either ZL-3101 dose regimen, we discontinued this program for reasons of futility.

Overview of Our License Agreements

Tesaro

In September 2016, we entered into a collaboration, development and license agreement with TESARO Inc., or Tesaro, which was subsequently acquired by GlaxoSmithKline plc, or GSK, under which we obtained an exclusive sub-license under certain patents and know-how that 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 (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 from GSK to develop and commercialize certain follow-on compounds of niraparib being developed by Tesaro 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 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 that is necessary or advisable to maintain compliance with the terms of Tesaro's license agreements with Merck Corp. and AstraZeneca UK Limited.

Under the terms of the agreement, we made an upfront payment of $15.0 million to Tesaro. If we achieve a specified regulatory, development and commercialization milestones, we may be required to pay aggregate milestone payments up to $39.5 million to Tesaro. In addition, if we successfully develop and commercialize the licensed products, we will pay Tesaro 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 to eliminate Tesaro's option to co-market niraparib in the licensed territory.

The agreement with Tesaro 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. Upon early termination of the agreement, we must grant to Tesaro an exclusive license under certain of our intellectual property to develop and commercialize the licensed products outside the licensed territory.

Paratek

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda, Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., 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 milestone payments up to $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.

Five Prime

In December 2017, we entered into a collaboration and license agreement with Five Prime Therapeutics, Inc., or Five Prime, under which we obtained exclusive rights to develop and commercialize Five Prime's proprietary afucosylated FGFR2b antibody known as FPA144, and all fragments, conjugates, derivatives and modifications thereof in mainland 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 FPA144 in combination with FOLFOX in front-line gastric and gastroesophageal cancer, or the 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 million and a milestone payment of $2.0 million to Five Prime. Additionally, we may be required to pay aggregate developmental and regulatory milestone payments up to $37 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 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 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.

Bristol-Myers Squibb

In March 2015, we entered into a collaboration and license agreement with Bristol-Myers Squibb Company, or 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 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 up to $114.5 million for the achievement of certain development and sales milestone events, 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.

Entasis

In April 2018, we entered into a collaboration and license agreement with Entasis Therapeutics Holdings, Inc., or Entasis, under which we obtained exclusive rights to develop and commercialize Entasis's proprietary compounds known as ETX2514 and ETX2514SUL, 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 (ETX2514SUL) 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 contract research organization) with clinical and financial support in the territory for the global pivotal Phase III clinical trial of ETX2514SUL as set forth in mutually agreed development plans.

We made an upfront payment of $5.0 million to Entasis, and we may be required to pay Entasis aggregate development, regulatory and research milestone payments up to $46.6 million and aggregate commercial milestone payments up to $52 million. We are also responsible for a portion of the costs of the global pivotal Phase III clinical trial of ETX2514SUL 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.

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. Sanofi retains the non-exclusive right to use the licensed compound to conduct internal research and manufacture the licensed compound and licensed product for such research.

We are obligated to use commercially reasonable efforts to develop and commercialize the licensed product in each of the major market countries. Sanofi has the option to exclusively negotiate with us to obtain the exclusive rights to commercialize the licensed product in the oncology field in such major market countries or throughout the world under certain circumstances.

Under the terms of the agreement, we made upfront payments to Sanofi totaling $0.5 million. We may be required to make milestone payments to Sanofi up to $31.0 million for the achievement of certain development and regulatory milestone events. In addition, we will pay Sanofi tiered royalties at percentage rates in the range of high single digits to low double digits 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 country-by-country basis. If we sublicense, transfer or assign (other than through a change of control transaction) the right to the licensed product to third parties, we are also required to pay to Sanofi a share of our sublicensing income.

The agreement with Sanofi 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. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to Sanofi. Sanofi has the right to terminate the agreement if we challenge any of the licensed patents. Sanofi may also terminate the agreement for our bankruptcy or insolvency. 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.

MacroGenics

In November 2018, we entered into a collaboration agreement MacroGenics Inc., or MacroGenics. Under the terms of the collaboration agreement, MacroGenics exclusively licensed to us regional development and commercialization rights to margetuximab, MGD013 and an undisclosed multi-specific TRIDENT molecule in preclinical development, or the TRIDENT molecule, and, together with margetuximab and MGD0213, 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 MacroGenics a non-refundable, up-front license fee in the amount of $25.0 million in January 2019. We also agreed to pay certain development and regulatory-based milestone payments of up to $140.0 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 MGD013 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.

Novocure

In September 2018, we entered into a License and Collaboration Agreement with Novocure Limited, or Novocure. Under the terms of the agreement, Novocure exclusively licensed to us the rights to perform clinical studies, sublicense to affiliates and third parties (subject to Novocure's consent), sell, offer for sale and import TTFields 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, up-front license fee in the amount of $15 million. We also agreed to pay certain development, regulatory and commercial milestone payments up to $78 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.

GSK

In August 2018, we elected to discontinue development of Fugan (ZL-3101), which we obtained worldwide, exclusive rights to in 2016 under our license and transfer agreement with GlaxoSmithKline (China) R&D Co., Ltd, or GSK China, an affiliate of GSK.

UCB

In January 2019, we terminated our license agreement with UCB Biopharma Sprl, under which we obtained an exclusive and worldwide license under certain patents and know-how of UCB Biopharma Sprl to develop, manufacture, use, sell, import and commercialize UCB Biopharma Sprl's proprietary antibody UCB3000, or the licensed compound, or ZL-1101 for the treatment, prevention and diagnosis of any human diseases. The license that we retained was reverted back to UCB Biopharma Sprl immediately upon termination of the license agreement and we have no continuing obligations (financial or otherwise) thereunder.

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 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, 2018, we exclusively licensed two issued patents in the PRC 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 the PRC 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 do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC.

Optune (TTFields)

As of December 31, 2018, we licensed eight issued patents in the PRC and Hong Kong that relate to Optune (TTFields). An additional seven patent applications that relate to Optune (TTFields) 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.

ZL-2401

As of December 31, 2018, we exclusively licensed four issued patents in the PRC directed to ZL-2401’s compound, formulations and crystal form and one pending patent application in the PRC directed to other crystalline forms of ZL-2401. The issued composition of matter patent covering ZL-2401 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 ZL-2401, which expire in 2029. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC, Hong Kong and Taiwan.

FPA144

As of December 31, 2018, we exclusively licensed one issued patent in the PRC 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 the PRC, 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 the PRC, Hong Kong and Taiwan.

ZL-2301

As of December 31, 2018, we exclusively licensed four issued patents in the PRC, one issued patent in Taiwan and one issued patent in Hong Kong that relate to ZL-2301. Of these issued patents, one patent in the PRC is a composition-of-matter patent that covers the ZL-2301 compound and its analogues. One patent in the PRC covers the medical use of ZL-2301. These patents are projected to expire in 2023. Our exclusively licensed patents also include a patent in the PRC that covers a manufacturing process for intermediates useful in the synthesis of ZL-2301's API. This patent is projected to expire in 2027. In addition, one patent we exclusively licensed in the PRC 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 the PRC and Hong Kong.

ETX2514

As of December 31, 2018, we exclusively licensed one issued patent in the PRC, one issued patent in Japan, and a corresponding issued patent or pending patent application in each of several additional jurisdictions in the territory of the Entasis Agreement, including Australia, Hong Kong, Taiwan and Korea. These issued patents or pending applications are directed to certain beta-lactamase inhibitor compounds, including ETX2514, 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 the PRC, 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.

ZL-2302

As of December 31, 2018, we exclusively licensed one issued patent application in the PRC. We also exclusively licensed two issued U.S. patents, one pending U.S. patent application, and 15 issued patents and 28 pending patent applications in other jurisdictions, including Australia, Canada, Europe, Japan, South Korea and Taiwan. The issued patents in this portfolio are directed to the pharmaceutical composition and therapeutic uses of ZL-2302, and are projected to expire between 2032 and 2033, excluding any additional term for patent term adjustments or patent term extensions in jurisdictions where such adjustments and extensions are available.

ZL-1101

As of December 31, 2018, we exclusively licensed one issued patent and one pending patent application in the PRC. We also exclusively licensed three issued U.S. patents, two pending U.S. patent applications and approximately 26 issued patents and 44 pending patent applications in other jurisdictions, including Australia, Canada, Europe, Hong Kong, Japan, South Korea, South Africa and Taiwan. The issued patents and pending patent applications in this portfolio cover antibody sequences and therapeutic uses of ZL-1101. The issued patents in this portfolio are projected to expire between 2030 and 2032.

Margetuximab

As of December 31, 2018, we exclusively licensed two pending patent applications in the PRC and one issued patent in Hong Kong. The issued patent and 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.

MGD013

As of December 31, 2018, we exclusively licensed three pending patent applications in the PRC, two issued patents in Hong Kong, and three pending patent applications in Taiwan. The issued patents and pending patent applications in this portfolio cover antibody sequences and therapeutic uses of MGD013. The issued patents and any patents issuing from the currently pending applications are projected to expire between 2035 and 2036.

Undisclosed multi-specific TRIDENT molecule

As of December 31, 2018, 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 the PRC 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 the PRC. 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 “再鼎医药” brands, as well as domain names incorporating some or all of these trademarks.

Employees

As of December 31, 2018, we employed a total of 309 full-time employees, including a total of 49 employees with M.D. or Ph.D. degrees. Of our workforce, 183 employees are engaged in research and development. None of our employees is represented by labor unions or covered by collective bargaining agreements.

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 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 SDA 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 2017, the drug regulatory system entered a new and significant period of reform. The State Council and the China 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 NMPA is 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. However, as of February 28, 2019, the proposed amendment to the Drug Administration Law and its implementing regulations has not been enacted by the National People's Congress.

Regulatory authorities

In the PRC, 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 the PRC, or the MOH, as part of the institutional reform of the State Council. Predecessors of the NMPA also include the former State Food and Drug Administration (SFDA) that was established in March 2003 and the State Drug Administration (SDA) 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 the PRC;
- 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 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 Ministry of Health, or MOH. Following the establishment of the former State Food and Drug Administration (SFDA) in 2003, the MOH was put in charge of the overall administration of the national health in the PRC excluding the pharmaceutical industry. The MOH performs a variety of tasks in relation to the health industry such as establishing medical institutes and producing professional codes of ethics for public medical personnel. The MOH is also responsible for overseas affairs, such as dealings with overseas companies and governments.

The central government expects to complete the restructuring at the state level by the end of 2018. Municipal and county level authorities must complete the restructure by first quarter of 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 13th 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 13th 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 the PRC.

Certain amendments to the PRC Drug Administration Law took effect on December 1, 2001. Subsequent amendments were also made on December 28, 2013 and April 24, 2015. 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 October 2017, the former CFDA released an amendment to the Drug Administration Law (Draft for Public Comments). This draft amendment reflects the former CFDA's recent reform initiatives on the market authorization holder system, clinical trial practices, drug review and approval practices and GMP and GSP certification. This amendment was further revised in late 2018, and the revision was submitted to the National People's Congress for legislative review in 2019.

The PRC 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 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 Preclinical 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 Preclinical Laboratory promulgated in 2017. In April 2007, the former SFDA promulgated the Administrative Measures for Certification of Good Laboratory Practice of Preclinical Laboratory, providing that the NMPA is responsible for certification of nonclinical research institutions. According to the Administrative Measures for Certification of Good Laboratory Practice of Preclinical Laboratory, 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 NMPA and published on the government website.

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 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 cover (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 October 2017, the former CFDA released the revised Administrative Measures for Drug Registration (Draft for Comments) to seek comments from the public, which as compared to the current Administrative Measures for Drug Registration, includes the following key highlights:

- fully implement the marketing authorization holder system;
- reform the review and approval system and enhance the efficiency of approval;
- differentiate categories of changes and implement category management;
- emphasize clinically oriented drug innovation and achieving consistency between generic drugs and originator's drugs.

Although there is no definitive timeline for the official enactment of the revised Administrative Measures for Drug Registration (Draft for Comments), it embodies a regulatory trend of promoting drug innovation, accelerating the drug registration process and setting forth higher quality and technical requirements.

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 CDE on behalf of the NMPA. This delegation of authority can shorten the approval timeline for the approval of a CTA.

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 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 Provisions, the former CFDA 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 Provisions 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.

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 National Health and Family Planning Commission 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. In July 2018, the NMPA and the NHC jointly released the Rules for Administration of the Requirements for and Recordal of Drug Clinical Trial Institutions. The Rules specify requirements for clinical trial institutions and recordal procedures. Pursuant to the Rules, a clinical trial institution should comply with the GCP requirements 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. A drug marketing authorization applicant should only engage a duly recorded clinical trial institution to carry out a drug clinical trial. To date, over 670 hospitals in China have successfully completed the recordal with the NMPA and NHC.

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 NDA application.

Pilot Plan for 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 marketing authorization holder system, or 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. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and GMP-certified, and are also located within the piloted regions. Drugs qualified for the MAH System are: (1) new drugs (including 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 above mentioned draft amendment to the Drug Administration Law (dated November 2018) proposes to roll out this MAH System nation wide. Uncertainties exist as to how this MAH System will be implemented universally to substitute the Pilot Plan.

Administrative Protection and Monitoring Periods for New Drugs

According to the Administrative Measures for Drug Registration, the 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 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.

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.

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 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.

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 Certificates

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.

A GMP certification 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 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. Two additional annexes were published in May 2015, with detailed requirements for IT systems and validation.

The GMP certificate is valid for a term of five years and an application for renewal must be submitted six months prior to its expiration date. 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 and the Pharmaceutical GMP Certificate.

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, or FDCA, 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 United States 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 investigational new drug application, or 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.

Preclinical 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 preclinical 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, 2019, the user fee for an application requiring clinical data, such as an NDA, is approximately $2.6 million. PDUFA also imposes an annual prescription drug program fee for human drugs of approximately $300,000. 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. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter 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 Complete Response Letter 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 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 June 2018, close to 1.2 billion urban employees and residents in China were enrolled in the national medical insurance program, representing a coverage rate of 83% 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 National Healthcare Security Administration (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.

Medicines included in the NRDL are divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the NRDL in their provincial Medical Insurance Catalogue, but have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the NRDL. As a result, the contents of Part B of the provincial Medical Insurance Catalogues may differ from region to region in the PRC.

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.

National List of Essential Drugs

On August 18, 2009, 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. 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. 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 MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation), or there 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 MOH, the 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 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.

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. The reduction in distribution tiers resulted in a decrease in distribution mark-ups, hence the supply prices to public hospitals would also be reduced.

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.

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. 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.

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 2027 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 Provisions for Drug Advertisement Examination, which were promulgated on March 13, 2007 and came into effect on 1 May 2007 and amended on December 21, 2018, an enterprise seeking to advertise its drugs must apply for an advertising approval code. The validity term of an advertisement approval number for pharmaceutical drugs is one year. The content of an approved advertisement may not be altered without prior approval. Where any alteration to the advertisement is needed, a new advertisement approval number shall be obtained by submitting a reapplication.

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 NMPA. 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 PRC (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 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

Investment activities in the PRC by foreign investors are principally governed by the Catalogue for the Guidance of Foreign Investment Industry, or the Catalogue, which was promulgated and is amended from time to time by the Ministry of Commerce, or the MOFCOM, and the National Development and Reform Commission, or NDRC, and together with Existing FIE Laws and their respective implementation rules and ancillary regulations. The Catalogue lays out the basic framework for foreign investment in China, classifying businesses into three categories with regard to foreign investment: “encourage,” “restricted” and “prohibited.”. Industries not listed in the Catalogue are generally deemed as falling into a fourth category “permitted” unless specifically restricted by other PRC laws. In addition, on June 28, 2018 the MOFCOM and the NDRC jointly promulgated the Special Management Measures (Negative List) for the Access of Foreign Investment, or the 2018 Negative List, which became effective on July 28, 2018 to amend the Guidance Catalogue and the previous negative list thereunder.

On March 15, 2019, the National People's Congress promulgated the FIL, which will come into effect on January 1, 2020 and upon then the FIL will replace the Existing FIE Laws. The FIL embodies an expected regulatory trend in PRC to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition.

According to the FIL, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either “restricted” or “prohibited” in the “negative list”. The FIL provides that foreign invested entities operating in foreign “restricted” or “prohibited” industries will require entry clearance and other approvals. However, it is unclear whether the “negative list” will differ from the 2018 Negative List. The FIL also provides several protective rules and principles for foreign investors and their investments in the PRC, including, among others, that local governments shall abide by their commitments to the foreign investors; foreign-invested enterprises are allowed to issue stocks and corporate bonds; except for special circumstances, in which case statutory procedures shall be followed and fair and reasonable compensation shall be made in a timely manner, expropriate or requisition the investment of foreign investors is prohibited; mandatory technology transfer is prohibited, allows foreign investors’ funds to be freely transferred out and into the territory of PRC, which run through the entire lifecycle from the entry to the exit of foreign investment, and provide an all-around and multi-angle system to guarantee fair competition of foreign-invested enterprises in the market economy. In addition, foreign investors or the foreign investment enterprise should be imposed legal liabilities for failing to report investment information in accordance with the requirements. Furthermore, the FIL provides that foreign invested enterprises established according to the existing laws regulating foreign investment may maintain their structure and corporate governance within five years after the implementing of the FIL, which means that foreign invested enterprises may be required to adjust the structure and corporate governance in accordance with the current PRC Company Law and other laws and regulations governing the corporate governance.

The Interim Measures for Record-filing Administration of the Establishment and Change of Foreign-invested Enterprises, or FIE Record-filing Interim Measures, was issued by MOFCOM in October 2016 and revised in July 2018. Pursuant to FIE Record-filing Interim Measures, the establishment and change of foreign-invested enterprises are subject to record-filing procedures, instead of prior approval requirements, provided that the establishment or change does not involve special entry administrative measures. If the establishment or change of FIE matters involve the special entry administrative measures, the approval of the MOFCOM or its local counterparts is still required.

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 State Intellectual Property Office, or 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, 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 which was promulgated on September 2, 1993 and was amended on November 4, 2017, 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; or (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. 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. The PRC Trademark Law and its implementation rules protect registered trademarks. The PRC Trademark Office of State Administration of Industry and Commerce 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 June 30, 2017, we had two registered trademarks in China and four 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. 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, Interim Measures concerning the Maternity Insurance of Employees which become effective on December 14, 1994, 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, 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, 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

The principal regulations governing distribution of dividends paid by wholly foreign-owned enterprises include:

- Company Law of the PRC (1993), as amended in 1999, 2004, 2005 and 2013;
- Foreign Investment Enterprise Law of the PRC (1986), as amended in 2000 and 2016; and
- Administrative Rules under the Foreign Investment Enterprise Law (1990), as amended in 2001 and 2014.

Under these laws and regulations, foreign-invested enterprises in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise in China is required to set aside at least 10.0% of its after-tax profit based on PRC accounting standards each year to its general reserves until the accumulative amount of such reserves reach 50.0% of its registered capital. These reserves are not distributable as cash dividends. The foreign-invested enterprise has the discretion to allocate a portion of its after-tax profits to staff welfare and bonus funds. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

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.

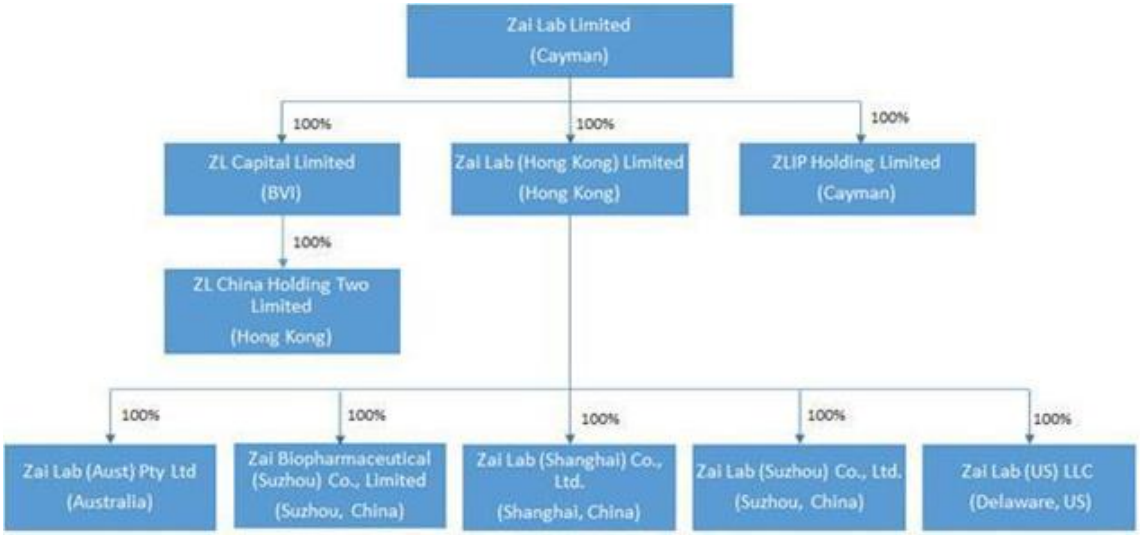
Other PRC National- and Provincial-Level Laws and Regulations

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 2020. We also have a 98 square meter office in Beijing, the lease for which expires in 2020. 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.

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 based in China and the United States 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 transform patients' lives in China and eventually leverage our capabilities to impact human health worldwide.

Since our founding in 2014, we have constructed a broad and validated innovative pipeline currently consisting of eight clinical-stage drug candidates with potentially differentiated profiles, in addition to other assets, through partnerships with global biopharmaceutical companies. Our clinical-stage portfolio includes seven late-stage assets targeting large, fast growing segments of China's pharmaceutical market. Across our broader portfolio, we currently have over 20 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, 2016, 2017 and 2018 was $37.5 million, $50.4 million and $139.1 million, respectively.

Basis of Presentation

Our consolidated statement of operations data for the years ended December 31, 2016, 2017 and 2018 and our consolidated statement of financial position data as of December 31, 2016, 2017 and 2018 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 six clinical-stage 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 a follow-on offering in September 2018. Through December 31, 2018, we have raised approximately $164.6 million in private equity financing and approximately $298.0 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 offering. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $32.2 million, $32.4 million and $97.5 million for the years ended December 31, 2016, 2017 and 2018, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our six clinical-stage drug candidates and continue research and development of our preclinical-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 prepare to commercialize, develop, and manufacture our products. 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. Eight 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 $17.1 million, $8.0 million and $59.2 million for the years ended December 31, 2016, 2017 and 2018, 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 the PRC are governed by the EIT Law and regulations. Under the EIT Law, the standard Enterprise Income Tax, or 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)	**2018**	**2017**	**2016**
Comprehensive Loss Data:			
Revenue	129	—	—
Cost of sales	(43)	—	—
Gross profit	86	—	—
Operating expenses:			
Research and development	$ (120,278)	$ (39,342)	$ (32,149)
Selling, general and administrative	(21,576)	(12,049)	(6,380)
Loss from operations	(141,768)	(51,391)	(38,529)
Interest income	3,261	527	403
Interest expenses	(40)		
Changes in fair value of warrants	—	200	(1,920)
Other income	1,968	933	2,534
Other expense	(1,909)	(403)	—
Loss before income tax and share of loss from equity method investment	(138,488)	(50,134)	(37,512)
Income tax expense	—	—	—
Share of loss from equity method investment	(587)	(250)	—
Net loss attributable to ordinary shareholders	$ (139,075)	$ (50,384)	$ (37,512)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	52,609,810	21,752,757	9,439,028
Net loss per share, basic and diluted	$ (2.64)	$ (2.32)	$ (3.97)

Year Ended December 31, 2018 Comparted 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
Preclinical 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 preclinical 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 preclinical 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. 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. 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 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 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 expense was 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

Other income increased by $1.0 million for year ended December 31, 2018 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 $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.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

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)	**2017**	**%**	**2016**	**%**
Research and development expenses:				
Personnel compensation and related costs	$ 9,370	23.8	$ 6,095	19.0
Licensing fees	7,948	20.2	17,108	53.2
Payment to CROs/CMOs/Investigators	14,993	38.1	6,759	21.0
Other costs	7,031	17.9	2,187	6.8
Total	$ 39,342	100.0	$ 32,149	100.0

Research and development expense increased by $7.2 million to $39.3 million for year ended December 31, 2017 from $13.6 million for year ended December 31, 2016. The increase in research and development expenses included the following:

- $3.3 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, 2017 and the grants of new share options and vesting of restricted shares to certain employees; and
- $8.2 million for increased payment to CROs/CMOs in fiscal year 2017 as we advanced our drug candidate pipeline; and
- $4.8 million for increased rental fee, lab consumables and professional service expenses.

These increases were offset by a $9.1 million decrease in licensing fees as we incurred $17.1 million in licensing fees in fiscal year 2016 compared to $8.0 million in licensing fees in fiscal year 2017.

The following table summarizes our research and development expenses by program for the years indicated.

	Year ended December 31,			
(in thousands)	2017	%	2016	%
Research and development expenses:				
Clinical programs	$ 12,614	32.1	$ 20,129	62.6
Preclinical programs	14,755	37.5	4,839	15.1
Unallocated research and development expenses	11,973	30.4	7,181	22.3
Total	$ 39,342	100.0	$ 32,149	100.0

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 preclinical programs, respectively. During the year ended December 31, 2016, 62.6% and 15.1% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. ZEJULA represented approximately 43% and 63% of our external research and development expense, which includes payments to CROs, CMOs and investigators, for the year ended December 31, 2017 and 2016, respectively. ZL-2401 represented approximately 45% of our external research and development expense, which includes licensing fees and payment to CROs and CMOs, for the year ended December 31, 2017. No other programs represented a significant amount of research and development expense for the years ended December 31, 2017 or December 31, 2016. 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.

General and Administrative Expenses

The following table sets forth the components of our general and administrative expenses for the years indicated.

	Year ended December 31,			
(in thousands)	2017	%	2016	%
General and Administrative Expenses:				
Personnel compensation and related costs	$ 7,331	60.9	$ 3,120	48.9
Professional service fee	2,977	24.7	2,691	42.2
Other costs	1,741	14.4	569	8.9
Total	$ 12,049	100.0	$ 6,380	100.0

General and administrative expenses increased by $5.6 million to $12.0 million for year ended December 31, 2017 from $6.4 million for year ended December 31, 2016. The increase in general and administrative expenses included the following:

- $4.2 million for increased personnel compensation and related costs which was primarily attributable to increased administrative personnel compensation costs, due to hiring of more personnel during year ended December 31, 2016 and the grants of new share options and vesting of restricted shares to certain employees; and
- $1.1 million for increased other costs due to the increase of rental, travel and depreciation expenses in fiscal year 2017.

Interest Income

Interest income increased by $0.1 million for year ended December 31, 2017 due to higher cash balance in 2016.

Changes in Fair Value of Warrants

On December 31, 2015, we entered into a warrant agreement with an investor to purchase up to 461,808 of our Series A2 preferred shares at $2.1651 per share. The fair value of the warrants of $2.0 million was expensed on the date of issuance and an additional $1.9 million change in fair value was expensed in 2016 on the re-measurement date. An additional $0.2 million income was recognized upon re-measurement in 2017. The warrants were exercised on July 19, 2017. Upon such conversion of the underlying preferred stock, the preferred stock was classified as a component of equity and was no longer subject to re-measurement.

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 $249,652 related to this investment was recorded for the year ended December 31, 2017.

Other Income

Other income decreased by $1.6 million for year ended December 31, 2017 primarily as a result of a decrease in governmental subsidies.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $50.4 million for the year ended December 31, 2017 compared to net loss attributable to ordinary shareholders of $37.5 million for the year ended December 31, 2016.

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.

Share-Based Compensation

Awards Granted to Employees

We grant share options to eligible employees, management and directors and account for these share-based awards in accordance with ASC 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 11 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, 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 purposes of applying ASC 250, and shall be applied prospectively to new awards.

Awards Granted to Non-Employees

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 non-employees.

Fair Value Measurements

We apply ASC Topic 820, *Fair Value Measurements and Disclosures*, of 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 and cash equivalents, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable, and other payables. 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 payables approximated their fair values due to the short-term maturity of these instruments. The warrant liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. We determined the fair values of the warrant liabilities with the assistance of an independent third party valuation firm, and we have measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of each reporting date.

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, 2017 and 2018, 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 $139.1 million, $50.4 million and $37.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $249.6 million. Our primary use of cash is to fund research and development costs. Our operating activities used $97.5 million, $32.4 million and $32.2 million of cash flows during the years ended December 31, 2018, 2017 and 2016, respectively. Historically, we have financed our operations principally through proceeds from private placements of preferred shares and warrants of $164.6 million as well as proceeds from our initial public offering and subsequent follow-on offering. As of December 31, 2018, we had cash and cash equivalents and short-term investments of $263.3 million. Our expenditures as a company principally focused on R&D, 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 December 31, 2018, 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 R&D 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, 2018, 2017 and 2016, 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 the PRC may further restrict our PRC subsidiaries from transferring funds to us in the form of dividends, loans and advances. As of December 31, 2018, amounts restricted are the paid-in capital of our PRC subsidiaries, which amounted to $91.0 million.

The following table provides information regarding our cash flows for the years ended December 31, 2018, 2017 and 2016:

	Year ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Net cash (used in) operating activities	$ (97,538)	$ (32,367)	$ (32,158)
Net cash (used in) investing activities	(212,554)	(10,434)	(2,730)
Net cash provided by financing activities	144,147	187,860	106,200
Effect of foreign exchange rate changes	(763)	652	(524)
Net (decrease) increases in cash and cash equivalents	$ (166,708)	$ 145,711	$ 70,788

Net cash used in operating activities

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.

During the year ended December 31, 2016, our operating activities used $32.2 million of cash, which resulted principally from our net loss of $37.5 million, adjusted for non-cash charges of $7.0 million, and by cash used in our operating assets and liabilities of $1.7 million. Our net non-cash charges during the year ended December 31, 2016 primarily consisted of $0.2 million depreciation expense, $4.9 million share-based compensation expense and $1.9 million loss from changes in fair value of warrants.

Net cash used in investing activities

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 used in investing activities was $10.4 million for the year ended December 31, 2017 compared to $2.7 million for the year ended December 31, 2016. The increase in cash used in investing activities was due to the construction of our small molecule and large molecule facilities and other investments in 2017.

Net cash provided by financing activities

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 ADS in our subsequent follow-on offering in 2018.

Net cash provided by financing activities was $187.9 million for the year ended December 31, 2017 compared to $106.2 million for the year ended December 31, 2016. The increase was due to the issuance of Series C preferred shares and the issuance of ADS in our initial public offering.

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, 2018. Amounts we pay in future periods may vary from those reflected in the table.

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
			(in thousands)		
Operating Lease Obligations	$ 3,341	$ 2,169	$ 1,172	$ —	$ —
Purchase Obligations	1,455	1,455	—	—	—
Total	$ 4,796	$ 3,624	$ 1,172	$ —	$ —

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 ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The standard is effective on January 1, 2019, with early adoption permitted. We adopted the new standard on January 1, 2019 and use the effective date as the date of initial application. In July 2018, the FASB issued an update that provided an additional transition option that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the consolidated financial statements. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. We elected this optional transition method. As of December 31, 2018, we have $3.3 million of future minimum operating lease commitments that are not currently recognized on its consolidated balance sheets. Therefore, we would expect changes to its consolidated balance sheets for the recognition of these and any additional leases entered into in the future upon adoption.

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 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. As of December 31, 2018, there was $93,822 of total unrecognized compensation expense related to unvested non-employee options or RSU. We do not expect the requirements of ASU 2018-07 will have a material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): The amendments in ASU 2018-13 eliminate the requirements to disclose the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, valuation processes for Level 3 fair value measurements, and policy for timing of transfers between levels. ASU 2018-13 also provides clarification in the measurement uncertainty disclosure by explaining that the disclosure is to communicate information about the uncertainty in measurement as of the reporting date. In addition, ASU 2018-13 added the following requirements: 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 range and weighted average of significant unobservable inputs used in Level 3 fair value measurements. Finally, ASU 2018-13 updated language to further encourage entities to apply materiality when considering de minimis for disclosure requirements. The guidance will be applied retrospectively for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with the exception of amendments to changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used for Level 3 fair value measurements, and the narrative description of measurement uncertainty which will be applied prospectively. Early adoption is 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.

JOBS Act Exemptions and Foreign Private Issuer Status

We qualify as an “emerging growth company” as defined in the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, have more than $700.0 million in market value of our ordinary shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events; and
- Regulation FD, which regulates selective disclosures of material information by issuers.

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 and officers as of March 1, 2019, 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	54	Director, Chairman and Chief Executive Officer
Tao Fu	47	Director, President & Chief Operating Officer
Yongjiang Hei	56	Chief Medical Officer, Oncology
Harald Reinhart	67	Chief Medical Officer, Autoimmune and Infectious Diseases
Billy Cho	41	Chief Financial Officer
William Liang	48	Chief Commercial Officer
Ning Xu	54	Executive Vice President, Head of Clinical and Regulatory
James Yan	55	Executive Vice President, Pre-clinical Development and Program & Portfolio Management
Non-Management Directors		
Kai-Xian Chen	73	Director
Nisa Leung	48	Director
William Lis	54	Director
Peter Wirth	68	Director; Senior Advisor
John Diekman	76	Director
Other Key Employees		
Jonathan Wang	37	Senior Vice President, Head of Business Development
Bo Zhang	46	Senior Vice President, Chemistry, Manufacturing and Controls
Zhengqi (Mary) Sun	52	Vice President, Regulatory Affairs
Xiaopeng (Tom) Feng	46	Vice President, Finance
Yunpeng Su	44	Vice President, Head of Biologics Discovery, China
Scientific Advisors		
Lieping Chen	62	Scientific Advisor
Richard A. Flavell	73	Scientific Advisor
Gwen Fyfe	67	Scientific Advisor
Neal Rosen	68	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 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 Bristol-Myers Squibb 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.

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 GlaxoSmithKline. 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.

Non-Management Directors

Kai-Xian Chen, Ph.D. joined our company as Director in 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 Science and Technology Association. 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 Ministry of Science and Technology, or 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 the PRC's 10th -13th Five Year Plans. In 1999, Professor Chen was elected as a member of the Chinese Academy of Sciences. Prior to that, Professor Chen 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 served as Chief Executive Officer and a Director of Portola Pharmaceuticals, Inc. from 2010 until 2018 after serving as Chief Operating Officer and Chief Business Officer from 2008 until 2009. Under his leadership, Portola successfully grew from a discovery stage company to a fully integrated R&D and commercial organization, and independently advanced: Andexxa and Bevyxxa from discovery and early stage development through commercial launch; cerdulatinib, a novel immunology and oncology compound, from discovery through Phase III. He led corporate partnerships and private and public financings including an initial public offering in 2013. The company's valuation grew from $250 million to $2.7 billion during his tenure. Prior to Portola, Mr. Lis held executive and management positions at Scios, Inc. (a Johnson & Johnson company) from 2003 to 2008 where he last served as Vice President of Commercial Operations and Business Development, having led efforts for the in-licensing, and then the strategic development and pre-commercial launch for Xarelto; and served on the Janssen West Coast Research and Development Committee. He also held positions of increasing responsibility at Millennium Pharmaceuticals, Inc. (previously COR Therapeutics, Inc.) from 1998 to 2003 in sales and marketing, medical affairs and business development for INTEGRILIN and early stage compounds. Earlier in his career, he was involved in the U.S. commercial launch of several products with multiple pharmaceutical companies, including Lovenox and Rilutek while at Rhone-Poulenc Rorer. Mr. Lis served as a member of the Bio Board of Directors, Emerging Companies Section in 2015 and 2016 and served as an Independent Director of Eidos Therapeutics, Inc. since December, 2018. 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-focused biotechnology company; director of 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.

Other Key Employees and Advisors

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.

Bo Zhang, Ph.D. has been our Senior Vice President, chemistry, manufacturing and controls since 2014. Prior to joining our company, Dr. Zhang was a director of the nature product business unit at GlaxoSmithKline, where he was responsible for chemistry, manufacturing and controls development. From 2010 to 2013, Dr. Zhang served as Senior Director of Hutchison Medi-Pharma, where he was responsible for chemistry, manufacturing and controls development. Before returning to China, Dr. Zhang had significant experience at Pfizer in the United States. Dr. Zhang received a Ph.D. in analytical chemistry from Iowa State University and a masters degree in chemical fibers from Sichuan University.

Mary Sun has been our Vice President of Regulatory since October 2018. Prior to joining our company, she had been working at Pfizer for nearly 20 years as regulatory Project & Effectiveness Director, leading team to provide supports for more than 30 in-line products maintenance, and more than 10 new products registration in China. Ms. Sun also had significant experience in many therapeutic areas, especially oncology and anti-inflammation areas. Under her leadership, the team successfully received over ten NDA approvals in China such as Palbociclib, Crizotinib, Sunitinib, Axitinib, Tofacitinib and Lyrica. Before joining Pfizer, Mary served as regulatory affairs head at Ethypharm, where she effectively established regulatory affairs team as the first regulatory colleague. She has been actively involved in several CDE working groups. Ms. Sun got her bachelor degree of Biology from Shanghai Normal University and completed Peking University MBA course.

Xiaopeng (Tom) Feng has been our Vice President, finance since 2017. Prior to joining our company, Mr. Feng was the Financial Director of Ascletis Bioscience Limited, where he was responsible for financial reporting and management. From 2012 to 2015, Mr. Feng served as financial controller of GMT Shipping Nigeria. From 2002 to 2011, Mr. Feng served as Financial Director in various subsidiaries of Hutchison China MediTech Limited. Mr. Feng received a bachelor of economics from Fudan University. He is a member of CICPA and a fellow member of the FCCA.

Yunpeng Su, M.D. has been our Vice President, Head of Biologics Discovery China since August 2018. He has also been a Visiting Professor in Institute of Health, the Chinese Academy of Sciences since March 2016. Prior to joining our company, Dr. Su built novel antibody drug discovery platforms and led the research and development team to develop novel antibodies, bispecific antibodies and nanobodies at Simcere Pharmaceutical Group from 2011 to 2014 and NovoMab Biopharmaceuticals Inc. from 2011 to 2014. Prior to that, Dr. Su was Assistant Professor & Associate Director, Cancer Research Institute, Scott & White Hospital at Texas A&M University, College of Medicine, U.S. His research focused on a variety of anti-cancer drug discovery including antibodies, recombinant proteins and small molecules. Dr. Su received his M.Sc. in Protein Engineering and Molecular Biology from Peking University and Ph.D. in Biochemistry and Immunology from University of Oxford, UK.

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.

Gwen Fyfe, M.D. has served on our Scientific Advisory Board since 2016. Since 2009, Dr. Fyfe has been a consultant for venture capital firms and for a variety of biotechnology companies. From 1997 to 2009, Dr. Fyfe held various positions with Genentech Inc. (now a member of the Roche Group), including Vice President, Oncology Development and Vice President, Avastin Franchise Team, as well as the honorary title of Senior Staff Scientist. Dr. Fyfe played an important role in the development of Genentech's approved oncology agents including Rituxan, Herceptin, Avastin and Tarceva. From 1990 to 1997, Dr. Fyfe was Medical Director at Chiron Therapeutics. Dr. Fyfe currently serves as a director of Array Biopharma, Inc., Cascadian Therapeutics and Molecular Partners AG and previously served as a director of Infinity Pharmaceuticals, Inc. Dr. Fyfe received a medical degree from Washington University and is a board-certified pediatric oncologist. She has been an invited member of Institute of Medicine panels, National Cancer Institute working groups and grant committees and American Society of Clinical Oncologists oversight committees.

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.

B. Compensation

Employment Arrangements with Our Executive Officers

We have entered into employment agreements with each of our executive officers and our directors (other than our non-employee directors) (together, the "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 and Dr. Reinhart are each employed by Zai Lab (US) LLC pursuant to amended and restated employment agreements that became effective on January 25, 2019 and December 1, 2018, 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, Dr. Xu and Dr. Yan are 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 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 of the Company (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 of the Company (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, 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 original employment location (for Dr. Du, Dr. Reinhart and Mr. Fu, 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 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.

Executive officers working for Zai Lab (Shanghai) Co., Ltd., except for Dr. Reinhart, Mr. Fu and Mr. Cho, are 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 of the Company (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 (iv) 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, 2018, we paid aggregate salaries, bonuses and benefits (excluding equity-based grants) of approximately $4.35 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, 2018, we paid aggregate cash retainers (excluding equity-based grants and consulting fees) of approximately $216,848 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. The Administrator may grant performance awards that are intended to qualify as exempt performance-based compensation under Section 162(m), to the extent applicable, and awards that are not intended to so qualify.

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.

Performance criteria. Our 2017 Equity Plan provides for grants of performance awards subject to "performance criteria." Performance criteria with respect to those awards that are intended to qualify as "performance-based compensation" for purposes of Section 162(m) are limited to objectively determinable 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, consistent with the requirements of Section 162(m) of the Code, to the extent applicable): 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 including 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. To the extent consistent with the requirements of the performance-based compensation exception under Section 162(m) of the Code, the Administrator may provide in the case of any award intended to qualify for such exception that one or more of the performance criteria applicable to such award will be adjusted in an objectively determinable manner to reflect events (for example, but without limitation, acquisitions or dispositions) occurring during the performance period that affect the applicable performance criteria. 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 15, 2019.

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
Harald Reinhart	66,666		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
	100,000	(2)	N/A		N/A	March 2, 2018
Ning Xu	211,666		N/A	US$	0.60	March 5, 2015
	450,000		N/A	US$	0.60	October 22, 2015
James Yan	333,333		N/A	US$	0.60	October 22, 2015
	83,333		N/A	US$	1.74	August 25, 2016
William Liang	375,000		N/A	US$	23.80	June 4, 2018
	125,000	(2)	N/A		N/A	June 4, 2018
Yongjiang Hei	375,000		N/A	US$	22.00	August 6, 2018
	125,000	(2)	N/A		N/A	August 6, 2018
Peter Wirth	12,500	(2)	N/A		N/A	January 1, 2018
	12,500	(2)	N/A		N/A	January 10, 2019
Tao Fu	25,000	(2)	N/A		N/A	September 20, 2017
	12,500	(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
Kaixian Chen	12,500	(2)	N/A		N/A	August 30, 2018
	12,500	(2)	N/A		N/A	January 10, 2019
William Lis	12,500	(2)	N/A		N/A	October 8, 2018
	12,500	(2)	N/A		N/A	January 10, 2019

(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 (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. The maximum amount payable to any participant in any calendar year under awards intended to satisfy the requirements of the performance-based compensation exception under Section 162(m) of the Code, to the extent applicable, is $5,000,000.

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, and any amendment will be approved by our stockholders if required by Section 162(m) of the Code.

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. Further, commencing in calendar year 2018, non-employee directors became eligible to receive an annual grant of 12,500 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 seven directors, of whom two 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 Professor Kai-Xian Chen, 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 Professor Chen each satisfies 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 Professor Kai-Xian Chen, 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 consists 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.

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, 2018, 2017 and 2016, we had 309, 88 and 50 full-time employees, respectively. None of our employees are represented by labor unions or covered by collective bargaining agreements. The number of employees by function as of the end of the period for our fiscal years ended December 31, 2018, 2017 and 2016 was as follows:

By Function	2018	2017	2016
Research and Development	183	52	36
Commercial	55	—	—
Manufacture	46	20	4
General and Administrative	25	16	10
Total	309	88	50

E. Share Ownership.

We had 58,355,903 ordinary shares outstanding as of March 1, 2019. The following table and accompanying footnotes set forth information relating to the beneficial ownership of our ordinary shares as of March 1, 2019 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)	9,601,826	15.9 %
Tao Fu(2)	20,833	*
Harald Reinhart(3)	56,666	*
Yongjiang Hei	—	—
Billy Cho(4)	100,000	*
William Liang	—	—
Ning Xu(5)	487,832	*
James Yan(6)	266,648	*
Peter Wirth(7)	312,500	*
John Diekman(8)	20,833	*
Nisa Leung	—	—
Kai-Xian Chen	—	—
William Lis	—	—
All Executive Officers and Directors as a Group	10,867,138	17.7 %
Beneficial Owners of 5% or More of our Ordinary Shares:		
QM 11 Limited(9)	10,470,933	17.9 %
Investment funds affiliated with Advantech Capital(10)	7,167,397	12.3 %
The Z Trust(11)	4,289,930	7.4 %
FMR, LLC(12)	5,810,578	10.0 %
Investment funds affiliated with Sequoia Capital(13)	3,884,152	6.6 %
KPCB China Fund II, L.P.(14)	3,437,311	5.9 %

* 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 2,195,850 ordinary shares issuable to Dr. Du upon exercise of vested options and options exercisable within 60 days of March 1, 2019. Includes 6,030,323 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 20,833 vested restricted shares and restricted shares will be vested within 60 days of March 1, 2019.

(3) Includes 56,666 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 1, 2019.
(4) Includes 80,000 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 1, 2019 and 20,000 vested restricted shares and restricted shares will be vested within 60 days of March 1, 2019.
(5) Includes 487,832 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 1, 2019.
(6) Includes 266,648 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 1, 2019.
(7) Includes 12,500 vested restricted shares and restricted shares will be vested within 60 days of March 1, 2019.
(8) Includes 20,833 vested restricted shares and restricted shares will be vested within 60 days of March 1, 2019.
(9) Based on a Schedule 13G filed on February 13, 2019. The address for QM 11 Limited is Units 4206-06 Gloucester Tower, The Landmark, Central, Hong Kong.
(10) Based on a Schedule 13G filed on February 13, 2018. Consists of (i) 6,734,064 ordinary shares held by Maxway Investment Limited and (ii) 433,333 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.
(11) The address for The Z Trust is 16015 Huebner BLF, San Antonio, Texas 78248-1469.
(12) Based upon the information provided by FMR LLC in a Schedule 13G filed on February 13, 2019. Abigail P. Johnson is a Director 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) Based on a Schedule 13G filed on February 14, 2018. Consists of (i) 2,986,278 ordinary shares held by Sequoia Capital CV IV Holdco, Ltd. and (ii) 897,874 ordinary shares held by SCC Growth I Holdco A, Ltd. The address for Sequoia Capital CV IV Holdco, Ltd. and SCC Growth I Holdco A, Ltd. is Conyers Trust Company (Cayman) Limited, P.O. Box 2681, Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman, KY1-1111, Cayman Islands.
(14) Based on a Schedule 13G filed on February 22, 2019. The address for KPCB China Fund II, L.P. is c/o Campbells Corporate Services Limited, Floor 4, Willow House, Cricket Square, PO Box 268 Grand Cayman KY1-1104, Cayman Islands.

As of March 1, 2019, 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 1, 2019, we had nine holders of record with addresses in the United States, including Citibank, N.A., depositary of our ADS program, which held 27,091,114 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, 2018 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 6,030,323 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. Each of Dr. Du and Marietta Wu are managers of Quan GP. In the first half of 2017, Zai sold its interest in three entities to the Quan Fund, for a total consideration of approximately $500,000.

Qiagen (Suzhou) Translational Medicine Co., Ltd.

An immediate family member of Dr. Du is owner of Qiagen (Suzhou) Translational Medicine Co., Ltd., or Qiagen. We incurred $125,679 in research and development expenses to Qiagen for drug research and development services for the year ended December 31, 2018.

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 enterprise income tax 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 the PRC;

(ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC;

(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 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 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%. The PRC 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 the PRC 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 the PRC resident enterprise; and (ii) it must have directly owned such percentage in the PRC 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 the PRC 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 December 31, 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 ("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 RMB26.9 million and RMB25.7 million, which were denominated in RMB, as of December 31, 2018 and 2017, respectively, representing 6% and 2% of the cash and cash equivalents as of December 31, 2018 and 2017, respectively.

Our business mainly operates in the PRC with most 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, the PRC 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 the PRC 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, 2018 and 2017, all of our 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 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 2.1%, 1.6% and 2.0% in 2018, 2017 and 2016, 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

As an ADS holder you 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 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 $0.1 million, after deduction of applicable U.S. taxes, for the year ended December 31, 2018 and 2017, 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.

For the period from September 20, 2017, the date that the F-1 Registration Statement was declared effective by the SEC, to December 31, 2018, we used the net proceeds from our initial public offering as follows:

- approximately $34.5 million for research development costs driven primarily by ZEJULA, ZL-2401 and ZL-2301;
- 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.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus dated September 20, 2017 filed with the SEC pursuant to Rule 424(b)(4). Our management retains broad discretion over the allocation and use of the remaining net proceeds of our U.S. initial public offering.

.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, 2018, 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, 2018 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, 2018.

C. Attestation Report of the Registered Public Accounting Firm

This annual report on Form 20-F does not include an attestation report of our independent registered public accounting firm because we qualified as an "emerging growth company" as defined under the JOBS Act as of December 31, 2018.

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 ACCOUNTANT 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.

	2018	2017
	US$	US$
	(in thousands)	
Audit Fees(1)	$ 550	$ 405

(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.

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. CORPORATE 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)
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 (incorporated by reference to Exhibit 10.10 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.7#	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
10.16*^	Collaboration Agreement by and between MacroGenics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated November 29, 2018
10.17	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)
10.18*#	Fourth Amended and Restated Founder Employment Agreement between Samantha (Ying) Du and Zai Lab Limited dated December 1, 2018
10.19*#	Amended and Restated Employment Agreement between William Ki Chul Cho and Zai Lab (Hong Kong) Limited dated March 22, 2019
10.20#	Founder Employment Agreement between Ning Xu and Zai Lab (Hong Kong) Limited dated May 6, 2014 (incorporated by reference to Exhibit 10.14 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.21#	Employment Agreement between James Yan and Zai Lab (Hong Kong) Limited dated March 10, 2015 (incorporated by reference to Exhibit 10.15 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.22*#	Second Amended and Restated Employment Agreement between Harald Reinhart and Zai Lab (Hong Kong) Limited dated December 28, 2018
10.23#	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)
10.24#	Employment Agreement between Ning Xu and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2017 (English translation) (incorporated by reference to Exhibit 10.19 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#	Employment Agreement between James Yan and Zai Lab (Shanghai) Co., Ltd. dated September 1, 2015 (English translation) (incorporated by reference to Exhibit 10.20 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
10.26*#	Amended and Restated Employment Agreement between Tao Fu and Zai Lab (US) LLC dated December 3, 2018
10.27*#	Amended and Restated Employment Agreement between Yongjiang Hei and Zai Lab (US) LLC dated March 22, 2019

10.28	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)
10.29	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)
15.1**	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
15.2**	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

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* 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.

^ Confidential treatment has been requested as to certain portions, which portions have been omitted and submitted separately to the Securities and Exchange Commission.

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: March 29, 2019

Zai Lab Limited

Index to Consolidated Financial Statements

Report of independent registered public accounting firm

To the Board of Directors and Shareholders of Zai Lab Limited

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Zai Lab Limited (the "Company") and its subsidiaries (collectively referred to as the "Group") as of December 31, 2018 and 2017, 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, 2018, and the related notes and the financial statement schedules included as Schedule I (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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on the Group's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Deloitte Touche Tohmatsu Certificated Public Accountants LLP

Shanghai, China

March 29, 2019

We have served as the Company's auditor since 2017.

Zai Lab Limited

Consolidated balance sheets

(In U.S. dollars ("$") except for number of shares)

	Note	As of December 31, 2017 $	As of December 31, 2018 $
Assets			
Current assets:			
Cash and cash equivalents	3	229,660,148	62,951,607
Short-term investments	4	—	200,350,000
Accounts receivable		—	89,708
Inventories	5	—	3,822
Prepayments and other current assets		954,506	5,749,260
Total current assets		230,614,654	269,144,397
Investments in equity investees	6	1,650,348	3,149,855
Prepayments for equipment		126,411	275,853
Property and equipment, net	7	11,853,764	20,494,482
Intangible assets, net		20,089	321,566
Long term deposits		306,825	556,738
Value added tax recoverable		5,062,137	8,044,258
Total assets		**249,634,228**	**301,987,149**
Liabilities and shareholders' equity			
Current liabilities:			
Short-term borrowings	9	—	3,642,616
Accounts payable		8,967,685	37,432,035
Other payables	10	3,101,459	7,766,843
Total current liabilities		12,069,144	48,841,494
Deferred income		2,394,124	2,063,942
Total liabilities		**14,463,268**	**50,905,436**
Commitments and contingencies (Note 19)			
Shareholders' equity			
Ordinary shares (par value of US$0.00006 per share; 83,333,333 shares authorized, 49,912,570 and 58,006,967 shares issued and outstanding as of December 31,2017 and 2018, respectively)		2,995	3,481
Subscription receivable		(18)	—
Additional paid-in capital		345,269,688	498,043,011
Accumulated deficit		(110,551,613)	(249,626,508)
Accumulated other comprehensive income	15	449,908	2,661,729
Total shareholders' equity		**235,170,960**	**251,081,713**
Total liabilities and shareholders' equity		**249,634,228**	**301,987,149**

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of operations

(In U.S. dollars ("$") except for number of shares)

	Note	Year ended December 31, 2016 $	2017 $	2018 $
Revenue		—	—	129,452
Cost of sales		—	—	(43,590)
Gross profit		—	—	85,862
Operating expenses:				
Research and development		(32,149,157)	(39,341,518)	(120,278,023)
Selling, general and administrative		(6,380,144)	(12,049,518)	(21,575,921)
Loss from operations		(38,529,301)	(51,391,036)	(141,768,082)
Interest income		403,266	527,351	3,260,634
Interest expense		—	—	(39,672)
Changes in fair value of warrants		(1,920,000)	200,000	—
Other income		2,533,966	933,158	1,968,325
Other expense		(143)	(403,997)	(1,909,549)
Loss before income tax and share of loss from equity method investment		(37,512,212)	(50,134,524)	(138,488,344)
Income tax expense	8	—	—	—
Share of loss from equity method investment		—	(249,652)	(586,551)
Net loss		(37,512,212)	(50,384,176)	(139,074,895)
Net loss attributable to ordinary shareholders		(37,512,212)	(50,384,176)	(139,074,895)
Loss per share - basic and diluted	12	(3.97)	(2.32)	(2.64)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		9,439,028	21,752,757	52,609,810

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of comprehensive loss

(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Net loss	(37,512,212)	(50,384,176)	(139,074,895)
Other comprehensive (loss) income, net of tax of nil:			
Foreign currency translation adjustments	(594,912)	1,148,440	2,211,821
Comprehensive loss	**(18,120,630)**	**(49,235,736)**	**(136,863,074)**

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of shareholders' (deficit) equity

(In U.S. dollars ("$") except for number of shares)

	Ordinary shares		Additional paid in capital	Subscription receivable	Accumulated deficit	Accumulated other comprehensive loss (income)	Total
	Number of Shares	Amount					
		$	$	$	$	$	$
Balance at January 1, 2016	8,885,184	533	4,388,410	(1)	(22,655,225)	(103,620)	(18,369,903)
Issuance of ordinary shares upon vesting of restricted shares	771,991	46	(42)	(4)	—	—	—
Share-based compensation	—	—	4,925,278	—	—	—	4,925,278
Net loss	—	—	—	—	(37,512,212)	—	(37,512,212)
Foreign currency translation	—	—	—	—	—	(594,912)	(594,912)
Balance at December 31, 2016	9,657,175	579	9,313,646	(5)	(60,167,437)	(698,532)	(51,551,749)
Issuance of ordinary shares upon vesting of restricted shares	1,666,145	100	(87)	(13)	—	—	—
Exercise of shares option	100,834	6	65,494	—	—	—	65,500
Exercise of warrant	461,808	28	4,699,972	—	—	—	4,700,000
Conversion of convertible preferred shares to ordinary shares	28,443,275	1,707	163,605,437	—	—	—	163,607,144
Issuance of ordinary shares upon initial public offering, net of issuance cost of $2,770,299	9,583,333	575	157,654,120	—	—	—	157,654,695
Share-based compensation	—	—	9,931,106	—	—	—	9,931,106
Net loss	—	—	—	—	(50,384,176)	—	(50,384,176)
Foreign currency translation	—	—	—	—	—	1,148,440	1,148,440
Balance at December 31, 2017	49,912,570	2,995	345,269,688	(18)	(110,551,613)	449,908	235,170,960
Issuance of ordinary shares upon vesting of restricted shares	338,332	20	(38)	18	—	—	—
Exercise of shares option	256,065	16	195,695	—	—	—	195,711
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $651,527	7,500,000	450	140,348,023	—	—	—	140,348,473
Share-based compensation	—	—	12,229,643	—	—	—	12,229,643
Net loss	—	—	—	—	(139,074,895)	—	(139,074,895)
Foreign currency translation	—	—	—	—	—	2,211,821	2,211,821
Balance at December 31, 2018	58,006,967	3,481	498,043,011	—	(249,626,508)	2,661,729	251,081,713

The accompanying notes are an integral part of these consolidated financial statements.

Zai Lab Limited

Consolidated statements of cash flows

(In U.S. dollars ("$") except for number of shares)

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Operating activities			
Net loss	(37,512,212)	(50,384,176)	(139,074,895)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation of property and equipment	198,224	545,705	1,634,377
Amortization of intangible assets	781	2,422	15,398
Amortization of deferred income	—	(78,000)	(312,000)
Share-based compensation	4,925,278	9,931,106	12,229,643
Share of loss from equity method investment	—	249,652	586,551
Loss on disposal of property and equipment	—	12,961	704
Change in fair value of warrants	1,920,000	(200,000)	—
Changes in operating assets and liabilities:			
Accounts receivable	—	—	(89,708)
Inventories	—	—	(3,822)
Prepayments and other current assets	(74,507)	(810,979)	(4,794,754)
Long term deposits	(267,980)	(38,845)	(249,913)
Value added tax recoverable	(1,376,921)	(3,685,216)	(2,982,121)
Accounts payable	(929,716)	8,444,347	28,464,350
Other payables	242,187	1,950,152	7,056,350
Deferred income	716,835	1,693,690	(18,182)
Net cash used in operating activities	(32,158,031)	(32,367,181)	(97,538,022)
Cash flows from investing activities:			
Purchases of short-term investments	—	—	(200,350,000)
Purchase of cost method investment	(500,000)	—	—
Disposal of cost method investment	—	500,000	—
Purchase of equity method investment	—	(1,900,000)	(2,086,058)
Purchase of property and equipment	(2,223,882)	(9,102,330)	(10,015,005)
Disposal of property and equipment	—	82,789	—
Purchase of intangible assets	(5,615)	(14,690)	(102,834)
Net cash used in investing activities	(2,729,497)	(10,434,231)	(212,553,897)
Cash flows from financing activities:			
Proceed from short-term borrowings	—	—	3,642,616
Proceed from issuance of convertible preferred shares, net of issuance cost	106,200,000	29,100,000	—
Proceeds from exercise of warrants	—	1,000,000	—
Proceeds from exercises of stock options	—	65,500	195,711
Proceeds from issuance of ordinary shares upon public offerings	—	160,424,994	141,000,000
Payment of public offering costs	—	(2,730,299)	(691,527)
Net cash provided by financing activities	106,200,000	187,860,195	144,146,800
Effect of foreign exchange rate changes on cash and cash equivalents	(524,398)	652,595	(763,422)
Net increase (decrease) in cash and cash equivalents	70,788,074	145,711,378	(166,708,541)
Cash and cash equivalents - beginning of the year	13,160,696	83,948,770	229,660,148
Cash and cash equivalents - end of the year	83,948,770	229,660,148	62,951,607
Supplemental disclosure on non-cash investing and financing activities:			
Payables for purchase of property and equipment	—	413,657	1,708,663
Payables for intangible assets	—	—	225,158
Payables for public offering costs	—	40,000	—
Conversion of convertible preferred shares	—	163,607,144	—
Exercise of warrants	—	3,700,000	—
Supplemental disclosure of cash flow information:			
Interest expense paid	—	—	35,799

The accompanying notes are an integral part of these consolidated financial statements.

(In U.S. dollars ("$") except for number of shares)

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, including in the fields of oncology, autoimmune and infectious disease therapies.

As of December 31, 2018, 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
Zai Lab (Shanghai) Co., Ltd.	The People's Republic of China ("PRC" or "China")	January 6, 2014	100%	Development and commercialisation of innovative medicines
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

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 estimating the useful lives of long-lived assets, assessing the impairment of long-lived assets, revenue recognition, 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 ("$"). The Group's PRC subsidiaries determined their functional currency to be Chinese Renminbi ("RMB"). The Group's Australia subsidiary determined its functional currency to be Australia dollar ("A$"). 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 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.

(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. Interests are 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.

(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 the period that the decline in value is first identified. No inventory provision was recorded as of December 31, 2018.

(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.

For equity investments over which the Group does not have significant influence or control, the cost method of accounting is used. Under the cost method, 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.

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, 2016, 2017 and 2018.

(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) Long term deposits

Long term deposits represent amounts paid in connection with the Group's long-term lease agreements.

(m) 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.

(n) 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, 2016, 2017 and 2018 were $781, $2,422 and $15,398, respectively. Amortization expenses of the Group's intangible assets are expected to be approximately $206,881, $41,584, $26,562, $24,940 and $21,599 for the years ended December 31, 2019, 2020, 2021, 2022, 2023 and thereafter, respectively.

(o) 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, 2016, 2017 and 2018, there was no impairment of the value of the Group's long-lived assets.

(p) 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 and cash equivalents, short-term investments, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other payables. As of December 31, 2017 and 2018, 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 payable approximated their fair values due to the short-term maturity of these instruments.

(q) 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 recognizes 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 principal source of revenue is product sales. The contracts with customers generally contain a single performance obligation and 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 customer upon delivery.

The timing between the recognition of revenue for product sales and the receipt of payment is not significant. Therefore the Group 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

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 customer, maintains inventory risk until delivery to the customer 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.

(r) 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 preclinical testing of the Group’s technologies under development and clinical trials such as payments to contract research organizations (“CROs”), 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 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.

(s) 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 $2,065,510, $855,158 and $1,332,419 were included in other income for the years ended December 31, 2016, 2017 and 2018, 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 $912,124 and $893,942 were recorded in deferred income as of December 31, 2017 and 2018 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 year ended December 31, 2017 and 2018, $78,000 and $312,000 were recorded in other income, respectively, and $1,482,000 and $1,170,000 were recorded in deferred income as of December 31, 2017 and 2018, respectively.

(t) Leases

Leases are classified at the inception date as either a capital lease or an operating lease. the Group assesses a lease to be a capital lease if any of the following conditions exist: (1) ownership is transferred to the lessee by the end of the lease term, (2) there is a bargain purchase option, (3) the lease term is at least 75% of the property's estimated remaining economic life or (4) the present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date. A capital lease is accounted for as if there was an acquisition of an asset and an incurrence of an obligation at the inception of the lease. The Group has no capital leases for the years presented.

All other leases are accounted for as operating leases wherein rental payments are expensed on a straight-line basis over the periods of their respective lease terms. The Group leases office space and employee accommodation under operating lease agreements. Certain of the lease agreements contain rent holidays. Rent holidays are considered in determining the straight-line rent expense to be recorded over the lease term. The lease term begins on the date of initial possession of the lease property for purposes of recognizing lease expense on straight-line basis over the term of the lease.

(u) 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.

(v) 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

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.

(w) 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.

(x) 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.

(y) 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 the PRC, no geographical segments are presented.

(z) Concentration of risks

Concentration of suppliers

The following suppliers accounted for 10% or more of research and development expenses for the years ended December 31, 2016, 2017 and 2018:

	Year ended December 31,		
	2016	2017	2018
	$	$	$
A	14,625,500	*	*
B	*	7,651,617	*
C	*	7,104,015	*
D	*	*	25,515,178
E	*	*	14,664,364

* Represents less than 10% of research and development expenses for the years ended December 31, 2016, 2017 and 2018.

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, 2017 and 2018, 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 RMB25,660,869 and RMB26,878,093, which were denominated in RMB, as of December 31, 2017 and 2018, respectively, representing 2% and 6% of the cash and cash equivalents as of December 31, 2017 and 2018, respectively.

(aa) 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.

(ab) Recent accounting pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize leases on balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with terms of longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The standard is effective on January 1, 2019, with early adoption permitted. The Group adopted the new standard on January 1, 2019 and used the effective date as the date of initial application. In July 2018, the FASB issued an update that provided an additional transition option that allows companies to continue applying the guidance under the lease standard in effect at that time in the comparative periods presented in the consolidated financial statements. Companies that elect this option would record a cumulative-effect adjustment to the opening balance of retained earnings on the date of adoption. The Group elected this optional transition method. As of December 31, 2018, the Group has $3.3 million of future minimum operating lease commitments that are not currently recognized on its consolidated balance sheets (see Note 19). Therefore, the Group would expect changes to its consolidated balance sheets for the recognition of these and any additional leases entered into in the future upon adoption.

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 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. As of December 31, 2018, there was $93,822 of total unrecognized compensation expense related to unvested non-employee options or restricted shares. The Group does not expect the requirements of ASU 2018-07 will have a material impact on the consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): The amendments in ASU 2018-13 eliminate the requirements to disclose the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, valuation processes for Level 3 fair value measurements, and policy for timing of transfers between levels. ASU 2018-13 also provides clarification in the measurement uncertainty disclosure by explaining that the disclosure is to communicate information about the uncertainty in measurement as of the reporting date. In addition, ASU 2018-13 added the following requirements: 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 range and weighted average of significant unobservable inputs used in Level 3 fair value measurements. Finally, ASU 2018-13 updated language to further encourage entities to apply materiality when considering de minimis for disclosure requirements. The guidance will be applied retrospectively for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, with the exception of amendments to changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used for Level 3 fair value measurements, and the narrative description of measurement uncertainty which will be applied prospectively. Early adoption is 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.

3. Cash and cash equivalents

	As of December 31,	
	2017	2018
	$	$
Cash at bank and in hand	204,008,828	36,778,028
Cash equivalents	25,651,320	26,173,579
	229,660,148	62,951,607
Denominated in:		
US$	224,878,393	58,253,341
RMB (note (i))	3,927,163	3,916,262
Hong Kong dollar (”HK$"□	—	19,890
Australia dollar ("A$")	854,592	762,114
	229,660,148	62,951,607

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. Short-term investment

Short-term investment primarily comprises of the time deposits with original maturities between three months and one year. For the year ended December 31, 2018, the Group recorded the interest income of $2.4 million from the short-term investments in the consolidated statements of operations.

5. Inventories

The Group’s inventory balance of $3,822 as of December 31, 2018 is a finished drug product purchased from Tesaro Inc.(“Tesaro”) for distribution in Hong Kong.

6. 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 RMB26.3 million (or $4.0 million) in cash, representing 20% of the equity interest of JING. RMB13.1 million (or $1.9 million) of which was paid by the Group in 2017, and the remainder RMB13.2 million (or $2.1 million) was paid in 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 $249,652 and $586,551 for the year ended December 31, 2017 and 2018, respectively.

In October 2016, the Group invested $500,000 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 $500,000 and no gain/loss was recognized upon disposal (Note 13).

(In U.S. dollars ("$") except for number of shares)

7. Property and equipment, net

Property and equipment consist of the following:

	As of December 31,	
	2017	2018
	$	$
Office equipment	273,339	384,088
Electronic equipment	160,772	599,495
Vehicle	81,360	77,460
Laboratory equipment	1,686,133	3,916,615
Manufacturing equipment	2,832,726	9,368,930
Leasehold improvements	3,227,150	4,607,975
Construction in progress	4,252,894	3,747,838
	12,514,374	22,702,401
Less: accumulated depreciation	(660,610)	(2,207,919)
Property and equipment, net	11,853,764	20,494,482

Depreciation expenses for the years ended December 31, 2016, 2017 and 2018 were $198,224, $545,705 and $1,634,377, respectively.

8. 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, 2016, 2017 and 2018, 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.

(In U.S. dollars ("$") except for number of shares)

PRC

Zai Lab (Shanghai) Co., Ltd., Zai Lab (Suzhou) Co., Ltd., and Zai Biopharmaceutical (Suzhou) Co., Ltd. are subject to the statutory rate of 25% in accordance with the Enterprise Income Tax law (the "EIT Law").

No provision for income taxes has been required to accrue because the Company and all of its owned subsidiaries are in cumulative loss positions for all the periods presented.

Loss before income taxes consists of:

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Cayman	2,454,660	3,886,673	1,218,542
BVI	—	8,375	1,873
PRC	26,111,094	40,971,742	127,711,113
HK	8,010,908	6,240,462	7,777,758
US	—	—	2,350,761
AUST	935,550	(723,076)	14,848
	37,512,212	50,384,176	139,074,895

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, 2016, 2017 and 2018 are as follows:

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Statutory income tax rate	25%	25%	25%
Share-based compensations	(2.92%)	(3.27%)	(1.93%)
Non-deductible expenses	(1.59%)	(0.79%)	(0.38%)
Prior year tax filing adjustment	—	—	1.55%
Effect of different tax rate of subsidiary operation in other jurisdictions	(3.33%)	(3.06%)	(0.76%)
Changes in valuation allowance	(17.16%)	(17.88%)	(23.48%)
Effective income tax rate	—	—	—

The principal components of the deferred tax assets and liabilities are as follows:

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Deferred tax assets:			
Depreciation of property and equipment, net	3,892	5,964	14,827
Government grants	166,336	187,762	186,811
Net operating loss forwards	8,086,361	17,075,387	49,726,611
Less: valuation allowance	(8,256,589)	(17,269,113)	(49,928,249)
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 2017 and 2018, the Group has determined that the deferred tax assets on temporary differences and net

(In U.S. dollars ("$") except for number of shares)

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, 2017 and 2018. Amounts of operating loss carry forwards were $34,716,071, $72,137,289 and $204,693,365 for the year ended December 31, 2016, 2017 and 2018, respectively, which are expected to expire from 2020 to 2028.

Movement of the valuation allowance is as follows:

	2017	2018
	$	$
Balance as of January 1,	(8,256,589)	(17,269,113)
Additions	(9,012,524)	(32,659,136)
Balance as of December 31,	(17,269,113)	(49,928,249)

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.

9. Short-term borrowings

On June 25, 2018, Zai Lab (Suzhou) Co. Ltd. entered into a three-year facility agreement for RMB25,000,000 (or $3,642,616) with a local commercial bank, and the outstanding borrowing under this agreement was RMB 20,000,000 (or $2,914,093) as of December 31, 2018, which will be due in 2019. 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.

On December 12, 2018, Zai Biopharmaceutical (Suzhou) Co. Ltd. entered into a three-year facility agreement for RMB40,000,000 (or $5,828,185) with a local commercial bank, the outstanding borrowing under this agreement was RMB 5,000,000 (or $728,523) as of December 31, 2018, which will be due in 2019. 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.

10. Other payables

Other payables consist of followings:

	As of December 31,	
	2017	2018
	$	$
Payroll	1,607,740	3,699,169
Professional service fee	714,764	1,564,070
Payables for purchase of property and equipment	413,657	1,708,663
Payables for purchase of intangible assets	—	225,158
Others	365,298	569,783
	3,101,459	7,766,843

11. 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 $8,028,572 or $1.2857 per share and $18,278,572 or $2.1651 per share, respectively. In August 2014, $2,000,000 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 $1,980,000 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 $53,100,000 or $9.5464 per share and $53,100,000 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 $30,000,000 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 Series A1, A2, B1, B2 and C Preferred Shares are as follows:

Conversion rights

Each holder of Series A1, A2, B1 and B2 Preferred Shares shall have the right, at such holder’s sole discretion, to convert all or any portion of the Series A1, A2, B1 and B2 Preferred Shares into ordinary shares based on a one-for-one basis at any time. The initial conversion price is the issuance price of Series A1, A2, B1 and B2 Preferred Shares.

Each holder of Series C Preferred Shares shall have the right, at such holders’ sole discretion, to convert all or any portion of the Series C Preferred Shares into ordinary shares based at any time. The initial conversion price shall equal the lower of (1) the issuance price of Series C Preferred Shares and (2) Calculated Price which is one hundred percent minus the discount rate of fifteen percent (the “Discount Rate”) multiplied by the offering price of the ordinary shares of the Company to the public on the date of the Qualified Initial Public Offering (“QIPO”). The Discount Rate will increase at increments of an additional two percent as of the first day of each successive six months period after June 2018 but shall in no event exceed twenty percent.

The conversion price of Series A1, A2, B1, B2 and C Preferred Shares is subject to adjustment in the event of (1) stock splits, share combinations, share dividends and distribution, recapitalizations and similar events, and (2) issuance of new securities at a price per share less than the conversion price in effect on the date of or immediately prior to such issuance. In that case, the conversion price shall be reduced concurrently to the subscription price of such issuance.

The Series A1, A2, B1, B2 and C Preferred Shares will be automatically converted into ordinary shares at the then applicable conversion price upon the earlier of (1) the closing of a QIPO, or (2) the date specified by written consent or agreement of majority holders of Series A1, A2, B1, B2 and C Preferred Shares.

Voting rights

The Series A1, A2, B1, B2 and C Preferred Shares are entitled to vote with ordinary shareholders on an as-converted basis. The holders of the Preferred Shares also have certain veto rights including, but not limited to, an increase or decrease in the total number of directors and change of board composition, appointment or removal of senior management, approval of business plan and operating budget, dividend declaration, any merger, split, reorganization or consolidation.

Dividends

The holders of Series A1, A2, B1, B2 and C Preferred Share may be entitled to receive dividends accruing at the rate of 8% per annum of the issuance price of Preferred Shares (the “Dividend Rate”). For holders of Series C Preferred Shares, the Dividend Rate shall increase by an additional one percent per annum for each successive six months period after June 2018 but shall in no event exceed ten percent.

In addition, holders of Series A1, A2, B1, B2 and C Preferred Shares are also entitled to dividends on the Company's ordinary shares on an as if converted basis and must be paid prior to any payment on ordinary shares. All dividends shall be payable only when, as, and if declared by the Board of Directors and shall be noncumulative.

Liquidation preference

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series A1 and A2 Preferred Shares are entitled to receive, prior to any distribution to the holders of ordinary shares, an amount per share equal to the Series A original issue price, plus accrued but unpaid dividends (the "Series A Preference Amount").

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series B1 and B2 Preferred Shares are entitled to receive, prior to any distribution to the holders of ordinary shares, an amount per share equal the Series B original issue price plus five percent (5%) simple interest on such Series B issue price accrued annually from the applicable Series B issue date, plus accrued but unpaid dividends (the "Series B Preference Amount").

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of Series C Preferred Shares are entitled to receive, prior to any distribution to the holders of any other class or series of equity securities, an amount per share equal the issuance price of Series C Preferred Shares plus non-compounding simple interest accruing at five percent (5%) per annum on the issuance price and plus any accrued but unpaid dividends (the "Series C Preference Amount").

In the event insufficient funds are available to pay in full the Preference Amount in respect of each preferred shareholders, the sequence of liquidation right of all series of preferred shares was as follows:

(1) Series C Preferred Shares;

(2) Series B1 and B2 Preferred Shares;

(3) Series A1 and A2 Preferred Shares.

After the Preference Amount has been paid, any remaining funds or assets legally available for distribution shall be distributed pro rata among the preferred shareholders together with ordinary shares.

A liquidation event includes, (1) any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary; the exclusive licensing of all or substantially all of the Group Companies’ intellectual property, taken as a whole, to a third party; (2) any sale of all or substantially all of the assets of the Group to a third party unaffiliated with any member of the Group; or (3) the transfer (whether by merger, reorganization or other transaction) in which a majority of the outstanding voting power of the Company is transferred (excluding any sale of shares by the Company for capital raising purposes).

(In U.S. dollars ("$") except for number of shares)

Redemption

In the event that a QIPO had not been completed by June 2022, holders of the Series C Preferred Shares may at any time thereafter require that the Company redeem all of the Series C Preferred Shares held by such holder at a redemption price per share equal to the sum of (1) an amount equal to the original issuance price, and (2) an additional amount which would result in holders of Series C Preferred Shares receiving an internal rate of return of fifteen percent after taking into consideration the payment of issuance price of Series C Preferred Shares and all prior distributions received.

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, 2016, the Company recognized a loss from the increase in fair value of the warrants of $1.9 million. For the year ended December 31, 2017, the Company recognized a gain from the decrease in fair value of the warrants of $0.2 million.

12. Loss per share

Basic and diluted net loss per share for each of the years presented are calculated as follow:

	For the year ended December 31,		
	2016	2017	2018
Numerator:			
Net loss attributable to ordinary shareholders	(37,512,212)	(50,384,176)	(139,074,895)
Denominator:			
Weighted average number of ordinary shares-basic and diluted	9,439,028	21,752,757	52,609,810
Net loss per share-basic and diluted	(3.97)	(2.32)	(2.64)

(In U.S. dollars ("$") except for number of shares)

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, 2016, 2017 and 2018, 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,		
	2016	2017	2018
Number of Series A1 Shares outstanding	8,466,665	—	—
Number of Series A2 Shares outstanding	8,442,221	—	—
Number of Series B1 Shares outstanding	5,562,335	—	—
Number of Series B2 Shares outstanding	3,973,096	—	—
Share options	7,228,141	6,548,377	8,761,735
Non-vested restricted shares	2,309,490	693,333	1,112,001
Warrants	461,808	—	—

13. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of December 31, 2018:

Company Name	Relationship with the Group
Quan Venture Fund I, L.P.	Significantly influenced by Samantha Du, founder, chairman and CEO of the Company
Qiagen (Suzhou) Translational Medicine Co., Ltd.	Significant influence held by Samantha Du's immediate family

In 2018, the Group incurred $125,679 research and development expense with Qiagen (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 $500,000 and no gain/loss was recognized upon disposal.

14. 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 March 2016, the Group granted 1,157,793 share options to certain of the Group's management and employees at an exercise price of $1.2 per share. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting anniversary year after the grant date.

In August 2016, the Group granted 1,760,368 share options to certain of the Group's management and employees at an exercise price of $1.74 per share, respectively. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting on the anniversary of the grant date each year.

In August and December 2016, the Group granted 416 and 416 share options to certain individual advisors of the Group at an exercise price of $1.74 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 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.

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 reference, thus the exercise multiple is 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.

(In U.S. dollars ("$") except for number of shares)

The following table presents the assumptions used to estimate the fair values of the share options granted in the years presented:

	March 2016	August 2016	December 2016	May 2017	September 2017	2018
Risk-free rate of return	2.8%	2.5%	3.4%	3.2%	3.5%	2.7%-3.2%
Contractual life of option	10 years	10 years	10 years	10 years	10 years	10 years
Expected term	n/a	n/a	n/a	n/a	n/a	6.5 years
Estimated volatility rate	70%	70%	70%	70%	70%	70%
Expected dividend yield	0%	0%	0%	0%	0%	0%
Fair value of underlying ordinary shares	7.14	8.04	8.04	9.60	27.93	17.60-24.58

A summary of option activity under the Plan during the years ended December 31, 2016, 2017 and 2018 is presented below:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
		$	Years	$
Outstanding at January 1, 2016	4,309,232	0.60	9.68	18,874,438
Granted	2,918,993	1.53	—	—
Forfeited	(84)	1.74	—	—
Outstanding at December 31, 2016	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
Vested and Exercisable as of December 31, 2018	3,321,376	1.01	6.93	73,775,871
Vested or expected to vest as of December 31, 2018	8,761,735	7.47	7.80	138,009,758

(In U.S. dollars ("$") except for number of shares)

The weighted-average grant-date fair value of the options granted in 2016, 2017 and 2018 were $6.94, $13.92 and $14.03 per share, respectively. The Group recorded compensation expense related to the options of $3,524,733, $4,751,933 and $9,403,059 for the year ended December 31, 2016, 2017 and 2018, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Selling, general and administrative	1,472,993	2,215,282	4,428,266
Research and development	2,051,740	2,536,651	4,974,793
Total	3,524,733	4,751,933	9,403,059

As of December 31, 2018, there was $46,006,585 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 2.80 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 of the Company (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 $141,971. 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 $1,152,600 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 have 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

On August 10, 2015, the Company entered into a restricted share arrangement with an individual advisor to secure their services, for 166,667 ordinary shares authorized for grant. In general, restrictions limit the sale or transfer of these shares during a three year period, and restrictions lapse proportionately over the three year period. During the three year period the Company upon voluntary or involuntary termination of service agreement by the individual advisor will repurchase unvested restricted shares at par (the “Repurchase Right”). On July 15, 2016 and August 25, 2016, 58,333 and 75,000 ordinary shares were authorized for grant to the individual advisor with the same Repurchase Right. The Repurchase Right terminates over the three years commencing August 10, 2015, July 15, 2016 and August 25, 2016 in 36 equal monthly instalments thereafter, or

(In U.S. dollars ("$") except for number of shares)

immediately prior to the consummation of an IPO of the Company. Any additional securities or cash received as the result of ownership of such shares, such as a share dividend, become subject to restriction in the same manner. For all restricted shares, the individual advisor has delegated his voting rights to the CEO of the Company. This arrangement has been accounted for as a reverse stock split followed by the grant of a restricted stock award under a performance-based plan. Accordingly, the Group measures the fair value at the date the services are completed which is monthly.

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 $840,000 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 $2,421,288 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.

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 2018:

	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

As of December 31, 2018, there was $14,386,103 of total unrecognized compensation expense related to non-vested restricted shares. The Group recorded compensation expense related to the restricted shares of $1,400,545, $5,179,173 and $2,826,584 for the year ended December 31, 2016, 2017 and 2018, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	Year ended December 31,		
	2016	2017	2018
	$	$	$
Selling, general and administrative	825,822	3,848,165	2,206,046
Research and development	574,723	1,331,008	620,538
Total	1,400,545	5,179,173	2,826,584

(In U.S. dollars ("$") except for number of shares)

15. Accumulated other comprehensive loss

The movement of accumulated other comprehensive loss is as follows:

	Foreign currency translation adjustments
	$
Balance as of January 1, 2016	(103,620)
Other comprehensive loss	(594,912)
Balance as of December 31, 2016	(698,532)
Other comprehensive income	1,148,440
Balance as of December 31, 2017	449,908
Other comprehensive income	2,211,821
Balance as of December 31, 2018	2,661,729

16. Licenses and collaborative arrangement

The following is a description of the Group's significant collaboration agreements for the year ended December 31, 2016, 2017 and 2018.

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 $15.0 million 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.

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 $7.5 million to Paratek which was recorded as a research and development expense in 2017. The Group made a milestone payment of $5.0 million to Paratek for the achievement of milestone upon receipt of the first regulatory approval for the Product in the U.S. in 2018. 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 Greater China 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 Greater China territory: China, Hong Kong, Macau, and Taiwan. The Group will be responsible for conducting the Phase III FIGHT trial in Greater China, including screening, enrolment and treatment of patients, and for commercialization of FPA144 in the Greater China 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 Greater China.

The Group made an upfront payment of $5.0 million in January 2018, and made a milestone payment of $2.0 million to Five Prim for the achievement of a milestone by enrolling the first patient in Phase III FIGHT trail of the Product in China in October 2018. 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 Greater China. And the Group is also eligible to receive a royalty from Five Prime on net sales of FPA144 outside of Greater China.

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 $5.0 million upfront fees to Entasis upon entering the agreement in 2018. And 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 $2.0 million 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 Greater China 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 $15.0 million 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 Greater China.

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 $25.0 million to MacroGenics in January 2019, and will make future milestone payments upon the achievement of potential development and regulatory-based milestone payments. 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.

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. The Group made $0.3 million and $7.0 million milestone payment under these agreements for the years ended December 31, 2017 and 2018, respectively. 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 $1,118.3 million 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.

17. 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 U.S. dollars ("$") except for number of shares)

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 and 2018, 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, 2017 and 2018, amounts restricted are the paid-in capital of the Group's PRC subsidiaries, which amounted to $80,951,618 and $90,951,618, respectively.

18. 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 $288,666, $579,094 and $1,424,873 for the years ended December 31, 2016, 2017 and 2018, respectively.

19. Commitments and Contingencies

(a) Operating lease commitments

The Group leases office facilities under operating leases expiring on different dates. Payments under operating leases are expensed on a straight-line basis over the periods of their respective leases, and the terms of the leases do not contain rent escalation, contingent rent, renewal, or purchase options.

There are no restrictions placed upon the Group by entering into these leases. Total expenses under these operating leases were $285,742, $916,612 and $1,494,456 for the years ended December 31, 2016, 2017 and 2018, respectively.

Future minimum lease payments under operating lease agreements at December 31, 2018 were as follows:

	Year ended December 31, $
2019	2,168,770
2020	1,007,476
2021	164,418
2022 and thereafter	—
Total lease commitment	3,340,664

(b) Purchase commitments

As of December 31, 2018, the Group’s commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statement was $1,454,796 which is expected to be incurred within one year.

(c) 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 16).

20. Subsequent events

In January 2019, the Group terminated the license agreement with UCB Biopharma Sprl ("UCB"), under which the Group obtained an exclusive and worldwide license under certain patents and know-how of UCB to develop, manufacture, use, sell, import and commercialize UCB's proprietary antibody UCB3000, or the licensed compound, or ZL-1101 for the treatment, prevention and diagnosis of any human diseases. The license that the Group retained was reverted back to UCB immediately upon termination of the license agreement and the Group has no continuing obligations (financial or otherwise) thereunder.

In February 2019, the Group granted 5,000 share options to certain management and employees of the Group at the exercise price of $29.12per share under the 2017 Plan. 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 on the anniversary date one year after the grant date.

In March 2019, the Group granted 168,500 share options to certain management and employees of the Group at the exercise price of $27.75 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 on the anniversary date one year after the grant date.

In January 2019, 50,000 ordinary shares were authorized for grant to the 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.

In March 2019, 45,000 ordinary shares were authorized for grant to certain management and employees of the Group. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary of the date of the agreement.

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed balance sheets

(In U.S. dollars ("$") except for number of shares)

	As of December 31,	
	2017	2018
	$	$
Assets		
Current assets:		
Cash and cash equivalents	181,910,618	745,980
Short-term investment	—	200,350,000
Prepayments and other current assets	450,333	2,912,408
Total current assets	182,360,951	204,008,388
Investment in subsidiaries	54,885,326	48,747,970
Total assets	**237,246,277**	**252,756,358**
Liabilities and shareholders' deficits		
Liabilities		
Current liabilities:		
Other payables	593,317	504,645
Total current liabilities	593,317	504,645
Deferred income	1,482,000	1,170,000
Total liabilities	**2,075,317**	**1,674,645**
Shareholders' equity		
Ordinary shares (par value of US$0.00006 per share; 83,333,333 shares authorized, 49,803,050 and 58,006,967 shares outstanding as of December 31, 2017 and 2018, respectively)	2,995	3,481
Subscription receivable	(18)	—
Additional paid-in capital	345,269,688	498,043,011
Accumulated deficit	(110,551,613)	(249,626,508)
Additional other comprehensive income	449,908	2,661,729
Total shareholders' equity	**235,170,960**	**251,081,713**
Total liabilities and shareholders' equity	**237,246,277**	**252,756,358**

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 U.S. dollars ("$") except for number of shares)

	Year Ended December 31,		
	2016	2017	2018
	$	$	$
Operating Expenses:			
Research and development	—	—	(234,185)
General and administrative	(534,660)	(4,114,144)	(4,250,655)
Loss from operations	**(534,660)**	**(4,114,144)**	**(4,484,840)**
Interest income	—	50,060	3,041,842
Changes in fair value of warrants	(1,920,000)	200,000	—
Equity in loss of subsidiaries	(35,057,552)	(46,598,092)	(137,943,897)
Other income	—	78,000	312,000
Loss before income tax	**(37,512,212)**	**(50,384,176)**	**(139,074,895)**
Income tax expense	—	—	—
Net loss attributable to ordinary shareholders	**(37,512,212)**	**(50,384,176)**	**(139,074,895)**
Net loss	(37,512,212)	(50,384,176)	(139,074,895)
Other comprehensive (loss) income, net of tax of nil:			
Foreign currency translation adjustment	(594,912)	1,148,440	2,211,821
Comprehensive loss	**(38,107,124)**	**(49,235,736)**	**(136,863,074)**

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed statements of cash flows

(In U.S. dollars ("$") except for number of shares)

	Year Ended December 31,		
	2016	2017	2018
	$	$	$
Cash flows from Operating activities:			
Net loss	(37,512,212)	(50,384,176)	(139,074,895)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Amortization of deferred income	—	(78,000)	(312,000)
Share based compensation	534,660	3,346,039	1,408,110
Change of fair value of warrants	1,920,000	(200,000)	—
Equity in loss of subsidiaries	35,057,552	46,598,092	137,943,897
Changes in operating assets and liabilities:			
Prepayments and other current assets	—	(450,333)	(2,462,075)
Other payables	—	553,317	(48,672)
Deferred income	—	1,560,000	—
Net cash provided by operating activities	—	944,939	(2,545,635)
Cash flows from investing activities:			
Purchases of short-term investments	—	—	(200,350,000)
Investment in subsidiaries	(84,501,020)	(31,707,566)	(118,773,187)
Net cash used in investing activities	(84,501,020)	(31,707,566)	(319,123,187)
Cash flows from financing activities:			
Proceed from issuance of convertible preferred shares, net of issuance cost	106,200,000	29,100,000	—
Proceeds from exercise of warrants	—	1,000,000	—
Proceeds from exercises of stock options	—	65,500	195,711
Proceeds from issuance of ordinary shares upon public offerings	—	160,424,994	141,000,000
Payment of public offering costs	—	(2,730,299)	(691,527)
Net cash provided by financing activities	106,200,000	187,860,195	140,504,184
Effect of foreign exchange rate changes on cash and cash equivalent	—	—	—
Net increase (decrease) in cash and cash equivalents	21,698,980	157,097,568	(181,164,638)
Cash and cash equivalents-beginning of the year	3,114,070	24,813,050	181,910,618
Cash and cash equivalents-end of the year	24,813,050	181,910,618	745,980

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, 2017 and 2018, 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 10.15

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

LICENSE AND COLLABORATION AGREEMENT

This **License and Collaboration Agreement** (this "***Agreement***") is made as of September 10th, 2018 (the "***Effective Date***"), by and between **NovoCure Limited**, a corporation organized and existing under the laws of Jersey ("***NVCR***"), having a registered address at Second Floor, No. 4 The Forum, Grenville Street, St. Helier, Jersey JE2 4UF, and **Zai Lab (Shanghai) Co., Ltd.**, a limited company organized under the laws of P.R. of China ("***Zai***"), having a place of business at 4560 Jinke Rd, Bldg. 1, 4/F, Pudong, Shanghai, China, 201210. NVCR and Zai are referred to in this Agreement individually as a "***Party***" and collectively as the "***Parties***."

Recitals

Whereas, NVCR is an oncology company that has developed proprietary TT Fields delivery systems (including a device known as Optune) for the treatment of cancer and controls certain patents and know-how relating to its TT Fields therapy and delivery system, and NVCR is seeking a partner for development and commercialization of the Licensed Product in the Territory;

Whereas, Zai is a company engaged in the research, development and commercialization of pharmaceutical and medical device products in the greater China region; and

Whereas, Zai wishes to obtain from NVCR an exclusive license to develop and commercialize the Licensed Product in the Territory, and NVCR is willing to grant such a license to Zai, all in accordance with the terms and subject to the conditions set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing premises and the covenants contained herein, the receipt and sufficiency of which are acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

The terms of this Agreement with the initial letters capitalized, whether used in the singular or plural, shall have the meanings set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 ***"Active Product***" means a medical device or system.

1.2 "***Affiliate***" means, with respect to an Entity, any Entity that controls, is controlled by, or is under common control with such Entity, for so long as such control exists. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of an Entity, whether by the ownership of more than fifty percent (50%) of the voting stocking of such Entity, by contract or otherwise.

1.3 "***Applicable Laws***" means collectively all laws, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit or similar right granted under any of the foregoing) and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party's activities in connection with this Agreement.

1.4 "***AQSIQ***" means the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of China.

1.5 "***Bridging Study***" means an additional Clinical Trial consisting of up to fifty (50) patients from the Territory that allows extrapolation of a foreign pivotal data package to support Regulatory Approval of such Licensed Product in the Territory.

1.6 "***Business Day***" means a day other than a Saturday, Sunday or a day on which banking institutions in New York, United States, or Shanghai, China are required by Applicable Laws to remain closed.

1.7 "***Calendar Quarter***" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.8 "***Calendar Year***" means each 12-month period commencing on January 1.

1.9 "***CMDE***" means Center for Medical Device Evaluation of China and any successor agency(ies) or authority thereto having substantially the same function.

1.10 "***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 International Conference on Harmonization's 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.

1.11 "***Clinical Trial***" means any human clinical trial of a Licensed Product in the Field.

1.12 "***Change of Control***" means, with respect to a Party:

(a) the acquisition by any individual, Entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) who or which constitute(s) a Third Party of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended) of fifty percent (50%) or more of the combined voting power of the then-outstanding voting securities of such Party entitled to vote generally in the election of directors of such Party (the "***Outstanding Voting Securities***");

(b) the consummation of any acquisition, merger or consolidation of such Party by any Third Party (a "***Business Combination Transaction***"), unless immediately following such Business Combination Transaction, the Persons who were the beneficial owners of the Outstanding Voting Securities immediately prior to such Business Combination Transaction beneficially own, directly or indirectly, fifty percent (50%) or more of the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of directors of the corporation or other Entity resulting from such Business Combination Transaction (including a corporation or other Entity which as a result of such transaction owns the then-outstanding securities of such Party or all or substantially all of such Party's assets either directly or through one or more subsidiaries); or

(c) such Party or any of its Affiliates sells or transfers to any Third Party in one or more related transactions properties or assets representing all or substantially all of such Party's business or assets to which the subject matter of this Agreement relates.

1.13 "***Commercialization***" or "***Commercialize***" means all activities directed to marketing, promoting, advertising, exhibiting, distributing, detailing, selling (and offering for sale or contracting to sell) or otherwise commercially exploiting (including pricing and reimbursement activities) a Licensed Product in the Field in the Territory (including importing and exporting activities within the Territory in connection therewith); provided, however, that Commercialization shall exclude manufacturing activities (including manufacturing activities related to Commercialization).

1.14 "***Commercialization Plan***" means, with respect to a Licensed Product, the written strategic and tactical plans, timelines and budget for the Commercialization of such Licensed Product in the Field and in the Territory.

1.15 "***Commercially Reasonable Efforts***" means, the performance of obligations or tasks in a manner consistent with the reasonable practices of companies in the medical devices and biopharmaceutical industries having similar financial resources allocated for the development and commercialization of a product having similar technical and regulatory factors and similar market potential, profit potential and strategic value, and that is at a similar stage in its development or product life cycle as the Licensed Product, taking into account all relevant factors, in each case based on [***]. Commercially Reasonable Efforts requires [***].

1.16 "***Confidential Information***" of a Party means, subject to Section 10.2, all Know-How, unpublished patent applications and other non-public information and data of a financial, commercial, business, operational or technical nature of such Party that is disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, in each case in connection with this Agreement or the Confidentiality Agreement, whether made available orally, visually, in writing or in electronic form. All New IP shall be Confidential Information of NVCR.

1.17 "***Control***" or "***Controlled***" means the possession by a Party (whether by ownership, license or otherwise) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms and conditions set forth herein, or (b) with respect to Patents, intangible Know-How or other intellectual property rights, the legal authority or right to grant a license, sublicense, access or right to use (as applicable) under such Patents, intangible Know-How or other intellectual property rights to the other Party on the terms and conditions set forth herein, in each case of (a) and (b), without breaching the terms of any agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use or (sub)license or incurring any additional fee or charge.

1.18 "***Cover***" means, with respect to a Patent, a Valid Claim of such Patent would (absent a license thereunder or ownership thereof) be infringed by the manufacture, use, sale or importation of the applicable product. Cognates of the word "Cover" shall have correlative meanings.

1.19 "***Develop***" or "***Development***" or "***Developing***" means all development activities for any Licensed Product that are directed to obtaining Regulatory Approval(s) of such Licensed Product and to support appropriate usage for such Licensed Product in the Field, including: all clinical activities, testing and studies of such Licensed Product; safety, tolerability and pharmacological studies conducted in connection with the Clinical Trials of such Licensed Product; distribution of such Licensed Product for use in Clinical Trials (including placebos and comparators); statistical analyses; the preparation, filing and prosecution of any application for Regulatory Approval for such Licensed Product in the Territory, with respect to Development activities conducted under the Territory Development Plan; development activities directed to label expansion (including prescribing information) or obtaining Regulatory Approval for one or more additional Indications following initial Regulatory Approval; development activities conducted after receipt of Regulatory Approval that are required or requested in writing by a Regulatory Authority as a condition of, or in connection with, obtaining or maintaining a Regulatory Approval; and pharmacoeconomic studies relating to the Indication for which the applicable Licensed Product is being developed; in each case above, including investigator- or institution-sponsored studies for which a Party is providing material or assistance or otherwise has written obligations to such investigator or institution; and all regulatory activities related to any of the foregoing; provided, however, that Development shall exclude Commercialization and manufacturing activities (including manufacturing activities related to Development).

1.20 "***Dollar***" or "**$**" means the U.S. dollar, and "$" shall be interpreted accordingly.

1.21 "***Entity***" means a partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization.

1.22 "***FDA***" means the United States Food and Drug Administration or any successor entity thereto.

1.23 "***Field***" means all human therapeutic (including the treatment of side effects) and preventative uses in the field of oncology.

1.24 "***First Commercial Sale***" means, with respect to any Licensed Product in any country or jurisdiction, the first sale of such Licensed Product to a Third Party for distribution, use or consumption in such country or jurisdiction after Regulatory Approvals, as applicable, have been obtained for such Licensed Product in such country or jurisdiction.

1.25 "***Fully Burdened Manufacturing Cost***" means, with respect to any Licensed Product supplied by or on behalf of NVCR to Zai hereunder if such Licensed Product (or any precursor or intermediate thereof) is manufactured by a Third Party manufacturer [***].

1.26 "***GAAP***" means United States generally accepted accounting principles, consistently applied.

1.27 "***GBM***" means glioblastoma.

1.28 "***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 and (b) 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.

1.29 "***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 FDA, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.30 "***Governmental Authority***" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.31 "***Indication***" means a separate and distinct tumor type that a Licensed Product is intended to treat, prevent, cure, or ameliorate, or that is the subject of a Clinical Trial and where it is intended that the data and results of such Clinical Trial (if successful) shall be used to support a Regulatory Submission and approval that is intended to result in distinct labeling within the indications section of the label relevant to usage in such tumor type that is separate and distinct from another tumor type.

1.32 "***Invention***" means any information, discovery, improvement, modification, process, method, design, protocol, formula, data, invention, algorithm, forecast, profile, strategy, plan, result, know-how and trade secret, patentable or otherwise, that is discovered, generated, conceived or reduced to practice by or on behalf of either Party (including by its Affiliates, employees, agents or contractors), whether solely or jointly, in the course of the performance of this Agreement, including all rights, title and interest in and to the intellectual property rights therein and thereto.

1.33 "***Know-How***" means any non-public information, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols, SOPs, formulas, data, inventions, algorithms, forecasts, profiles, strategies, plans, results, know-how and trade secrets (in each case, patentable, copyrightable or otherwise), but excluding any Patents and physical substances.

1.34 "***Licensed Product***" means any TT Fields treatment and TT Fields delivery system developed by NVCR and/or its Affiliates, including the device branded as Optune® in the United States (whether alone as the sole Active Product or as a combination with other Active Product(s)).

1.35 "***Minimal Reimbursement*** Price" means a minimal monthly reimbursement price per Licensed Product equal to the greater of [***].

1.36 "***Net Sales***" means with respect to a Licensed Product, the gross amount billed or invoiced by or for the benefit of Zai and its Affiliates, licensees and sublicensees (each of the foregoing, a "***Seller***") to Third Parties ("***Buyers***") in *bona fide* arm's length transactions with respect to such Licensed Product, less the following deductions, in each case to the extent actually allowed, paid, accrued or specifically allocated with respect to such Licensed Product, and not otherwise recovered by or reimbursed to Seller:

(a) transportation charges and other charges directly related thereto, such as insurance, in each case, to the extent actually incurred and not charged to or reimbursed by the customer;

(b) sales, excise taxes or VAT paid by the Seller imposed specifically upon the sale of such Licensed Product and actually paid by Zai to the relevant tax authority for the sale of the Licensed Product, but not including any tax assessed against the income derived from such sale;

(c) discounts and chargebacks actually granted, allowed or incurred, and deducted, solely in connection with the sale of such Licensed Product that are not otherwise attributable to other products of Zai and its Affiliates, *provided however*, that where any such discount is based on sales of a bundled set of products in which is included, the discount may be deducted under this Section 1.35(c) only to the extent allocated to such Licensed Product on a pro rata basis;

(d) allowances or credits to such Buyer actually given and not in excess of the selling price of such Licensed Product on account of rejection, outdating, recalls or return of such Licensed Product;

(e) amounts written off by reason of uncollectible debt if and when actually written off or allowed, after commercially reasonable debt collection efforts have been exhausted, provided that [***]; and

(f) rebates or reimbursements to wholesalers and other distributors, pharmacies and other retailers, buying groups (including group purchasing organizations), health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, Governmental Authorities, or other institutions or health care organizations, where such payments are in the ordinary course of business and not attributable to other products of Zai and its Affiliates.

No deduction shall be made for any item of cost incurred by any Seller in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) to (f) of the foregoing sentence; provided that Licensed Products transferred to Buyers in connection with clinical and non-clinical research and trials, Licensed Product samples, compassionate sales or use, or an indigent program or similar *bona fide* arrangements in which a Seller agrees to forego a normal profit margin for good faith business reasons shall give rise to Net Sales only to the extent that any Seller invoices or receives amounts therefor. [***] If a single item falls into more than one of the categories set forth in clauses (a)-(f) above, such item may not be deducted more than once.

Such amounts shall be determined from the books and records of the Seller, and shall be calculated in accordance with GAAP.

Sales between Zai and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales except if such purchaser is an end user, in which case such sales will give rise to Net Sales. Otherwise, the subsequent sale of such Licensed Product by such Affiliate or sublicensee shall be included in the calculation of Net Sales.

With respect to any sale of any Licensed Product in a given country for any substantive consideration other than monetary consideration on arm's length terms (which has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary consideration), for purposes of calculating the Net Sales, such Licensed Product shall be deemed to be sold exclusively for cash at the average Net Sales price charged to Third Parties for cash sales of such Licensed Product in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, at the fair market value as determined in good faith based on pricing in comparable markets).

Net Sales shall be calculated on an accrual basis, in a manner consistent with Zai's accounting policies for external reporting purposes, as consistently applied, in accordance with GAAP.

1.37 "***NMPA***" means the National Medical Products Administration of the People's Republic of China and any successor agency(ies) or authority thereto having substantially the same function.

1.38 "***NSCLC***" means non-small-cell lung carcinoma.

1.39 "***NVCR IP***" means NVCR Know-How and NVCR Patents.

1.40 "***NVCR Know-How***" means all Know-How Controlled by NVCR as of the Effective Date or at any time during the Term that is necessary or reasonably useful for the Development, or Commercialization of Licensed Products in the Field in the Territory, including all Know-How within the New IP; provided, however, that NVCR Know-How shall exclude all Know-How that comes into NVCR's Control as a result of a Change of Control of NVCR.

1.41 "***NVCR Patents***" means all Patents in the Territory Controlled by NVCR as of the Effective Date or at any time during the Term that Cover a Licensed Product in the Field, including all Patents in the Territory claiming New IP; provided, however, that NVCR Patents shall exclude all Patents that come into NVCR's Control as a result of a Change of Control of NVCR. **Exhibit A** includes the NVCR Patents that are owned or exclusively licensed by NVCR and that are existing as of the Effective Date; provided, that, for the avoidance of doubt, any Patent that otherwise meets the definition of a NVCR Patent shall still be considered a NVCR Patent even if such Patent is not identified on **Exhibit A**.

1.42 "***Optune Trademarks***" means the trademarks containing the words "Optune" set forth on Schedule 1.41, including all applications and registrations Controlled by NVCR and/or its Affiliates therefor in the Territory.

1.43 "***Patents***" means any U.S., foreign, international or regional patent application or patent in any jurisdiction (including any provisional, non-provisional, divisional, continuation or continuation-in-part application, and any patents that issue thereon); and any reissue, renewal, re-examination, substitution, extension or addition of any of the foregoing patents or applications; and any foreign equivalents of any of the foregoing (as more fully set forth in this Agreement).

1.44 "***Patent Prosecution***" means activities directed to (a) preparing, filing and prosecuting applications (of all types) for any Patent, (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding whether to abandon or maintain Patent(s), (d) listing in regulatory publications (as applicable), (e) patent term extension applications and maintenance, and (f) settling any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding.

1.45 "***Person***" means any individual, unincorporated organization or association, governmental authority or agency or Entity.

1.46 "***PRC***" means the People's Republic of China, which for the purposes of this Agreement shall exclude Hong Kong, Macau and Taiwan.

1.47 "***Product Improvement***" means any improvement made [***].

1.48 "***Product Updates***" means any improvement made [***].

1.49 "***Regulatory Approval***" means, with respect to a Licensed Product in a country or region in the Territory, all approvals that are necessary for the commercial sale of such Licensed Product for use in the Field in such country or region in the Territory, excluding any pricing and reimbursement approvals except to the extent required by Applicable Law to sell the Licensed Product in such country or region.

1.50 "***Regulatory Authority***" means any applicable Governmental Authority responsible for granting Regulatory Approvals or any pricing or reimbursement approvals, as applicable, for Licensed Products, including the NMPA, CMDE, AQSIA and any corresponding national or regional regulatory authorities.

1.51 "***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 any pricing or reimbursement approvals, as applicable, 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.

1.52 "***RMB***" means the official currency of the PRC.

1.53 "***Sanctioned Country***" means, at any time, a country or territory that is itself the subject or target of any Sanctions (at the time of this Agreement, Cuba, Iran, North Korea, Sudan and Syria).

1.54 "***Sanctions***" means (a) economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by the United States government and administered by the U.S. Treasury Department's Office of Foreign Assets Control ("***OFAC***"), the United Nations Security Council, the European Union or Her Majesty's Treasury of the United Kingdom, and (b) economic or financial sanctions imposed, administered or enforced from time to time by the United States State Department, the United States Department of Commerce or the United States Department of the Treasury.

1.55 "***Sanctions List***" means any of the lists of specifically designated nationals or designated Persons held by the U.S. government and administered by OFAC, the United States State Department, the United States Department of Commerce or the United States Department of the Treasury or the United Nations Security Council or any similar list maintained by the European Union, any other EU Member State or any other U.S. government entity, in each case as the same may be amended, supplemented or substituted from time to time.

1.56 "***Specifications***" mean the requirements and standards for each Licensed Product to be supplied by NVCR to Zai under this Agreement as set forth on Schedule 1.55 attached hereto, as amended or supplemented in writing in accordance with this Agreement.

1.57 "***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 value add taxes ("***VAT***").

1.58 "***Territory***" means the PRC, Hong Kong, Macau and Taiwan (each of which for purposes of this Agreement shall each be deemed a region).

1.59 "***Third Party***" means any Person other than a Party or an Affiliate of a Party.

1.60 "***TT Fields***" means Tumor Treating Fields, or TTFields, which are low intensity, alternating electric fields that disrupt cell division through physical interactions with key molecules during mitosis in solid tumor cancers.

1.61 ***"TT Fields Multi-Regional Clinical Study"*** means a global Clinical Trial of the Licensed Product sponsored by NVCR for an Indication which includes Clinical Trials to be conducted in multiple regions, including the PRC, in accordance with a [***] Plan**.**

1.62 "***United States***" means the United States of America.

1.63 "***Valid Claim***" means: (a) a claim in an issued Patent that has not: (i) expired or been canceled; (ii) been declared invalid by an unreversed and unappealable or unappealed decision of a court or other appropriate body of competent jurisdiction; (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (iv) been abandoned in accordance with or as permitted by the terms of this Agreement or by written agreement of the Parties; or (b) a claim that has been pending [***] or less from the date that the first action on the merits (excluding restriction requirements, notices to file missing parts, and the like) was received in a patent application in which such claim is examined, and that has not been abandoned (without the possibility of refiling) or finally rejected by the applicable Governmental Authority or court (and from which no appeal is or can be taken). For clarity, if a claim is canceled and refiled in a continuing application, the period of pendency is calculated from the date that the first action on the merits as to that claim was first received.

1.64 Additional Definitions. The following table identifies the location of definitions set forth in various Sections of this Agreement:

Term	***Section***
Agreement	Introduction
Alliance Manager	Section 3.1
Anti-Corruption Laws	Section 11.7(a)(i)
Arbitration Notice	Section 15.3(a)
Arbitrators	Section 15.3(b)
Business Combination Transaction	Section 1.12(b)
Buyers	Section 1.35
Claims	Section 12.1
Clinical Supply Agreement	Section 7.1
Commercial Supply Agreement	Section 7.2
Competing Product	Section 2.4(a)
Competing Program	Section 2.6
Confidentiality Agreement	Section 16.6
Continuing Technology Transfer	Section 4.1
Development Target	Section 5.2
Development Target Deadline	Section 5.2
Disclosing Party	Section 10.1(a)
Disclosure Schedule	Article 11
Dispute	Section 15.1
Divestiture	Section 2.5
Effective Date	Introduction
Ex-Territory Infringement	Section 13.3
Examined Party	Section 9.7
Executive Officers	Section 3.2(f)
Global Brand Elements	Section 8.4(b)
[***] Plan	Section 5.3(a)
Indemnified Party	Section 12.3
Indemnifying Party	Section 12.3
Initial Technology Transfer	Section 4.1
JDC	Section 3.2(f)(ii)
JSC	Section 3.2(a)
License	Section 2.1
Losses	Section 12.1
New IP	Section 13.1(a)
NMPA Submission Timeline	Section 5.1(c)
NVCR	Introduction
NVCR Indemnitees	Section 12.1
Outstanding Voting Securities	Section 1.12(a)
Party/Parties	Introduction

Paying Party	Section 9.8(c)
Product Infringement	Section 13.3
Product Marks	Section 13.5
Publication	Section 10.4
Receiving Party	Section 10.1(a)
Recipient	Section 9.8(c)
Representatives	Section 10.1(c)
Review Period	Section 10.4(a)
Royalty Term	Section 9.3(b)
Rules	Section 15.3(a)
Safety Agreement	Section 6.5(a)
Seller	Section 1.35
Supply Agreement Term Sheet	Section 7.3
Technology Transfer	Section 4.1
Term	Section 14.1
Territory Development Plan	Section 5.4
VAT	Section 1.56
Zai	Introduction
Zai Indemnitees	Section 12.2

ARTICLE 2
LICENSE

2.1 License Grants to Zai.

(a) Subject to the terms and conditions of this Agreement, NVCR hereby grants to Zai (i) an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2, under the NVCR IP and any Regulatory Approvals and Regulatory Submissions owned and held by NVCR or its Affiliates in the Territory to Develop, distribute, use, sell, offer for sale, import and otherwise Commercialize Licensed Products in the Field in the Territory (the "***License***") and (ii) a non-exclusive license, with the right to grant sublicenses solely in accordance with Section 2.2, under the NVCR IP to perform the Development activities [***] to the extent permitted by this Agreement.

(b) On a Licensed Product-by-Licensed Product basis, unless and until the Parties reach any alternative agreement on the supply of the Licensed Products, Zai shall purchase and NVCR shall supply the Licensed Products for Zai's Development and Commercialization of the Licensed Products in the Territory pursuant to Clinical Supply Agreement and Commercial Supply Agreement in accordance with Article 7. The Commercial Supply Agreement shall contain the customary change control provisions to address any Product Updates, certain Product Improvements, incremental changes to the Specifications, or incremental improvements to the Licensed Product. If the Product Improvements are so significant that such Licensed Product will need to be approved by the Regulatory Authorities as a new product, then a new or amended Commercial Supply Agreement shall be entered into between NVCR and Zai.

2.2 Right to Sublicense.

(a) Subject to the terms and conditions of this Agreement, Zai shall have the right to grant sublicenses of the License: (i) to its Affiliates, provided that (A) such sublicense shall automatically terminate if such sublicensee ceases to be an Affiliate of Zai, and (B) Zai's right to grant sublicenses shall not apply to Affiliates who become Affiliates after the Effective Date as a result of any stock or asset acquisition involving Zai; and (ii) subject to Section 5.8 and NVCR's prior written approval, to contract research organizations, distributors and other Third Party subcontractors for the sole purpose of, with respect to the License, performing Zai's obligations with respect to the Development, and Commercialization of Licensed Products in the Field in the Territory. Notwithstanding the foregoing, except for sublicenses of the License to its Affiliates in accordance with Section 2.2(a)(i), Zai shall obtain NVCR's prior written consent if Zai wishes to sublicense any of Zai's rights or obligations under this Agreement with respect to any region within the Territory. Notwithstanding the grant of any sublicense hereunder, Zai shall remain liable for any breach or default of the applicable terms and conditions of this Agreement by any of its sublicensees.

(b) Zai will not grant a sublicense to any sublicensee that has been debarred or disqualified by a Regulatory Authority. Zai will ensure that, prior to engaging any sublicensee that such sublicensee is subject to written agreement containing the following terms and conditions: (i) each such sublicensee must protect and keep confidential any Confidential Information of the Parties, including in accordance with Article 10; (ii) NVCR has 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 Section 9.7); (iii) the sublicense does not impose any payment obligations or liability on NVCR; (iv) each sublicense shall contain the same indemnification and intellectual property assignment provisions as in this Agreement; and (v) the sublicense is otherwise consistent with the terms of this Agreement. Zai will promptly provide a copy of the executed agreement with each sublicensee to NVCR, which copy may be redacted to remove financial terms. Zai shall ensure that its sublicensees comply with the terms and conditions of this Agreement and Zai will remain directly responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any sublicensee.

2.3 No Implied Licenses; Negative Covenant. Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any trademarks, Patents or patent applications of the other Party. Zai shall not, and shall not permit any of its Affiliates or sublicensees to, practice any NVCR IP outside the scope of the License.

2.4 Non-Compete.

(a) Subject to Section 2.5, during the Term, Zai shall not, and shall ensure that its Affiliates and sublicensees hereunder do not, directly or indirectly, engage in, independently or for or with any Third Party, any [***](a "***Competing Product***") in the Territory, other than Licensed Products in accordance with this Agreement.

(b) During the Term, NVCR shall not, and shall ensure that its Affiliates and sublicensees hereunder do not, directly or indirectly, engage in, independently or for or with any Third Party, any development or commercialization of a Competing Product in the Territory and in the Field, other than Licensed Products in accordance with this Agreement. NVCR shall use, and cause its Affiliates or Third Parties acting on its behalf to use, good faith efforts to design, develop, label, market, and/or sell any Competing Product for use outside the Field in humans in the Territory in such a way that would prevent or discourage any use of such Competing Product in the Field in the Territory.

2.5 Acquisition of Competing Programs. If a Third Party becomes an Affiliate of Zai, or otherwise assumes this Agreement, after the Effective Date through merger, acquisition, consolidation or other similar transactions with Zai, then regardless of whether such transaction results in a Change of Control of Zai, if as of the date of the closing of such transaction, such Affiliate or any Affiliate of such new Affiliate was engaged in the research, development, manufacture or commercialization of a product that would compete with any Licensed Product (a "***Competing Program***"), then Zai and its new Affiliate will have [***] to wind down (i.e., discontinue all development and commercialization) or complete the Divestiture of such Competing Program. "***Divestiture***" means the sale or transfer or exclusive license of rights to the Competing Program to a Third Party without the retention or reservation of any rights, license or interest (other than solely an economic interest and, in the event of termination, customary residual rights) in such Competing Program.

2.6 Control & Management of Licensed Products. Zai shall use Licensed Products for Development and Commercialization as expressly contemplated by this Agreement. Zai shall not, and shall not permit its Affiliate or any Third Party any re-use any component of the Licensed Products that are disposable (i.e., arrays), reverse engineering of the Licensed Products or any component thereof, diversion of any Licensed Product, inappropriate disposal of Licensed Product, failure to collecting Licensed Product upon treatment stoppage.

2.7 No Diversion. Zai and its Affiliates shall not, and shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its and their licensees and sublicensees not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like outside of the Territory or for purposes of medical tourism from countries in which NVCR is developing or commercializing the Licensed Product. Zai shall not engage, and shall not permit its Affiliates and sublicensees to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of such product residing or located in any country or jurisdiction outside the Territory, or solicit orders from any prospective purchaser residing or located in any country or jurisdiction outside the Territory. If Zai or its Affiliates or sublicensees receives any order for a Licensed Product for use from a prospective purchaser located or residing in a country or jurisdiction outside the Territory, Zai shall immediately refer that order to NVCR and shall not accept any such orders. Zai shall not deliver or tender (or cause to be delivered or tendered), nor permit its Affiliates and sublicensees to, deliver or tender (or cause to be delivered or tendered) any Licensed Product for use outside the Territory.

ARTICLE 3
GOVERNANCE

3.1 Alliance Managers. Each Party shall appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (the "***Alliance Manager***"), which Zai Alliance Manager shall be fluent in English. The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, provided that all communications between the Parties shall be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC (as a non-voting participant) and JDC meetings. An Alliance Manager may also bring any matter to the attention of the JSC or JDC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

3.2 Joint Steering Committee.

(a) Formation. Within [***], the Parties shall establish a joint steering committee (the "***JSC***") to monitor and coordinate the Development and Commercialization of Licensed Products in the Field in the Territory. The JSC will be composed of an equal number of representatives from each Party and a minimum of [***] representatives of each Party, with (i) at least [***] senior-level representatives from Zai who are fluent in English, (ii) at least [***] representative of each Party that have direct knowledge and expertise in the development and commercialization of products similar to Licensed Products.

(b) Role. The JSC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement; (ii) review and discuss the overall strategy for the Development and Commercialization of Licensed Products in the Field in the Territory; (iii) review and discuss the initial Territory Development Plan and review, discuss, and approve any amendments thereto in accordance with Section 5.4; (iv) review and discuss any material amendments to the [***] Plan that are related to the Territory in accordance with Section 5.3(c); (v) review, discuss, and approve the Commercialization Plan and amendments thereto including the reimbursement price for the Licensed Product in the Territory; (vi) establish and oversee the JDC as necessary or advisable to further the purpose of this Agreement; (vii) discuss potential implications of Zai's decision to file and hold Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory in its own name; (viii) discuss and approve clinical supply arrangements; (ix) review and discuss annually a charitable care strategy (covering compassionate sales or use, or an indigent program) for the Licensed Products in the Field in the Territory; and (x) perform such other functions as expressly set forth in this Agreement or allocated to the JSC 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; or (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

(d) Meetings. The JSC shall hold meetings at such times as it elects to do so, but shall meet no less frequently than [***] per Calendar Year, in a manner and at a location as agreed upon by the Parties. Each Party shall bear its own expenses related to participation in and attendance at such meetings by its respective JSC representatives.

(e) Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, 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 will provide prior written notice to the other Party. Such Party will 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 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 [***] days after such matter was brought to the JSC for resolution, such matter shall be referred to the Chief Executive Officer of NVCR (or an executive officer of NVCR designated by the Chief Executive Officer of NVCR who has the power and authority to resolve such matter) and the Chief Executive Officer of Zai (or an executive officer of Zai designated by the Chief Executive Officer of Zai who has the power and authority to resolve such matter) (collectively, the "***Executive Officers***") for resolution. If the Executive Officers cannot resolve such matter within [***] days after such matter has been referred to them, then:

(i) Zai shall have the final decision-making authority with respect to (1) Development of Licensed Products in the Field in the Territory which are not part of the [***] Plan and would not reasonably be expected to have a materially adverse effect on a global study or Development, manufacture or Commercialization of Licensed Products outside the Territory and (2) subject to clause (3) of Section 3.2(f)(ii), Commercialization of Licensed Products, including sales force deployment decisions, in the Field in the Territory; provided that: (3) Zai shall not make any decision that is inconsistent with its obligations to use Commercially Reasonable Efforts to Develop and Commercialize the Licensed Products in the Field and in the Territory or would reasonably be expected to (A) materially adversely affect the continued Development or Commercialization of Licensed Products outside the Territory or the Field; or (B) cause NVCR to be in violation of Applicable Laws as the owner and holder of Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory. In the event that NVCR believes that any decision made by Zai pursuant to this Section 3.2(f)(i) is inconsistent with clauses (1) through (3) of this Section 3.2(f)(i), then NVCR shall so notify

Zai, and Zai's decision shall not go into effect unless and until (x) Zai, within [***] days of such notification, refers such matter to an independent Third Party expert selected by mutual agreement of the Parties who has at least [***] years of experience in the medical device and/or oncology therapeutic field (or who has such other similar credentials as mutually agreed by the Parties), and (y) such Third Party expert decides that Zai's decision is not in conflict with clause (3) of this Section 3.2(f)(i). Such Third Party expert shall be instructed to render its decision within [***] days of the date that such matter is referred to such Third Party expert, with the costs for such independent Third Party expert to be shared equally by the Parties. Except in cases of fraud or manifest error on the part of such Third Party expert, the decision of such Third Party expert shall be final and binding on the Parties (and, for clarity, such matter shall not be subject to the dispute resolution procedures set forth in Article 15);

(ii) NVCR shall have the final decision-making authority with respect to (1) any Development, manufacture or Commercialization activities in the Territory which is reasonably expected to have a materially adverse effect on a global study or Development, manufacture or Commercialization of Licensed Products outside the Territory (provided that NVCR shall not make any such decision that would materially increase Zai's obligations above those set forth in the initial [***] Plan agreed between the Parties without Zai's written consent), (2) any research, Development, manufacturing or Commercialization of Licensed Products outside the Territory or the Field, and (3) the level of reimbursement of a Licensed Product in the Territory if the reimbursement price proposed for the Licensed Product is less than the Minimal Reimbursement Price. The Parties acknowledge that the healthcare market and reimbursement systems in China are evolving and shall continue to review pricing and reimbursement strategies for Licensed Products. The Parties may mutually agree, in writing, to amend the Minimal Reimbursement Price in the future. Notwithstanding the foregoing, NVCR shall not make any decisions that would materially affect Zai's ability to comply with Applicable Laws or cause Zai to breach any Applicable Laws.

(g) Joint Development Committee. The JSC shall promptly establish a joint development committee (the "***JDC***"), which is subject to the supervision and oversight of the JSC, to review, discuss, coordinate and share information regarding (i) the Development of Licensed Products in the Territory, (ii) the progress of the Regulatory Approvals and Regulatory Submissions for Licensed Products in the Territory, and (iii) data generated (for which each Party has the right to reference in regulatory filings) from the other Party's and their licensees' ongoing and future Clinical Trials and filings for obtaining Registration Certification for medical devices for all indications for the Licensed Products. The JDC will meet with a frequency and in a manner as determined by the JSC. The JSC shall resolve any disputes that arise within the JDC within [***] days after any such matter is brought to the JSC for resolution. In no event shall the authority of the JDC exceed the authority of the JSC. Each Party shall be responsible for all of its own expenses of participating in the JDC.

ARTICLE 4
TECHNOLOGY TRANSFERS

4.1 Technology Transfer. NVCR shall use good faith efforts to, within [***] days of the Effective Date, provide and transfer to Zai the NVCR Know-How which shall be that exists on the Effective Date and was not previously provided to Zai (the "***Initial Technology Transfer***"). Thereafter, during the Term, NVCR shall (a) at each meeting of the JSC (and, in any event, on a quarterly basis if any JSC meeting is not held in a particular Calendar Quarter), provide Zai with a summary of additional NVCR Know-How (if any) developed or included in the License and details of any Product Updates and Product Improvements developed [***], (b) transfer any such NVCR Know-How and Product Updates to Zai [***], and (c) provide Zai with reasonable access to NVCR personnel involved in the research and Development of Licensed Products, either in person at NVCR's facility or by teleconference (the "***Continuing Technology Transfer,***" and together with the Initial Technology Transfer, the "***Technology Transfer***"). Thereafter, during the Term, at JSC meetings, NVCR shall keep Zai reasonably informed of NVCR's Development activity as it relates to Zai's Development and Commercialization in the Territory. For the avoidance of doubt, NVCR personnel shall not be obligated to travel to Zai's facilities, and NVCR's transfer obligations under this Section 4.1 shall apply solely to the extent the NVCR Know-How is reasonably necessary to support Zai's Development and Commercialization of the Licensed Product in the Field in the Territory in accordance with this Agreement.

ARTICLE 5
DEVELOPMENT PROGRAM

5.1 Diligence and Responsibilities.

(a) Zai shall be responsible for and use Commercially Reasonable Efforts to (i) Develop Licensed Products in the Field in the Territory in accordance with the Territory Development Plan, (ii) perform the Development activities assigned to Zai [***], and (iii) Commercialize Licensed Products in the Field in the Territory.

(b) Zai shall use Commercially Reasonable Efforts to conduct the tasks assigned to it in the Territory Development Plan, and the tasks [***] and achieve the objectives set forth therein. Zai shall conduct such tasks in a timely, professional manner and in compliance with the Territory Development Plan and [***] Plan, as applicable, and all Applicable Laws, including GLP, GCP and cGMP. NVCR may conduct such tasks assigned to it, and any other activities assigned to it under this Agreement, through one or more Affiliate or Third Party designees.

(c) No later than [***] days following the Effective Date, the Parties will cooperate to finalize, and shall mutually agree upon prior to attachment to this Agreement in **Exhibit B**, a written timeline (the "***NMPA Submission Timeline***") for Regulatory Submissions to the NMPA, which NMPA Submission Timeline may be amended upon mutual agreement by the Parties from time to time. Zai will develop the timelines for other indications within [***] days after the Effective Date.

5.2 Development Target. Zai shall, (a) within [***] months of the [***], obtain Regulatory Approval for the Licensed Product for the same Indication in the Territory; provided, however, [***], Zai shall obtain Regulatory Approval for the Licensed Product for the same Indication in the Territory within [***] months of the [***]; (b) [***] within [***] months after the Effective Date; and (c) [***] within (i) [***] months after [***], or (ii) [***] months after [***] (each such Zai obligation a "***Development Target***" and each such corresponding deadline a "***Development Target Deadline***"); provided that each such Development Target Deadline shall be extended by [***] days or such other period of time as agreed in writing by the Parties if (x) Zai demonstrates to NVCR that Zai has utilized Commercially Reasonable Efforts to achieve the corresponding Development Target by the corresponding Development Target Deadline and (y) such inability to achieve such Development Target by the corresponding Development Target Deadline is due to (i) reasons outside of Zai's control including changes to the regulatory process or Applicable Laws, or delays caused by Governmental Authorities including delays in providing necessary approvals or responses; or (ii) NVCR exercising its final decision making authority with Zai's objection.

5.3 [***] Plan.

(a) NVCR's global Development of Licensed Products will be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 5.3, the "***[***] Plan***"), which the Parties agree shall include (i) TT Fields Multi-Regional Clinical Studies for (1) the NSCLC Indication, (2) the pancreatic cancer Indication, and (3) the ovarian cancer Indication, for each of which, Zai [***]; and (ii) a [***].

(b) The Parties shall discuss and agree upon the initial [***] Plan within [***] days following the Effective Date. In addition to Zai's Development activities under the Territory Development Plan, Zai shall [***]. The [***] Plan shall include (i) an outline only of NVCR's global Clinical Trials for Licensed Products, (ii) details and timelines of the [***], (iii) details and timelines of any other Development activities [***], and (iv) [***], which for each of the TT Fields Multi-Regional Clinical Studies for the NSCLC Indication, the pancreatic cancer Indication and the ovarian cancer Indication, shall be up to [***], using its Commercially Reasonable Efforts.

(c) From time to time, NVCR may make and implement amendments to the then-current [***] Plan. To the extent such amendments are (x) material, and (y) relate to the Territory, NVCR shall submit such proposed amendments to the JSC for review and discussion before adopting such amendments.

5.4 Territory Development Plan. Except for the activities [***] pursuant to Section 5.3, all Development by Zai of Licensed Products in the Territory under this Agreement shall be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 5.4 and Section 3.2, the "***Territory Development Plan***"), which Territory Development Plan shall contain in reasonable detail all major Development activities (including all Clinical Trials) for Licensed Products in the Territory and the timelines for achieving such activities. Attached hereto as **Exhibit C** is an initial

draft of the Territory Development Plan and attached hereto as **Exhibit B** is a NMPA Submission Timeline for the indications of recurrent and newly diagnosed GBM. From time to time as needed thereafter, Zai shall propose amendments to the Territory Development Plan in consultation with NVCR and submit such proposed updated or amended Territory Development Plan to the JSC for review, discussion and approval. Once approved by the JSC, the amended Territory Development Plan shall become effective. For clarity, the Territory Development Plan and amendments thereto must be consistent with the [***] Plan and the [***] Plan shall take precedent in case of any conflict or inconsistency between the Territory Development Plan and the [***] Plan.

5.5 Development Costs. Zai shall be solely responsible for all costs and expenses incurred by or on behalf of Zai in the Development of Licensed Products in the Territory, including the performance of Development activities under the Territory Development Plan and the Development activities [***] and shall provide for reimbursement of NVCR's costs for the assistance provided to Zai in the Development of Licensed Products in the Territory, including the costs incurred in acting as the holder of the Regulatory Approvals and Regulatory Submissions of the Licensed Products on behalf of Zai in the Territory.

5.6 Development Reports. The status, progress and results of Zai's Development activities under this Agreement and NVCR's development activities for the Licensed Product in the Field outside the Territory will be discussed at meetings of the JSC. At least [***] Business Days before each regularly scheduled JSC meeting, Zai will 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 NVCR and sufficient to enable NVCR to determine Zai's compliance with its diligence obligations pursuant to Section 5.1. In addition, Zai will make available to NVCR such additional information about its Development activities as may be reasonably requested by NVCR from time to time. All updates and reports generated pursuant to this Section 5.6 shall be the Confidential Information of Zai.

5.7 Data Exchange and Use. In addition to its adverse event and safety data reporting obligations pursuant to Section 6.5, each Party shall promptly provide the other Party with copies of all data and results and all supporting documentation (e.g. protocols, CRFs, analysis plans) controlled by such Party that are generated by or on behalf of such Party or its Affiliates or sublicensees, if applicable, in the Development of Licensed Products; provided that NVCR shall only be required to provide Zai such data, results and documentation to the extent it comprises NVCR Know-How and is reasonably necessary or useful for Zai's Development and Commercialization of the Licensed Products in the Field and in the Territory. Zai shall have the right to use and reference such data and results provided by NVCR, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field and in the Territory. NVCR and its designees shall have the right to use and reference such data and results provided by Zai, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products outside the Field or the Territory.

5.8 Subcontractors. Zai shall have the right to engage subcontractors for purposes of conducting activities assigned to it under this Agreement or for which it is responsible under this Agreement, to the extent such subcontractors are set forth in the initial Territory Development Plan approved by NVCR or the [***] Plan, or otherwise with NVCR's prior written consent. Zai shall cause any subcontractor engaged by it to be bound by written obligations of confidentiality and non-use consistent with this Agreement prior to performing any activities. Zai shall cause its subcontractors to assign to Zai (or, in the case of academic institutions and Third Party manufacturers, use reasonable efforts to cause such subcontractor to so assign) all intellectual property made by such subcontractor in the course of performing such subcontracted work. Zai shall remain directly responsible for any obligations under this Agreement that have been delegated or subcontracted to any subcontractor and shall be directly responsible for the performance of its subcontractors.

5.9 Records. Zai will maintain appropriate records in either tangible or electronic form of (a) all significant Development 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 Development or Commercialization of a Licensed Product under this Agreement, in each case in accordance with Zai's usual documentation and cGMP record retention practices. Such records will 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, will be at a level of detail appropriate for patent and regulatory purposes. Zai will document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines. Upon NVCR's request, Zai will, and will cause its Affiliates and Sublicensees, to provide to NVCR copies of such records (including access to relevant databases, if any) of Development and Commercialization activities to the extent necessary or useful for the Development and Commercialization of the Licensed Product outside the Territory, including for regulatory and patent purposes. All such records, reports, information and data provided will be subject to the confidentiality provisions of Article 10.

ARTICLE 6
REGULATORY

6.1 Holder of Regulatory Approvals and Regulatory Submissions. NVCR shall initially be the holder of Regulatory Approvals and Regulatory Submission for Licensed Products in the Territory. At Zai's request during the Term, (a) the JSC will discuss in good faith whether to transfer manufacturing responsibilities for Licensed Products for the Territory to Zai, and (b) the Parties will discuss in good faith whether to enable Zai to hold Regulatory Approvals and Regulatory Submissions in the Territory, including any pricing or reimbursement approvals, whether by transfer to Zai of such Regulatory Approvals and Regulatory Submissions or through the submission of a new application for Regulatory Approval in the Territory submitted by Zai, in each case ((a) or (b)), to the extent permitted by Applicable Law and in accordance therewith. If agreed by the Parties, NVCR shall reasonably cooperate with Zai, at Zai's expense, to enable Zai to hold any or all such Regulatory Approvals and Regulatory Submissions.

6.2 Zai's Responsibilities.

(a) Zai shall be responsible [***] for all regulatory activities leading up to and including the obtaining of Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products from Regulatory Authorities in the Field and in the Territory, provided that, Zai shall conduct such regulatory activities (and any and all regulatory activities delegated to Zai in this Agreement or by NVCR during the Term in connection with the Development and Commercialization of the Licensed Product in the Territory during such time that NVCR is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory) as the express, exclusive, and authorized legal agent of record for NVCR in the Territory, and provided further, that such actions shall be taken on behalf of NVCR and for the benefit of Zai in the Territory. Promptly after the Effective Date and from time to time during the Term, the Parties shall conduct such actions and execute such documents as are required for Zai to act as NVCR's express, exclusive, and authorized legal agent of record in the Territory. Notwithstanding the foregoing, to the extent permitted under Applicable Laws, Zai may file, obtain and maintain (on behalf of NVCR, which will be the holder of) Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory.

(b) Zai shall promptly provide to NVCR for review and comment drafts of all Regulatory Submissions prepared by or on behalf of Zai, including English summaries thereof. NVCR shall have the right to review and comment on such Regulatory Submissions and Zai shall consider in good faith any comments received from NVCR and incorporate all comments that are reasonable or necessary for protecting NVCR's interest as licensor of the Licensed Product or holder of the Regulatory Submission or Regulatory Approval in the Territory. In addition, each Party shall promptly notify the other Party of any Regulatory Submissions and any comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and shall provide the other Party with copies thereof as soon as reasonably practicable. If any such Regulatory Submission, comment or correspondence is not in English, Zai shall also promptly provide NVCR with a written English summary of any comments or other correspondences received from a Regulatory Authority with respect to a Regulatory Submission.

(c) Each Party shall promptly provide the other Party with notice after receiving notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Licensed Product in the Field. Zai shall lead any such meeting or discussion, provided, however, that NVCR or its designee shall have the right, but not the obligation, to attend and participate in such meeting or discussion. If NVCR elects not to attend such meeting or discussion, Zai shall provide NVCR with a written summary thereof in English promptly following such meeting or discussion.

6.3 NVCR's Responsibilities. Except if filed or obtained by Zai in its own name, solely as permitted under Section 6.1, NVCR shall own and hold all Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Field and in the Territory for the benefit of Zai, and shall, promptly upon Zai's request, provide access to and copies of such Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals to Zai, as applicable. NVCR shall reasonably cooperate with Zai in obtaining any Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for a Licensed Product in the Field and in the Territory including by providing, to the extent Controlled by NVCR, prompt access to clinical data, and other data, information, and documentation for Licensed Products in the Field, that is included in the NVCR Know-How, including any Regulatory Approvals or Regulatory Submissions for the Licensed Products in the Field in the Territory and outside the Territory (which are reasonably useful in the Territory).

6.4 Right of Reference. Each Party hereby grants to the other Party the right of reference to all Regulatory Submissions pertaining to Licensed Products in the Field submitted by or on behalf of such Party or its Affiliates in and outside the Territory. Zai may use such right of reference to NVCR's Regulatory Submissions solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field in the Territory as NVCR's authorized legal agent and exclusive general distributor of record or on its own behalf to the extent permitted by Applicable Laws and this Agreement. NVCR may use the right of reference to Zai's Regulatory Submissions, if any, solely for the purpose of seeking, obtaining and maintaining regulatory approval of Licensed Products outside the Territory or, to the extent permitted pursuant to this Agreement, in the Territory. Each Party shall bear its own costs and expenses associated with providing the other Party with the right of reference and sharing of data and information pursuant to this Section 6.4.

6.5 Adverse Events Reporting.

(a) Promptly following the Effective Date, but in no event later than [***] days thereafter, Zai and NVCR shall develop and agree in a written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "***Safety Agreement***"). Such Safety Agreement shall describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting and exchange of information between the Parties concerning adverse events or any other safety issue of any significance and product quality and product complaints involving adverse events, in each case with respect to Licensed Products and sufficient to permit each Party and its Affiliates, licensees or sublicensees to comply with its legal obligations with respect thereto, including, for clarity, NVCR's obligations as the owner or holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory, as applicable.

(b) Zai shall maintain an adverse event database for Clinical Trials conducted in the Territory under the Territory Development Plan [***]. Zai shall be responsible for reporting to the applicable Regulatory Authorities in the Territory, on NVCR's behalf during such time that NVCR is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory, all quality complaints, adverse events and safety data

related to Licensed Products for all Clinical Trials conducted in the Territory under the Territory Development Plan or the [***] Plan, as well as responding, on NVCR's behalf during such time that NVCR is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory, to safety issues and to all requests of Regulatory Authorities related to Licensed Products in the Field and in the Territory. Zai shall provide to NVCR access to Zai's adverse event database for the Territory. NVCR shall maintain a global adverse event database for Clinical Trials conducted under the [***] Plan at [***] cost and expense, except for any costs allocated to [***] pursuant to Section 5.5.

6.6 Safety and Regulatory Audits. Upon reasonable notification, NVCR or its representatives shall be entitled to conduct an audit of safety and regulatory systems, procedures or practices of Zai, its Affiliates, sublicenses or subcontractors (including Clinical Trial sites) relating to Licensed Products no more often than [***] Calendar Year. Zai shall promptly notify NVCR of any inspection of Zai, its Affiliates, sublicenses or subcontractors (including Clinical Trial sites) by any Regulatory Authority relating to Licensed Products and shall provide NVCR with all information pertinent thereto. NVCR shall have the right, but not the obligation, to be present at and participate in any such inspection.

6.7 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 NVCR of such contact, inspection or notice or action within [***] hours thereof. NVCR shall have the right to review and comment on any responses to Regulatory Authorities that pertain to a Licensed Product, provided that Zai shall have the final decision-making authority with respect to such responses to the extent relating solely to such Licensed Product in the Field and in Territory and such responses would not have any negative impact on the research, Development, manufacturing or Commercialization of any Licensed Product outside the Territory, but shall incorporate all such reasonable comments of NVCR during such time that NVCR is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory. The costs and expenses of any regulatory action in the Territory shall be borne solely by [***].

6.8 No Harmful Actions. If NVCR believes that Zai is taking or intends to take any action with respect to the Licensed Product that could have a material adverse impact upon the regulatory status of the Licensed Product outside the Territory, NVCR will have the right to bring the matter to the attention of the JSC and the Parties will discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (a) Zai will not communicate with any Regulatory Authority having jurisdiction outside the Territory, unless so ordered by such Regulatory Authority, in which case Zai will immediately notify NVCR of such order; and (b) Zai will not submit any Regulatory Submissions or seek regulatory approvals for the Licensed Product outside the Territory. To the extent practicable, NVCR will provide Zai with any information that reasonably could affect the Development or Commercialization of the Licensed Product in the Territory, prior to making such information public.

6.9 Notification of Threatened Action. Each Party will immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by any Regulatory Authority, which may affect the safety or efficacy claims of any Licensed Product or the continued marketing of any Licensed Product. Upon receipt of such information, the Parties will consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

ARTICLE 7
SUPPLY

7.1 Development Supply. NVCR shall have the sole right, through a Third Party contract manufacturer, to manufacture and supply to Zai all Licensed Products required by Zai for Development use in the Territory under the Territory Development Plan and for Zai's [***] responsibilities under the [***] Plan, including the conduct of TT Fields Multi-Regional Clinical Studies. The Parties shall use good faith efforts to enter into an agreement pursuant to which NVCR would supply such Licensed Products for such Development use by Zai ("***Clinical Supply Agreement***") within [***], pursuant to which:

(a) Except as set forth in Section 7.1(b), NVCR shall supply the Licensed Products pursuant to this Section 7.1 at a transfer price equal to [***].

(b) For a TT Fields Multi-Regional Clinical Study, NVCR shall supply Licensed Products to Zai sufficient to conduct activities in the Territory contemplated under the TT Fields Multi-Regional Clinical Studies [***].

7.2 Commercial Supply. The Parties shall use Commercially Reasonable Efforts to agree [***] on the principal terms of a commercial supply agreement (the "***Commercial Supply Agreement***") pursuant to which Zai shall purchase commercial supply of a Licensed Product from NVCR at [***] in order to fulfill Zai's obligations under this Agreement, which terms shall be consistent with the terms and conditions of this Agreement and the terms and conditions of any agreement between NVCR and its Third Party manufacturing partner(s), to the extent applicable to commercial supply of Licensed Product in the Field in the Territory. Zai shall purchase its commercial requirements for Licensed Product in the Territory from NVCR pursuant to the Commercial Supply Agreement.

7.3 Supply Agreements. The Parties agree that the Clinical Supply Agreement and Commercial Supply Agreement shall contain terms substantially consistent with those contained in the supply agreement term sheet attached hereto as **Exhibit D** (the "***Supply Agreement Term Sheet***") subject to deviations agreed by the Parties.

ARTICLE 8
COMMERCIALIZATION

8.1 Commercialization Diligence. Zai shall be responsible for, and shall use Commercially Reasonable Efforts to Commercialize each Licensed Product that has obtained Regulatory Approval in the Field in the Territory, provided that, Zai shall Commercialize each such Licensed Product (during such time that NVCR is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory) as the exclusive general distributor of NVCR in the Territory, and provided further, that Zai will book all product sales for the Licensed Product in the Territory. Promptly after the Effective Date and from time to time during the Term, the Parties shall execute such documents and conduct such actions as are required for Zai to act as NVCR's exclusive general distributor in the Territory and to book sales for the Licensed Product in the Territory in accordance with this Agreement. Zai shall conduct all Commercialization of Licensed Products in the Field in the Territory in accordance with the Commercialization Plan for such Licensed Product and all Applicable Laws, at [***].

8.2 Commercialization Plan. The Commercialization Plan with respect to a Licensed Product shall contain in reasonable detail the major Commercialization activities, including revenue targets, planned for such Licensed Product in the Territory and estimated timelines for achieving such activities. Attached hereto as **Exhibit E** is an initial draft of the Commercialization Plan for the use of the Licensed Product in treating recurrent and newly diagnosed GBM. From time to time Zai shall propose updates or amendments to the Commercialization Plan and Zai shall submit the proposed updated or amended Commercialization Plan to the JSC for review, discussion, and approval before adopting such update or amendment.

8.3 Commercialization Reports. Zai will 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 will be in a form to be agreed by the JSC and will 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 NVCR and sufficient to enable NVCR to determine Zai's compliance with its diligence obligations pursuant to Section 8.1. In addition, Zai will make available to NVCR such additional information about its Commercialization activities as may be reasonably requested by NVCR from time to time. For clarity, Zai will not be required to include information in its updates and reports under this Section 8.3 that it does not otherwise create for its own internal purposes. All updates and reports generated pursuant to this Section 8.3 shall be the Confidential Information of Zai.

8.4 Coordination of Development and Commercialization Activities.

(a) Within [***] days after the Effective Date, Zai shall use Commercially Reasonable Efforts to establish a patient support system for the Development and Commercialization of Licensed Products in the Territory and other infrastructures in the Territory that are reasonably necessary to enable Zai, its Affiliates, and its sublicensees, to exercise its rights and perform its obligations under this Agreement in relation to Development and Commercialization of the Licensed Products in the Field and in the Territory and NVCR shall provide reasonable support. Zai shall [***].

(b) Zai acknowledges that NVCR may decide to develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Development and Commercialization of Licensed Products on a global basis (such branding elements, collectively, the "***Global Brand Elements***"). NVCR shall own all rights in such Global Brand Elements, and shall grant Zai the exclusive right to use such Global Brand Elements in connection with the Development and Commercialization of Licensed Products in the Field and in the Territory. Zai shall Develop and Commercialize Licensed Products in the Territory in a manner consistent with the Global Brand Elements.

(c) Zai acknowledges that NVCR has developed certain manuals, instruction booklets and other written materials for use, Development and/or Commercialization of the Licensed Products. NVCR hereby grants Zai an exclusive license to use, distribute, disseminate, reproduce, publicly display, and translate such materials solely as necessary for Zai use, Development and/or Commercialization of the Licensed Products in the Territory during the Term and for no other purpose. Zai will [***].

ARTICLE 9
PAYMENTS

9.1 Upfront Payment. Zai shall pay to NVCR a one-time, non-refundable, non-creditable upfront payment of fifteen million Dollars ($15,000,000) within [***] Business Days after the Effective Date.

9.2 Milestone Payments. Zai shall notify NVCR in writing of the achievement by or on behalf of Zai, its Affiliates or sublicensees of any milestone event set forth in this Section 9.2 promptly after the occurrence thereof, and Zai shall pay NVCR each non-refundable, non-creditable milestone payment set forth in the tables below within [***] calendar days of the achievement of such milestone event by or on behalf of Zai, its Affiliates or sublicensees.

Milestone Event	Milestone Payment
Development Milestones	
1. [***]	$[***]
2. [***]	$[***]
Regulatory Milestones	
3. [***]	$[***]
4. [***]	$[***]
5. [***]	$[***]
6. [***]	$[***]
Net Sales Milestones	
7. Calendar Year’s Net Sales of all Licensed Products in the Territory exceeds $[***]	$[***]
8. Calendar Year’s Net Sales of all Licensed Products in the Territory exceeds $[***]	$[***]
9. Calendar Year’s Net Sales of all Licensed Products in the Territory exceeds $[***]	$[***]

(a) Milestone Conditions.

(i) Each milestone payment set forth above shall be payable only once.

(ii) If any Net Sales milestone event occurs for a particular Licensed Product without one of the prior Net Sales milestone events occurring for such Licensed Product, then the milestone payment to be made with respect to the prior milestone event for such Licensed Product shall be paid at the same time as the payment for the subsequent milestone event for such Licensed Product.

9.3 Royalty Payments to NVCR.

(a) Royalty Rates. Subject to the remainder of this Section 9.3, Zai shall make quarterly non-refundable, non-creditable royalty payments to NVCR on the Net Sales of all Licensed Products sold in the Territory, calculated by multiplying the applicable royalty rate set forth below by the corresponding amount of incremental, aggregated Net Sales of all Licensed Products sold in the Territory in the applicable Calendar Year. For each Calendar Year, the below tiered royalties are calculated such that the higher tiered royalties are only paid after the annual Net Sales exceed the top threshold of the previous tier.

Calendar Year, Net Sales of All Licensed Products in the Territory	**Royalty Rate**
1. <$[***]	[***]%
2. $[***] - $[***]	[***]%
3. >$[***]	[***]%

(b) Royalty Term. The royalty payments payable under this Section 9.3 shall be payable on a Licensed Product-by-Licensed Product and region-by-region basis from the First Commercial Sale of such Licensed Product in such region in the Territory until the latest of: (i) the [***] anniversary of the date of the First Commercial Sale of such Licensed Product in such region; (ii) the expiration of the last Valid Claim (including any patent term adjustments or extensions) within the NVCR Patents that Covers such Licensed Product (including composition of matter, method of use or making) in such region and (iii) the last to expire regulatory exclusivity period for such Licensed Product (the "***Royalty Term***").

(c) Royalty Reductions.

(i) Third Party Payments. If the Parties agree that a license under any Patent controlled by a Third Party in a region in the Territory is necessary for the manufacture or Commercialization of the Licensed Product that is sold or offered for sale in such region, then Zai shall have the right to deduct from the royalty payment that would otherwise have been due under Section 9.3(a) with respect to Net Sales of such Licensed Product in such region in a particular Calendar Quarter an amount equal to [***] of the royalties paid by Zai to such Third Party pursuant to such license on account of the sale of such Licensed Product in such region during such Calendar Quarter, subject to Section 9.3(c)(ii). In the event NVCR disputes whether such Third Party license is necessary, the matter shall be referred to the chief patent counsels of Zai and NVCR, or such other person at each Party holding a similar position designated by Zai or NVCR. The chief patent counsels shall meet promptly to discuss and resolve the matter. In the event that the chief patent counsels cannot agree on a resolution to the matter, then the Parties shall refer such matter for resolution to an independent patent attorney mutually agreed upon by the Parties who has at least [***] of experience in the biologics field and/or medical devices field (or who has such other similar credentials as mutually agreed by the Parties), and such attorney's decision on the matter shall be binding upon the Parties (and, for clarity, such matter shall not be subject to the dispute resolution procedures set forth in Article 15).

(ii) Royalty Floor. Notwithstanding the foregoing, during any Calendar Quarter in the Royalty Term for a Licensed Product in a particular region in the Territory, the operation of Section 9.3(c), individually or in combination shall not reduce the final royalty rate to [***].

(d) Royalty Reports and Payments. Within [***] days after the end of each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of the first Licensed Product is made anywhere in the Territory, Zai shall provide NVCR with a report that contains the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product and region-by-region basis: (i) the amount of Net Sales of such Licensed Product, (ii) a calculation of the royalty payment due on such Net Sales, including any royalty reduction made in accordance with Section 9.3(c), and (iii) the exchange rate used for converting any Net Sales recorded in a currency other than Dollars. Promptly following the delivery of the applicable quarterly report, NVCR shall invoice Zai for the royalties due to NVCR with respect to Net Sales by Zai, its Affiliates and their respective sublicensees for such Calendar Quarter, and Zai shall pay such amounts to NVCR in Dollars within [***] following Zai's receipt of such invoice, provided that, if a government or regulatory action (or inaction) prevents Zai from making such payment to NVCR within such [***] period, then Zai shall have up to [***] following its receipt of such invoice from NVCR to remit such payment to NVCR.

9.4 Payments to Third Parties. Except as expressly set forth herein, each Party shall be solely responsible for any payments due to Third Parties under any agreement entered into by such Party, with respect to the Licensed Product, as a result of activities hereunder.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

9.5 Currency; Exchange Rate. All payments to be made by Zai to NVCR or NVCR to Zai under this Agreement shall be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by NVCR or Zai, as applicable. Conversion of Net Sales recorded in local currencies shall be converted to Dollars at the exchange rate set forth in *The Wall Street Journal* or any successor thereto for the last day of the Calendar Quarter in which the applicable payment obligation became due and payable.

9.6 Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [***] percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue or (b) the maximum rate permitted by Applicable Laws; in each case calculated on the number of days such payment is delinquent, compounded monthly.

9.7 Financial Records and Audits. During the Term and for [***] years thereafter, each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the amount of royalty payments and other amounts payable under this Agreement. Upon reasonable prior notice, such records shall be open during regular business hours for a period of five years from the creation of individual records for examination by an independent certified public accountant selected by the examining Party and reasonably acceptable to the other Party for the sole purpose of verifying for the examining Party the accuracy of the financial reports furnished by the other Party (the "***Examined Party***") pursuant to this Agreement or of any payments made, or required to be made by such Examined Party, pursuant to this Agreement. Such audits shall not occur more often than [***]. Such auditor shall not disclose the Examined Party's Confidential Information to the examining Party or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the Examined Party or the amount of payments by the Examined Party under this Agreement. The Examined Party will pay any amounts shown to be owed to the examining Party but unpaid within [***] days after the accountant's report, plus interest (as set forth in Section 9.6) from the original due date. The examining Party shall bear the full cost of such audit unless such audit reveals an underpayment by the Examined Party of more than [***] of the amount actually due for the time period being audited, in which case the Examined Party shall reimburse the examining Party for the costs for such audit.

9.8 Taxes.

(a) Taxes on Income. Except as set forth in this Section 9.8 each Party shall be solely responsible for the payment of any and all income Taxes levied on account of all payments it receives under this Agreement.

(b) Sales Taxes and VAT. [***] shall bear any and all sales, use, VAT, transaction and transfer taxes and other similar charges (and any related interest and penalties) imposed on, or payable with respect to, such license or property; provided, however, that if Zai is required to withhold any Taxes (including withholding taxes as valued-added taxes), the provisions of Section 9.8(c) shall apply to such withheld VAT Taxes.

(c) Tax Cooperation. The Parties agree to cooperate with one another in accordance with Applicable Laws and use reasonable efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. To the extent either Party (the "***Paying Party***") is required to deduct and withhold Taxes on any payment to the other Party (the "***Recipient***"), the Paying Party shall notify the Recipient of such requirement prior to making the payment to the Recipient and provide such assistance to the Recipient, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in the Recipient's efforts to claim an exemption from or reduction of such taxes. The Paying Party shall, in accordance with Applicable Laws, deduct or withhold taxes from the amount due, remit such taxes to the appropriate tax authority when due, and furnish the Recipient with proof of payment of such taxes within [***] days following the payment. If taxes are paid to a tax authority, the Paying Party shall provide reasonable assistance to the Recipient to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid. To the extent such amounts are paid to the appropriate tax authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the Recipient.

ARTICLE 10
CONFIDENTIALITY; PUBLICATION

10.1 Duty of Confidence. Subject to the other provisions of this Article 10:

(a) Except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "***Disclosing Party***") shall be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "***Receiving Party***") and its Affiliates for the Term and [***] years thereafter;

(b) the Receiving Party may only use any Confidential Information of the Disclosing Party to the extent reasonably necessary to perform its obligations or exercise its rights under this Agreement; and

(c) a Receiving Party may disclose Confidential Information of the Disclosing Party to: (i) such Receiving Party's Affiliates, licensees and sublicensees; and (ii) employees, directors, agents, contractors, consultants and advisors of the Receiving Party and its Affiliates and sublicensees (collectively, "***Representatives***"), in each case to the extent reasonably necessary to perform its obligations or exercise its rights under this Agreement; provided that such Persons are bound by legally enforceable obligations to maintain the confidentiality of the Disclosing Party's Confidential Information in a manner consistent with the confidentiality provisions of this Agreement; provided that each Party shall remain responsible for any failure by its Affiliates, licensees and sublicensees, and its and its Affiliates' and licensees' and sublicensees' respective employees, directors, agents, consultants, advisors, and contractors, to treat such Confidential Information as required under this Section 10.1 (as if such Affiliates, licensees, sublicensees employees, directors, agents, consultants, advisors and contractors were Parties directly bound to the requirements of this Section 10.1).

10.2 Exemptions. Information of a Disclosing Party will not be deemed to be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

(a) is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

(b) is generally available to the public before its receipt from the Disclosing Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Representatives in breach of this Agreement;

(d) is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

(e) is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

10.3 Authorized Disclosures. Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) (i) the Patent Prosecution of NVCR Patents as contemplated by this Agreement; (ii) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Development, manufacturing or Commercialization of a Licensed Product (solely in the Territory in accordance with this Agreement, with respect to disclosures by Zai); or (iii) subject to Section 10.5, complying with Applicable Laws, including regulations promulgated by securities exchanges;

(b) disclosure of this Agreement, its terms and the status and results of Development or Commercialization activities to actual or *bona fide* potential investors, acquirors, (sub)licensees, lenders and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction or collaboration; provided that in each such case on the condition that such Persons are bound by confidentiality and non-use obligations consistent with this Agreement or customary for such type and scope of disclosure;

(c) such disclosure is required by judicial or administrative process (including in filings with Governmental Authorities), provided that in such event such Party shall, to the extent practical and legally permissible, promptly notify the other Party in writing of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article 10, and the Party disclosing Confidential Information pursuant to Applicable Laws or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information; or

(d) disclosure pursuant to Section 10.5.

Notwithstanding the foregoing, in the event a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to clause (ii) or (iii) of Section 10.3(a), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

10.4 Publications. Upon completion of a Clinical Trial and evaluation by NVCR of all data from such study, or upon early termination or abandonment of such study, upon prior written approval by NVCR, Zai may publicly present or publish any Clinical Trial data, non-clinical data or any associated results or conclusions generated by or on behalf of Zai pursuant to this Agreement solely for non-commercial purposes and solely to the extent that such data, results and conclusions are specific to the Territory and the Field (each such proposed presentation or publication, a "***Publication***"), provided that Zai may only make such Publication in accordance with NVCR's global publication strategy with respect to Licensed Products, and subject to the additional limitations set forth in this Section 10.4.

(a) Review Period. A copy of such disclosure will be given to NVCR for review at least [***] days prior to the date of submission for publication or of public disclosure ("***Review Period***"). NVCR will complete its review within the Review Period and will have authority to require that Zai delete from the disclosure any reference to NVCR's Confidential Information. Notwithstanding the Review Period, Zai shall not make any such publication without the written approval of NVCR (not to be unreasonably withheld), nor allow any other publication in connection therewith.

(b) Patent Filings. Subject to the provisions of the subparagraph (a) above, if during the Review Period, NVCR notifies Zai that it desires patent applications to be filed on any Inventions disclosed or contained in the disclosures, Zai will defer publication or other disclosure for a period, not to exceed an additional [***] days, sufficient to permit NVCR or its designee to have filed or to file any desired patent applications.

10.5 Publicity; Use of Names.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 10.3 and this Section 10.5. The Parties shall agree on a joint press release announcing this Agreement whose substance and the date and the time of the announcement shall be agreed by the Parties. No other disclosure of the existence or the terms of this Agreement may be made by either Party or its Affiliates except as provided in Section 10.3 and this Section 10.5. Each Party shall have the right to use the other Party's name and logo in presentations, its website, collateral materials and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued in accordance with this Section 10.5; provided that when Zai uses NVCR's corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases, and Zai shall include an accompanied explanatory text such as "Licensed from Novocure"; further provided that a Party will use the other Party's corporate name only in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of the other Party shall not be impaired, and in a manner consistent with best practices it uses with respect to its other collaborators.

(b) A Party may disclose this Agreement in securities filings with the Securities and Exchange Commission or equivalent foreign agency to the extent required by Applicable Laws. In such event, the Party seeking such disclosure shall prepare a draft confidential treatment request and proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no more than [***] Business Days after receipt of such confidential treatment request and proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by Applicable Laws. The Party seeking such disclosure shall reasonably consider any comments thereto provided by the other Party within such [***] Business Day period.

ARTICLE 11
REPRESENTATIONS, WARRANTIES, AND COVENANTS

The representations and warranties of each Party set forth in this Article 11 are made by the respective Party as of the Effective Date, subject to the information disclosed by such Party in the Disclosure Schedule attached hereto as Schedule 11 (the "***Disclosure Schedule***").

11.1 Representations, Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder; and

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Applicable Laws or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

11.2 Representations and Warranties of NVCR. NVCR represents and warrants to Zai that as of the Effective Date:

(a) it has the right under the NVCR IP to grant the Licenses to Zai, and it has not granted any license or other right under the NVCR IP that is inconsistent with the License;

(b) there is no pending litigation, nor has NVCR received any written notice from any Third Party, asserting or alleging that the Development, manufacture or Commercialization of the Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(c) there are no pending or, to NVCR's knowledge, no threatened (in writing), adverse actions, suits or proceedings against NVCR involving the NVCR IP or Licensed Product;

(d) the NVCR IP includes (i) all Know-How Controlled by NVCR or its Affiliates that is necessary, or to NVCR's knowledge reasonably useful, to Develop and Commercialize Licensed Products in the Field in the Territory as such Development and Commercialization is currently being conducted by NVCR or contemplated to be conducted by the Parties hereunder, and (ii) all Patents in the Territory that are owned or licensed by NVCR or its Affiliates that Cover a Licensed Product in the Field in the Territory.

(e) NVCR has complied with in material aspects with all material Applicable Laws applicable to (i) the prosecution and maintenance of the NVCR Patents and (ii) its Development and manufacture of Licensed Products in the Field;

(f) (i) NVCR has obtained, or caused its Affiliates to obtain, assignments from the inventors of all rights and embodiments in and to the NVCR IP that is solely owned by NVCR or its Affiliates, (ii) to its actual knowledge, all such assignments are valid and enforceable, and (iii) to its actual knowledge, the inventorship of the NVCR Patents that are solely owned by NVCR or its Affiliates is properly identified on each issued patent or patent application in such NVCR Patents; and

(g) NVCR and its Affiliates have taken commercially reasonable efforts consistent with industry practices to protect the secrecy, confidentiality and value of all NVCR Know-How that constitutes trade secrets under Applicable Laws.

(h) the Specifications attached hereto as Schedule 1.55 for the Licensed Product to be delivered to Zai under this Agreement are the same as the specifications for such Licensed Product procured by NVCR as of the Effective Date for development or commercialization in the United States and as required under the applicable regulatory approval for the Licensed Product outside the Territory.

11.3 Representations and Warranties of Zai. Zai represents and warrants to NVCR that as of the Effective Date:

(a) there are no legal claims, judgments or settlements against or owed by Zai or any of its Affiliates, or pending or, to Zai's actual knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations;

(b) Zai has sufficient financial wherewithal to (i) perform all of its obligations pursuant to this Agreement, and (ii) meet all of its obligations that come due in the ordinary course of business; and

(c) Zai has, or can readily obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development and Commercialization, and obtaining Regulatory Approvals.

11.4 Covenants of Zai. Zai covenants to NVCR that:

(a) in the course of performing its obligations or exercising its rights under this Agreement, Zai shall comply with all Applicable Laws, including, as applicable, cGMP, GCP, and GLP standards, and shall not employ or engage any Person who has been debarred by any Regulatory Authority, or, to Zai's knowledge, is the subject of debarment proceedings by a Regulatory Authority;

(b) Zai will only engage Clinical Trial sites under the Territory Development Plan and the [***] Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the NMPA;

(c) Zai and its Affiliates will not use any employees or contractors in the Development, manufacture or Commercialization of the Licensed Product who are, or have been, debarred or disqualified by any Regulatory Authority;

(d) Zai or its Affiliates shall not alter, modify, adapt, disassemble or reverse engineer the Licensed Product or any part thereof, or attempt to do the same to the Licensed Product or any part thereof; and

(e) Zai and its Affiliates shall comply with all of NVCR's storage, handling, standard operating procedures, patient support protocols, quality standards, guidelines, and any other similar internal standards.

11.5 Covenants of NVCR. NVCR covenants to Zai that during the Term:

(a) in the course of performing its obligations or exercising its rights under this Agreement, NVCR shall comply with all Applicable Laws applicable to its Development and manufacture of Licensed Products pursuant to this Agreement;

(b) All Licensed Products supplied by NVCR to Zai under this Agreement will comply with and be manufactured in accordance with the Specifications, subject to any supply agreement and any related quality agreement.

11.6 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS Article 11, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF NVCR OR ZAI; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

11.7 Compliance with Anti-Corruption Laws.

(a) Notwithstanding anything to the contrary in this Agreement, Zai agrees that:

(i) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (including the provisions of the United States Foreign Corrupt Practices Act, collectively "***Anti-Corruption Laws***") that may be applicable to one or both Parties;

(ii) it shall adhere to its own internal anti-corruption policies and 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) Zai represents and warrants that, to its knowledge, neither Zai nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of Zai or any of its Affiliates has taken any action in violation of any applicable Anti-Corruption Laws.

(iv) it will maintain records (financial and accounting) and supporting documentation related to the subject matter of the Agreement reasonably sufficient to document or verify compliance with the provisions of this Section 11.7, and upon request of NVCR, up to once per year and upon reasonable and at least [***] Business Days' advance notice, will provide a Third Party auditor mutually acceptable to the Parties

(as confirmed in writing) with access to such records for purposes of verifying compliance with the provisions of this Section 11.7. Written acceptance of a proposed Third Party auditor may not be unreasonably withheld. It is expressly agreed that the costs related to the Third Party auditor will be fully paid by NVCR, and that any auditing activities may not unduly interfere with the normal business operations of Zai and shall not continue for more than [***] Business Days without the written consent of Zai. Zai may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit. For the avoidance of doubt, the scope of the aforementioned audit shall be limited to the financial and accounting records and documentation of the subject matter of the Agreement; Zai is not obligated to provide any other such records or documentation.

(b) To its knowledge as of the Effective Date, 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 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 the payment or gift of anything of value, directly or

(iii) indirectly, to any Public Official (as defined in Section 11.7(d) below), for the purposes of:

(1) influencing any act or decision of any Public Official in his official capacity;

(2) inducing such Public Official to do or omit to do any act in violation of his lawful duty;

(3) securing any improper advantage; or

(4) inducing 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, none of the officers, directors (excluding the independent director whose identity has been disclosed to NVCR), employees of Zai or of 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 11.7, "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.

11.8 Compliance with Anti-Corruption and OFAC Laws. Zai, and all of its internal procedures where applicable, comply with all applicable Sanctions and requirements thereof, including through appropriate screening of all of its business partners, directors, officers and employees with respect to Sanctioned Countries and against Sanctions Lists, as well as Persons that are fifty percent (50%) or more owned or controlled by a Person targeted by Sanctions. During the five (5) years prior to the Effective Date, Zai has not been involved in any violation of Sanctions. Zai has not received any written notification from a Governmental Authority that it is in breach of Sanctions and, to Zai's knowledge, (to the extent Zai actually knows or should reasonably have known), no action, suit or proceeding by or before any Governmental Authority involving Zai with respect to Sanctions is pending or threatened.

ARTICLE 12
INDEMNIFICATION

12.1 By Zai. Zai shall indemnify and hold harmless NVCR, its Affiliates, and their respective directors, officers, employees and agents (individually and collectively, the "***NVCR Indemnitee(s)***") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) (individually and collectively, "***Losses***") incurred in connection with any claims, demands, actions or other proceedings by any Third Party, including by the NMPA or any other Regulatory Authority with jurisdiction in the Territory, (individually and collectively, "***Claims***") to the extent arising from (a) Zai's actions (or omissions) in the performance of its obligations with respect to Regulatory Submissions and interactions with Regulatory Authorities, in each case, as an agent of NVCR in the Territory, other Development and/or Commercialization activities, including the promotion, selling, storing, handling and/or distribution of a Licensed Product and product liability claims relating to the Licensed Product, by Zai or any of its Affiliates or Sublicensees, (b) the [***] of Zai or its Affiliates or sublicensees, or (c) Zai's breach of any of its representations or warranties 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 such Losses or Claims arise out of an NVCR Indemnitee's negligence or willful misconduct, breach of this Agreement, or material failure to abide by any Applicable Laws.

12.2 By NVCR. NVCR 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 incurred in connection with Claims against such Zai Indemnitee to the extent arising from (a) the Development, manufacture or

Commercialization of the Licensed Products by or on behalf of NVCR or any of its Affiliates or sublicensees (not including Zai or its Affiliates or sublicensees), including product liability claims, in each case outside of the Territory, (b) the [***] of NVCR or its Affiliates hereunder, or (c) NVCR's breach of any of its representations or warranties 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 such Losses or Claims arise out of any of a Zai Indemnitee's negligence or willful misconduct, breach of this Agreement or material failure to abide by any Applicable Laws.

12.3 Indemnification Procedure. If either Party is seeking indemnification under Section 12.1 or 12.2, it shall inform the other Party (the "***Indemnifying Party***") of the claim giving rise to the obligation to indemnify pursuant to such Section(s) within [***] Business Days after receiving written notice of the claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a claim shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If the Parties cannot agree as to the application of Section 12.1 or 12.2 as to any claim, pending resolution of the dispute pursuant to Article 15, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 12.1 or 12.2 upon resolution of the underlying claim.

12.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1, OR 12.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO CONFIDENTIALITY.

12.5 Insurance. Zai shall procure and maintain insurance during the Term and continue to purchase and maintain for a period of five (5) years thereafter, including product liability insurance (and to the extent not included in such product liability insurance, Clinical Trials insurance), adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed

or sold in the Territory. Without limiting the foregoing, such insurance coverage shall include additional insured status for NVCR and be, for product liability, [***] per occurrence and to the extent not included in such product liability insurance, for Clinical Trials, a minimum of [***] per loss occurrence, and in no event less than [***] in the aggregate. Such insurance shall not be construed to create a limit of Party's liability with respect to its indemnification obligations under Section 12.1. Zai shall provide NVCR with evidence of such insurance, and copy(ies) of the additional insured endorsement, upon request and shall provide NVCR with written notice at least [***] days prior to the cancellation, non-renewal or material changes in such insurance. Such insurance shall not be construed to create a limit of Zai's liability with respect to its indemnification obligations under this Article 12.

ARTICLE 13
INTELLECTUAL PROPERTY

13.1 Inventions.

(a) Ownership. Zai agrees and acknowledges that it is unlikely that Zai would create or own any new intellectual property as a result of Zai's Development or Commercialization activities in the Territory. If any intellectual property is generated by or on behalf of Zai as a result of Zai's Development or Commercialization activities in the Territory (the "**New IP**"), Zai agrees and hereby assigns all such New IP to NVCR and such New IP shall be solely owned by NVCR and shall be included in the NVCR IP and licensed to Zai in the Field in the Territory under Section 2.1.

(b) Disclosure. Zai shall promptly disclose to NVCR 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 NVCR for additional information relating thereto.

(c) Assignment of New IP. Zai shall and hereby does assign to NVCR all right, title and interest in and to all New IP. Zai shall take (and cause its Affiliates, sublicensees and their employees, agents, and contractors to take) such further actions reasonably requested by NVCR to evidence such assignment and to assist NVCR in obtaining patent and other intellectual property rights protection for the New IP. Zai shall obligate its Affiliates, sublicensees and contractors to assign all New IP to Zai (or directly to NVCR) so that Zai can comply with its obligations under this Section 13.1, and Zai shall promptly obtain such assignment.

13.2 Patent Prosecution.

(a) NVCR Patents.

(i) As between the Parties, NVCR shall have the right to control the Patent Prosecution of all NVCR Patents at NVCR's expense.

(ii) NVCR shall consult with Zai and keep Zai reasonably informed of the Patent Prosecution of the NVCR 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, NVCR 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 of the NVCR Patents for Zai's review and comment prior to the submission of such proposed filings and correspondence. Further, NVCR shall notify Zai of any decision to cease Patent Prosecution or maintenance of any NVCR Patents in the Territory. NVCR will consider Zai's comments on Patent Prosecution but will have final decision-making authority under this Section 13.2(a)(ii).

(b) Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 13.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

13.3 Patent Enforcement.

(a) Notice. Each Party shall notify the other within [***] Business Days of becoming aware of any alleged or threatened infringement by a Third Party of any of the NVCR Patents in the Territory, and any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any NVCR Patents (collectively "***Product Infringement***").

(b) Enforcement Rights. NVCR shall have the first right to bring and control any legal action to enforce NVCR Patents against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate, and NVCR shall consider in good faith the interests of Zai in such enforcement of the NVCR Patents. If NVCR 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 within [***] days after a written request from Zai to do so, or if NVCR discontinues the prosecution of any such action after filing without abating such infringement, then Zai shall have the right to enforce the NVCR Patents against such Product Infringement in the Territory at its own expense as it reasonably determines appropriate; provided that Zai shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any NVCR Patent without the prior written consent of NVCR.

(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 each such Party's sole cost and expense.

13.4 Infringement of Third Party Rights.

(a) Notice. If any Licensed Product used or sold by Zai, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent or other intellectual property rights in the Territory that are owned or controlled by such Third Party, Zai shall promptly notify NVCR within [***] days after 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.

(b) Defense. In the event that a claim is brought against either Party alleging the infringement, violation or misappropriation of any Third Party intellectual property right based on the manufacture, use, sale or importation of the Licensed Products in the Field and in the Territory, the Parties shall promptly meet to discuss the defense of such claim, and the Parties shall, as appropriate, enter into a joint defense agreement with respect to the common interest privilege protecting communications regarding such claim in a form reasonably acceptable to the Parties.

13.5 Product Trademarks. Subject to Section 8.4, the Parties agree to use the Optune Trademarks for marketing Licensed Products in the Territory and shall cooperate in good faith and jointly select other trademarks, logos, and trade names that conform with NVCR's global branding strategies for marketing Licensed Products in the Territory (together with the Optune Trademarks, the "***Product Marks***"). Zai shall not use any other trademarks or house marks of NVCR (including NVCR's corporate name) or any trademark confusingly similar thereto without NVCR's prior written consent. NVCR 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, at NVCR's cost and expense; provided that NVCR shall grant Zai a royalty free exclusive license to use such Product Marks in connection with the sale, offer for sale and other Commercialization activities of the Licensed Products in the Territory during the Term, with the right to sublicense following the provisions of Section 2.2. All goodwill and reputation generated by Zai's use of the Product Marks shall inure to the exclusive benefit of NVCR. Zai shall not by any act or omission use the Product Marks in any manner that disparages or reflects adversely on NVCR or its products, technologies, business or reputation. Zai shall not take any action that would interfere with or prejudice NVCR's ownership or registration of the Product Marks, the validity of the Product Marks. Zai further agrees to use the Product Marks in accordance with such brand usage guidelines and quality standards as may be reasonably established by NVCR and communicated to Zai from time to time in writing, or as may be agreed to by the Parties from time to time in writing. Zai shall submit to NVCR for approval, prior to their use, all product labels, product brochures, advertisements, and other materials and material changes thereto upon which Zai uses the Product Marks; provided that, (a) NVCR will approve or disapprove any such materials within [***] Business Days of Zai's submission; provided that if NVCR fails to respond within such period of time, such materials will be deemed approved if they are consistent with NVCR's brand usage guidelines; further

provided NVCR shall use good faith to approve or disapprove such materials within a period of time specified by Zai if Zai requests NVCR to provide an expedited approval for certain materials, and (b) following NVCR's approval in accordance with sub-clause (a), Zai will be free to use such materials without the necessity to obtain NVCR's approval for any subsequent use as long as such materials are not substantially different from the materials approved by NVCR.

ARTICLE 14
TERMS AND TERMINATION

14.1 Term. This Agreement shall be effective as of the Effective Date, and shall continue, on a region-by-region and Licensed Product-by-Licensed Product basis, in effect until [***] (the "***Term***"). On a region-by-region basis, upon [***], the License in such region shall become fully paid-up, perpetual, irrevocable and exclusive.

14.2 Termination

(a) Termination by Zai for Convenience. At any time, Zai may terminate this Agreement by providing written notice of termination to NVCR, which notice includes (i) an effective date of termination [***] months after the date of the notice if the First Commercial Sale of any Licensed Product has not occurred in the Field in the Territory as of the date of such notice, or (ii) an effective date of termination [***] months after the date of the notice if the First Commercial Sale of any Licensed Product in the Field in the Territory has occurred as of the date of such notice.

(b) Termination for Material Breach. If [***], then the non-breaching Party may deliver notice of such breach to the other Party stating the cause, and proposed remedy if any. For all such [***], the allegedly breaching Party shall have [***] from such notice to dispute or cure such breach, provided that if such breach is not reasonably capable of cure within such [***] period, but is capable of cure within [***] from such notice, the breaching Party may submit, within [***] of such notice, a reasonable cure plan to remedy such breach as soon as possible and in any event prior to the end of such [***] period, and, upon such submission, the [***] cure period shall be automatically extended for so long as the breaching Party continues to use diligent efforts to cure such breach in accordance with the cure plan, but for no more than [***] additional days. If [***], the matter shall be addressed under the dispute resolution provisions in Article 15, and the termination shall not become effective unless and until it has been determined under Article 15 that the allegedly breaching Party is in material breach of this Agreement and has failed to cure such breach within the time periods provided in this Section 14.2(b); provided that [***], if either Party disputes [***], the Parties agree to resolve the dispute as expeditiously as possible under Article 15, but in any event within [***] days after the occurrence of such dispute. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. A [***] shall be treated as a material breach of this Agreement and notwithstanding the foregoing provisions in this Section 14.2(b), [***] shall have [***] days to cure any breach [***]; provided that, if a government or regulatory action (or inaction) prevents [***] within such [***] day period, the Parties shall discuss in good faith to extend such [***] day period.

(c) Termination for Diligence Failure. Notwithstanding any other provision in Section 14.2(b), Zai's failure to perform its diligence obligations under Sections 5.1 or 8.1 shall be presumed to constitute a curable material breach of this Agreement, and if such material breach remains uncured or is determined to be uncurable, each, in accordance with Sections 14.2(b) and 14.2(c), NVCR may, at its sole discretion, terminate this Agreement immediately upon notice to Zai. If Zai believes such material breach can be cured, and Zai provides to NVCR, within [***] days of NVCR's notice to Zai, a statement of how such material breach can be cured, NVCR shall have [***] days from receipt of such statement to dispute such statement. If the Parties cannot agree on whether such material breach can be cured, the matter shall be addressed under the dispute resolution provisions in Article 15, and the termination shall not become effective unless and until it has been determined under Article 15 that such material breach cannot be cured or, if it is determined that such material breach can be cured, Zai fails to cure such material breach within the time periods for cure as set forth in Section 14.2(b). If it is determined or NVCR does not dispute that such material breach can be cured, Zai will have the right to cure such material breach within the time periods for the cure as set forth in Section 14.2(b).

(d) Termination for Patent Challenge. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, NVCR may terminate this Agreement in its entirety, immediately if Zai or its Affiliates or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any Patents owned or Controlled by NVCR anywhere in the world.

(e) 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 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 [***] of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(f) Full Force and Effect During Notice Period. This Agreement shall remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if any milestone event is achieved during the termination notice period, then the corresponding milestone payment is accrued and Zai shall remain responsible for the payment of such milestone payment even if the due date of such milestone payment may come after the effective date of the termination.

14.3 Effect of Termination. Upon the termination (but not the expiration) of this Agreement:

(a) Licenses. The License and all other rights granted by NVCR to Zai under the NVCR IP and copyrights and trademarks owned or Controlled by NVCR shall terminate and all sublicenses granted by Zai shall also terminate.

(b) Regulatory Submissions. Upon NVCR's written request, Zai shall provide NVCR with copies of all Regulatory Submissions for Licensed Products. To the extent Zai has obtained any ownership interest in a Regulatory Submission, and to the extent permissible under Applicable Law and commercially feasible, Zai shall assign to NVCR or shall provide NVCR with a right of reference with respect to such Regulatory Submissions, as NVCR determines at its reasonable discretion, at [***] cost and expense. In addition, upon NVCR's written request, Zai shall, at [***] cost and expense, provide to NVCR copies of all material related documentation, including material non-clinical, preclinical and clinical data that are held by or reasonably available to Zai, its Affiliates or sublicensees. The Parties shall discuss and establish appropriate arrangements with respect to safety data exchange, provided that NVCR will assume all safety and safety database activities no later than [***] months after termination.

(c) Inventory. At NVCR's election and request, Zai shall transfer to NVCR or its designee some or all inventory of Licensed Products (including all disposable (i.e., arrays), replacement components, Licensed Products retrieved after stoppage the like) then in the possession or control of Zai, its Affiliates or sublicensees.

(d) Wind Down and Transition. Zai shall be responsible, at [***] cost and expense, for the wind-down of Zai's, its Affiliates' and its sublicensees' Development, manufacture and Commercialization activities for Licensed Products. Zai shall, and shall cause its Affiliates and sublicensees to, reasonably cooperate with NVCR to facilitate orderly transition of the Development, manufacture and Commercialization of Licensed Products to NVCR or its designee, including (i) using reasonable efforts to assign or amend as appropriate, upon request of NVCR, any agreements or arrangements with Third Party vendors (including distributors) to Develop, manufacture, promote, distribute, sell or otherwise Commercialize Licensed Products or, to the extent any such Third Party agreement or arrangement is not assignable to NVCR, reasonably cooperating with NVCR to arrange to continue to provide such services for a reasonable time after termination; (ii) using reasonable efforts, to the extent it does not disrupt any of Zai's other operations as determined in its sole discretion, to transfer employees and independent contractors of Zai or its Affiliates, or its or their contractors, who provide technical support, or similar support, to users of the Licensed Product to NVCR or its designee; and (iii) to the extent that Zai or its Affiliate is performing any activities described above in (i) and (ii), reasonably cooperating with NVCR to transfer such activities to NVCR or its designee and continuing to perform such activities on NVCR's behalf for a reasonable time after termination until such transfer is completed.

(e) Ongoing Clinical Trial. If, at the time of such termination, Zai or its Affiliates are conducting any Clinical Trials, then, at NVCR's election on a Clinical Trial-by-Clinical Trial basis: (i) to the extent permissible under Applicable Law and commercially feasible, Zai shall, and shall cause its Affiliates to, cooperate with NVCR to transfer the conduct of such Clinical Trial to NVCR or its designees and complete such transfer promptly and, in any case, within [***] months after the termination effective date, and NVCR shall assume any and all liability for the conduct of such transferred Clinical Trial after the effective date of such transfer (except to the extent arising prior to the transfer date or from any willful misconduct or negligent act or omission by Zai, its Affiliates or their respective employees, agents and contractors); and (ii) Zai shall, at [***] cost and expense, orderly wind-down the conduct of any such Clinical Trial that is not assumed by NVCR under clause (i) above.

(f) Return of Confidential Information. At NVCR's election, Zai shall return (at NVCR's expense) or destroy all tangible materials comprising, bearing or containing any Confidential Information of NVCR that are in Zai's or its Affiliates' or sublicensees' possession or control and provide written certification of such destruction; provided that Zai may retain one copy of such Confidential Information for its legal archives solely to monitor compliance with its obligations herein, and provided further, that Zai 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 record retention and destruction practices that apply to its own general electronic files and information.

(g) NVCR's Responsibilities. Notwithstanding any provision to the contrary in this Section 14.3, if this Agreement is terminated by Zai under Section 14.2(b) or Section 14.2(e), NVCR shall be responsible for [***] and NVCR shall [***].

14.4 Termination Press Releases. In the event of termination of this Agreement for any reason, and subject to the provisions of Section 10.3, the Parties shall cooperate in good faith to coordinate public disclosure of such termination and the reasons therefor, and shall not, except to the extent required by Applicable Laws, disclose such information without the prior approval of the other Party. 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 investor reaction to such news.

14.5 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Article 1 (as applicable), Article 10, Article 12, Article 15, and Article 16 (as applicable), and Sections 5.7 (if a termination, only with respect to NVCR's use rights), 5.8 (with respect to responsibility for subcontractors), 9.7, 11.6, 13.1, 14.3, 14.4, 14.5, and 14.6 shall survive the expiration or termination of this Agreement.

14.6 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

ARTICLE 15
DISPUTE RESOLUTION

15.1 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 15.

15.2 Negotiation; Escalation. The Parties shall negotiate in good faith and use reasonable efforts to settle any Dispute under this Agreement. Any Dispute as to the breach, enforcement, interpretation or validity of this Agreement shall be referred to the Executive Officers for attempted resolution. In the event the Executive Officers are unable to resolve such Dispute within [***] days 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 15.3.

15.3 Arbitration.

(a) In the event of a Dispute that cannot be resolved between the Parties or the Executive Officers as set forth in Section 15.2, either Party shall be free to institute binding arbitration with respect to such Dispute in accordance with this Section 15.3 upon written notice to the other Party (an "***Arbitration Notice***") and seek remedies as may be available. Any Dispute unresolved under this Section 15.3 shall be settled by binding arbitration administered by International Chamber of Commerce (or any successor entity thereto) and in accordance with its arbitration rules and procedures then in effect, as modified in this Section 15.3 (the "***Rules***"), except to the extent such rules are inconsistent with this Section 15.3, in which case this Section 15.3 shall control. The proceedings and decisions of the arbitration shall be confidential, final and binding on the Parties, and judgment upon the award of such arbitrator may be entered in any court having jurisdiction thereof.

(b) Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three (3) arbitrators (the "***Arbitrators***"), with each arbitrator having not less than fifteen (15) years of experience in the medical device industry and subject matter expertise with respect to the matter subject to arbitration. Any Arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the particular Dispute. Each Party shall promptly select one Arbitrator each, which selections shall in no event be made later than [***] days after receipt of the Arbitration Notice. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrators chosen by the Parties, but in no event later than [***] days after the date that the last of such Arbitrators was appointed.

(c) Each Party shall bear its own costs and expenses (including legal fees and expenses) relating to the arbitration proceeding, except that the fees of the Arbitrators and other related costs of the arbitration shall be shared equally by the Parties, unless the Arbitrators determine that a Party has incurred unreasonable expenses due to vexatious or bad faith positions taken by the other Party, in which event the Arbitrators may make an award of all or any portion of such expenses (including legal fees and expenses) so incurred.

(d) The Arbitrators shall be required to render the decision in writing and to comply with, and the award shall be limited by, any express provisions of this Agreement relating to damages or the limitation thereof. No Arbitrator shall have the power to award punitive damages under this Agreement regardless of whether any such damages are contained in a proposal, and such award is expressly prohibited.

(e) The Arbitrators' decision and award shall be made within [***] of the filing of the arbitration demand, and the Arbitrators shall agree to comply with this schedule before accepting appointment. However, this time limit may be extended by agreement of the Parties or by the Arbitrators. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement. The Arbitrators shall, within [***] days after the conclusion of the hearing, issue a written award and statement of decision describing the material facts and the grounds for the conclusions on which the award is based, including the calculation of any damages awarded. The decision of the Arbitrators shall be final, conclusive and binding on the Parties and enforceable by any court of competent jurisdiction.

(f) Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, (A) the Parties shall [***]; and (B) in the event that the subject of the Dispute relates to the exercise by a Party of a termination right hereunder, including in the case of a material breach of this Agreement, the effectiveness of such termination shall be stayed until the conclusion of the proceedings under this Section 15.3.

(g) All arbitration proceedings and decisions of the Arbitrators under this Section 15.3 shall be deemed Confidential Information of both Parties under Article 10. The arbitration proceedings shall take place in [***], in the English language.

(h) Notwithstanding the foregoing, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights or trademark rights shall be submitted to a court of competent jurisdiction in the country in which such patent rights or trademark rights were granted or arose. Nothing in this Section 15.3 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

ARTICLE 16
MISCELLANEOUS

16.1 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), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances (except for a strike, lockout or labor disturbance with respect to the non-performing Party's respective employees or agents), fire, floods, earthquakes or other acts of God, or any generally applicable action or

inaction by any Governmental Authority (but excluding any government action or inaction that is specific to such Party, its Affiliates or sublicensees, such as revocation or non-renewal of such Party's license to conduct business). The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations despite the ongoing circumstances.

16.2 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party, except in whole: (a) by Zai to an Affiliate of Zai; (b) by NVCR to an Affiliate of NVCR; or (c) by NVCR to a similarly situated Third Party in the Field only in connection with a sale of all or substantially all assets that are pertinent to the Licensed Product. Any attempted assignment not in accordance with this Section 16.2 shall be null and void and of no legal effect. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

16.3 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) that, insofar as practical, implement the purposes of this Agreement.

16.4 Notices. All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by electronic mail (provided that a read receipt is received and retained by sender and such notice by electronic mail is 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 NVCR:

NovoCure Limited.
Second Floor
No.4 The Forum
Grenville Street
St. Helier
Jersey
JE2 4UF
[***]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

with a copy to:

Novocure Inc.
20 Valley Stream Parkway, Suite 300
Malvern, PA 19355
[***]

and

Sidley Austin LLP
787 Seventh Avenue
New York, NY 10019
[***]

and

Sidley Austin LLP
One South Dearborn
Chicago, IL 60603
[***]

If to Zai:

Zai Lab (Shanghai) Co., Ltd.
4560 Jinke Rd, Bldg. 1, 4/F
Pudong, Shanghai, China, 201210
[***]

with a copy to:

Ropes & Gray LLP
36F, Park Place
1601 Nanjing Road West
Shanghai 200040
[***]

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 electronic mail on a Business Day (or if delivered or sent on a non-Business Day, then on the next 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.

16.5 Governing Law. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, and enforced in accordance with, the internal laws of the [***], including its statutes of limitations.

16.6 Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties. The Parties agree that, effective as of the Effective Date, in the event of a conflict between this Agreement and that certain Mutual Non-Disclosure Agreement between Zai Lab (Hong Kong) Limited and NVCR dated as of May 15, 2018 (the "***Confidentiality Agreement***"), this Agreement shall govern, and that disclosures made to either Party, directly or indirectly, prior to the Effective Date pursuant to the Confidentiality Agreement shall be subject to the confidentiality and non-use provisions of this Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Agreement.

16.7 Headings. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.

16.8 Independent Contractors. It is expressly agreed that NVCR and Zai shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither NVCR nor Zai shall have the authority to make any statements, representations or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

16.9 Waiver. Any waiver of any provision of this Agreement shall be effective only if in writing and signed by NVCR and Zai. No waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

16.10 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.

16.11 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Laws.

16.12 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.13 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 pdf copies of counterpart execution pages of this Agreement and such pdf copies shall be legally effective to create a valid and binding agreement among the Parties.

{Signature Page Follows}

In Witness Whereof, the Parties intending to be bound have caused this License and Collaboration Agreement to be executed by their duly authorized representatives as of the Effective Date.

NovoCure Limited		**Zai Lab (Shanghai) Co., Ltd.**	
By:	/s/ William F. Doyle	By:	/s/ Samantha Du
Name:	William F. Doyle	Name:	Samantha Du
Title:	Executive Chairman	Title:	Chairman & CEO

List of Exhibits

Schedule 1.41:	**[***]**
Schedule 1.55:	**[***]**
Schedule 11:	**[***]**

Exhibit A:	**NVCR Patents**
Exhibit B:	**NMPA Submission Timeline**
Exhibit C:	**Territory Development Plan**
Exhibit D:	**Supply Agreement Term Sheet**
Exhibit E:	**Commercialization Plan**

Schedule 1.41
[***]

Schedule 1.55
[***]

Schedule 11
Disclosure Schedule

Exhibit A
NVCR Patents

Exhibit B
NMPA Submission Timeline

Exhibit C
Territory Development Plan

Exhibit D
Supply Agreement Term Sheet

Exhibit E
Commercialization Plan

Exhibit 10.16

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

COLLABORATION AGREEMENT

This Collaboration Agreement ("**Agreement**"), effective as of November 29, 2018 (the "**Effective Date**"), is entered into by and between MacroGenics, Inc., a Delaware corporation with a place of business at 9704 Medical Center Drive, Rockville, MD 20850 ("**MacroGenics**"), and Zai Lab (Shanghai) Co., Ltd., a P.R. of China company with a place of business at 4560 Jinke Rd, Bldg. 1, 4/F, Pudong, Shanghai, China, 201210 ("**Zai**"). MacroGenics and Zai may be referred to herein individually as a "**Party**" or collectively as the "**Parties.**"

Recitals:

A. MacroGenics has expertise in, and platforms for, the discovery and development of products for the treatment of patients with cancer, inflammatory and infectious diseases.

B. Zai has expertise in the research, development and commercialization of pharmaceutical products.

C. Zai and MacroGenics desire to enter into collaboration for the development of MacroGenics' anti-HER2 Antibody known as margetuximab, a therapeutic bi-specific binding protein directed against PD-1 and LAG3 and a therapeutic [***] directed against [***] based on MacroGenics' proprietary Trident™ platform, including in combination with other agents such as MacroGenics' anti-PD-1 Antibody known as MGA012, and if approved for commercialization, the commercialization of Product(s) (defined below) in the Territory, all upon the terms and conditions set forth in this Agreement.

D. MacroGenics desires to grant to Zai, and Zai desires to receive, an exclusive license for all Indications in the Field for all pharmaceutical forms of a Licensed Compound and Products for the Territory, upon the terms and conditions set forth in this Agreement.

In consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

Agreement:

1. **Definitions.** Unless specifically set forth to the contrary herein, the following capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth below:

1.1 "**Acting Improperly**" has the meaning set forth in Section 4.4(a).

1.2 "**Affiliate**" means with respect to any Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Section 1.2, "control" means (a) in the case of a corporate entity, direct or indirect ownership of at least fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause

Exhibit 10.16

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.

1.3 "**Antibody**" means a [***] molecule whose Fv encodes for a [***] and comprises or contains: (a) one or more immunoglobulin variable domains; or (b) fragments, variants, modifications or derivatives of such immunoglobulin variable domains; or (c) the nucleic acid consisting of a sequence of nucleotides encoding (or complementary to a nucleic acid encoding) the foregoing molecules in (a) or (b).

1.4 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti- corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism, including those within the Territory.

1.5 "**Applicable Laws and Regulations**" means all international, national, federal, state, regional, provincial, municipal and local government laws, rules, and regulations that apply to either Party or to the conduct of the Collaboration under this Agreement including cGMP, GCP, GBPS, and the laws, rules and regulations of the ICH, the United States and the Territory, each as may be then in effect, as applicable and amended from time to time.

1.6 "**Biosimilar Product**" means, with respect to a Product (but specifically excluding any MGA012 component thereof) sold in a Country or Region, a product that: (a) is marketed by a Third Party that has not obtained the rights to such product as a Sublicensee or distributor of, or through any other contractual relationship with, Zai or any of its Affiliates or Sublicensees; (b) contains the same or similar amino acid sequence as the applicable Product; and (c) with respect to a Region or Country of the Territory, has been granted Regulatory Approval as a biosimilar or interchangeable biological product by the applicable Regulatory Authority in such Region or Country according to a biosimilar regulatory pathway that is materially equivalent to that of Section 351(k) of the US Public Health Service Act (42 U.S.C. § 262(k)), as may be amended, or any subsequent or superseding law, statute or regulation.

1.7 "**BLA**" means (a) a Biologics License Application or New Drug Application ("**NDA**") filed with the FDA for marketing approval of a Product or any successor applications or procedures, and all supplements and amendments that may be filed with respect to the foregoing, or similar filings outside the Territory with applicable Regulatory Authorities, for approval to commercially market, import and sell a Product, or (b) similar filings in the Territory with applicable Regulatory Authorities, including the CFDA, for approval to commercially market, import and sell a Product. The term BLA shall exclude pricing and reimbursement approvals.

1.8 "**Business Day**" means a day on which banking institutions in Washington, DC, USA, Hong Kong, and Beijing, PRC are open for business, excluding any Saturday or Sunday.

1.9 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.10 "**Calendar Year**" means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.

1.11 "**CFDA**" means China Food and Drug Administration, or any successor agency thereto.

1.12 **cGMP**" or "**current Good Manufacturing Practices**" means current Good Manufacturing Practices as set forth in the FDCA and the Public Health Service Act (the "**PHS Act**"), and in regulations at 21 C.F.R. Parts 210, 211 and 600, as in effect at the time when any Product is being manufactured for clinical development or commercial use, when any Product is being sold or when any clinical trial regarding a Product is being conducted, provided, and to the extent applicable to such clinical trial, as such regulations are interpreted and enforced by the FDA, including as set forth in applicable guidance documents issued by the FDA, and in accordance with applicable, generally accepted industry standards, and the equivalent legal requirements in other applicable jurisdictions, including within the Territory, all as the same may be amended from time to time.

1.13 "**Clinical Data**" means all data generated or arising from the conduct of a Clinical Trial or other Development efforts under this Agreement.

1.14 "**Clinical Trial**" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Phase IV Clinical Trial or Registration Trial, as applicable.

1.15 "**CMC**" means Chemistry Manufacturing and Controls.

1.16 "**CMO**" means a contract manufacturing organization.

1.17 "**Collaboration**" means the program established under this Agreement, which includes collaborative Development of Products.

1.18 "**Combination Product**" mean (a) any single product comprising both (i) a Licensed Compound (or HER2 Trident Product, Margetuximab Product or MGD013 Product) and (ii) one or more other therapies or pharmaceutically active compounds or substances that is not a Licensed Compound; (b) any sale of a Product with another therapy(ies) or product(s) for a single invoice price; or (c) any sale of a Product as part of a bundle with other therapy(ies), product(s) or service(s) (i.e., where a Product and such other therapy(ies), product(s) or service(s) are sold for a single invoice price or where a discount, rebate or other amount that reduces the price of a Product is provided in exchange for (or otherwise conditioned upon) the purchase of such other therapy(ies), product(s) or services), to the extent not described in clause (a) or (b). The Licensed Compound (or HER2 Trident Product, Margetuximab Product or MGD013 Product) portion of any Combination Product shall be deemed the "**Licensed Component**" and the other portion of such Combination Product (including MGA012 or any other product Controlled by MacroGenics with respect to Combination Regimens) shall be deemed the "**Other Component**", and each Combination Product shall be deemed a Product hereunder.

1.19 "**Combination Regimen**" means, individually or collectively, as context requires, (a) a therapeutic combination comprising MGA012 and a Margetuximab Product or (b) a combination comprising MGA012 and a HER2 Trident Product, in each case ((a) and (b)) in concurrent or sequential administration.

1.20 "**Combination Regimen Study**" means, a Clinical Trial of a Combination Regimen conducted under the Global Development Plan or Territory Specific Development Plan in the Field in the Territory.

1.21 "**Commercial Supply Agreement**" has the meaning set forth in Section 5.1(b).

1.22 "**Commercialization**" or "**Commercialize**" means activities taken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sales force recruitment, sale and distribution of a pharmaceutical product and post-launch medical activities, including: (a) distribution for commercial sale; (b) strategic marketing, sales force, detailing, advertising, and market and product support; (c) medical education and liaison and any Phase IV Clinical Trials unless required as a condition for approval, to the extent permitted by this Agreement; (d) all customer support and product distribution, invoicing and sales activities; and (e) all post-approval regulatory activities, including those necessary to maintain Regulatory Approvals.

1.23 "**Commercialization Plan**" means a Commercialization plan, to be updated from time to time, the first of which shall be provided in writing to MacroGenics at least [***] months before the estimated Completion of the first Registration Trial, and which shall include: [***]

1.24 "**Commercially Reasonable Efforts**" means with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective of such Party under similar circumstances, it being understood and agreed that with respect to the Commercialization of a Licensed Compound and Products, such efforts shall be similar to those efforts and resources commonly used by pharmaceutical or biopharmaceutical companies, as applicable, of comparable size and resources to such Party for a similar biological or pharmaceutical product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, and the likelihood of Regulatory Approval given the regulatory structure involved.

1.25 "**Completion**" or "**Completed**" for a clinical trial means the [***].

1.26 "**Confidential Information**" means any and all non-public scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information and data, in any tangible or intangible form, including all Know-how subject to Section 9.7(c).

1.27 "**Control**," "**Controls**" or "**Controlled by**" means (except as used in Section 1.2), with respect to any item of or right under Patents or Know-how, the extent of the ability of a Party (whether through ownership or license, other than pursuant to this Agreement) to grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party or creating a payment obligation upon such Party (unless either (a) the other Party agrees to bear the applicable portion of such payment pursuant to Section 9.7 or otherwise or (b) such payment obligation arises under a MacroGenics Required Third Party Agreement), in each case, existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

1.28 "[***]" has the meaning set forth in Section 7.4(b).

1.29 "[***]" has the meaning set forth in Section 7.4(b).

1.30 "**Country**" means for the purposes of this Agreement each of PRC and Taiwan.

1.31 "**Cover**" means, with respect to a product, technology, process or method, that, in the absence of possession of the right (by ownership, license or otherwise) under a Valid Claim, the practice or exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

1.32 "**CRO**" means a clinical research organization.

1.33 "**Data Exclusivity Period**" means the period, if any, during which the CFDA (or, in regions or countries other than the PRC, an equivalent regulatory agency) prohibits reference, without the consent of the owner of a BLA, to the clinical and other data that is contained in such BLA and that is not published or publicly available outside of such BLA.

1.34 "**Deadlock**" has the meaning set forth in Section 2.1(d).

1.35 "**Depot Subcontractor**" means any subcontractor engaged by Zai to store, distribute, handle or otherwise possess Licensed Compounds, MGA012 or Product that was provided by MacroGenics to supply a Clinical Trial.

1.36 "**Develop**" or "**Development**" or "**Developing**" means research, discovery, and preclinical and clinical drug or biological development activities, including toxicology, formulation, statistical analysis, preclinical and Clinical Trials (but excluding Phase IV Clinical Trials unless required as a condition for approval) and regulatory affairs, approval and registration, in each case, of a Licensed Compound or a Product in the Field.

1.37 "**Development Costs**" means all costs incurred in connection with any Development activities, including (i) site investigator fees and monitoring costs, (ii) contract research organization and site management organization fees (iii) data management costs (iv) safety surveillance and reporting costs (v) patient costs, (vi) drug comparator and standard-of-care drug costs, (vii) drug administration costs, (viii) development, validation, and procurement costs related to any companion diagnostic product, and (ix) central and local lab costs.

1.38 "**Dispute**" means any dispute, claim, or controversy (other than matters that are within the decision-making authority of the JSC or a Party pursuant to Section 2.1(d), or are expressly stated herein to require the consent of both Parties) arising from or related to this Agreement or to the interpretation, application, breach, termination, or validity of this Agreement, including any claim of inducement of this Agreement by fraud or otherwise.

1.39 "**Executive Officer**" means, with respect to either Party, the Chief Executive Officer of such Party (or his or her designee who will be a senior executive directly reporting to the Chief Executive Officer of such Party and with authority to bind such Party).

1.40 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto.

1.41 "**FDCA**" means the Federal Food, Drug and Cosmetic Act, as amended.

1.42 "**Field**" means all human fields of use (including treatment and diagnosis), provided, however, that in the case of any Licensed Compound or Products covered by a Patent or other intellectual

property right licensed in one or more MacroGenics Third Party Agreement, "Field" shall be limited to the minimum extent necessary to comply with the terms of such MacroGenics Third Party Agreement for so long as such limitation is necessary to avoid a breach of the MacroGenics Third Party Agreement.

1.43 "**Financial Officers**" has the meaning set forth in Section 3.6(c).

1.44 "**First Change of Control of Zai**" means, the first occurrence of any of the following: (a) a transaction or series of related transactions pursuant to the same set of transactional documents in which a developer or marketer of healthcare related products and or services (including a biotechnology or pharmaceutical company) becomes the owner of more than fifty percent (50%) of the combined voting power of Zai's outstanding securities, or (b) the sale, lease or other transfer to a developer or marketer of healthcare related products and or services (including a biotechnology or pharmaceutical company) of all or substantially all of Zai's assets or business to which this Agreement relates; provided however that First Change of Control of Zai shall not include: (i) the issuance by Zai of securities of Zai in a bona fide financing transaction or series of related bona fide financing transactions, either in private placement, public offering or otherwise; (ii) the purchase of Zai's stock on the public market by one or more investors that are not biotechnology company or pharmaceutical companies; and/or (iii) any transaction that takes Zai private, or consolidates or reallocates stock ownership among Zai's existing investors.

1.45 "**First Commercial Sale**" means, with respect to any Product, the first sale to a Third Party for end use or consumption of such Product in the Territory after Regulatory Approval has been granted by the Regulatory Agency for the Product in the Territory.

1.46 "**FTE**" means [***] hours of work devoted to in direct support of specified Manufacturing, conducted by one or more qualified employees of MacroGenics or its Affiliate. For clarity, any individual contributing less than [***] hours per Calendar Year (or equivalent pro-rata portion thereof for the period beginning on the Effective Date and ending on the last day of the first Calendar Year) shall be deemed a fraction of an FTE on a pro-rata basis.

1.47 "**FTE Cost**" means, with respect to any period and MacroGenics or its Affiliate, the FTE Rate multiplied by the number of FTEs expended by MacroGenics or its Affiliate during such period; provided that Zai shall not be charged twice for any FTE Cost if such FTE Cost is already included as a component of Manufacturing Expenses payable under this Agreement.

1.48 "**FTE Rate**" means a rate of [***] per FTE per Calendar Year (pro-rated for the period beginning on the Effective Date and ending on the last day of the first Calendar Year); provided, however, that such rate shall be increased or decreased annually beginning on January 1, 2019 by the applicable CPI Adjustment. The FTE Rate is [***] and covers [***].

1.49 "**Fully Burdened Manufacturing Cost**" or "**FBMC**" means, with respect to Licensed Compounds, MGA012 and Products supplied by or on behalf of MacroGenics or its Affiliate hereunder, [***] of (1) MacroGenics' manufacturing cost of goods produced, if Manufactured by MacroGenics or its Affiliate or (2) [***], in each case ((1) and (2)) as determined for each stage of the manufacturing process, including [***] (except, in the case of (1), to the extent [***], or in the case of (2), to the extent [***]) and applicable FTE Costs, all in accordance with GAAP. Such Fully Burdened Manufacturing Cost shall further include [***].

1.50 "**GAAP**" means U.S. Generally Accepted Accounting Principles as the same may be in effect from time to time.

1.51 "**GBPS**" means the General Biological Products Standards as set forth in 21 C.F.R. Part 610, to the extent applicable to the Collaboration.

1.52 "**GCP**" or "**Good Clinical Practices**" means current Good Clinical Practices as set forth in the Applicable Laws and Regulations, such as FDCA and the PHS Act and regulations set forth at 21 C.F.R. Part 312, as well as (but not limited to) the requirements set forth in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and Commission Directive 2005/28/EC of 8 April 2005, to the extent applicable to a clinical trial regarding any Product, as such obligations are interpreted and enforced by the applicable Regulatory Authority (e.g., FDA and Member States of the European Union), and as interpreted under prevailing industry standards, including standards of medical ethics, applicable guidance documents issued by the FDA and any other Regulatory Authority, including ICH GCP, the informed consent requirements set forth in 21 C.F.R. Part 50 and the equivalent legal requirements in other applicable jurisdictions, the requirements relating to Institutional Review Boards set forth in 21 C.F.R. Part 56 and the equivalent legal requirements in other applicable jurisdictions, including within the Territory, all as the same may be amended from time to time.

1.53 "**Global Branding Strategy**" has the meaning set forth in Section 4.2.

1.54 "**Global Clinical Trial**" means a global clinical trial program for a Licensed Compound (or a Product) undertaken by MacroGenics or its Affiliates or permitted assigns or licensees, which includes one or more investigator sites within and outside the Territory.

1.55 "**Global Development Plan**" means the written Development plan attached to this Agreement as Exhibit C intended to support Development and Regulatory Approval of Licensed Compound(s) and Product in the Field both within the Territory and outside of the Territory, as may be updated and amended periodically in form and substance approved by the JSC in accordance with Section 3.3 and otherwise at times requested by the JDC or JSC.

1.56 "**GLP**" or "**Good Laboratory Practices**" means the recognized rules governing the conduct of non-clinical safety studies and ensuring the quality, integrity and reliability of study data as set forth in Applicable Laws and Regulations, such as 21 C.F.R. Part 58, and the equivalent legal requirements in other applicable jurisdictions, including within the Territory, all as the same may be amended from time to time.

1.57 "**Government Official**" means any Person employed by or acting on behalf of a government, government-owned or -controlled entity or public international organization; any political party, party official or candidate; any Person who holds or performs the duties of an appointment, office or position created by custom or convention; and any Person who holds himself out to be the authorized intermediary of any of the foregoing.

1.58 "**Health Insurance Portability and Accountability Act**" or "**HIPAA**" means the act enacted by the U.S. Congress in 1996 and took effect in 2003 that strictly dictates the parameters that

identifiable private health information (PHI) can be shared outside of the research environment, as amended.

1.59 "[***] **Trident**" means a therapeutic trivalent, [***] protein which binds to the [***] and which is generated from MacroGenics' proprietary Trident™ platform, in the form existing as of the Effective Date, provided that, in the event MacroGenics (or its Affiliates or sublicensees) develops one (1) or more other form(s) of such [***] protein during the Term that are Controlled by MacroGenics, then, upon written request of Zai, the definition of [***] Trident shall include such other form(s).

1.60 "[***] **Trident Product**" means a product that incorporates a biopharmaceutical form of HER2 Trident as an active ingredient.

1.61 "**ICH**" means the International Conference on Harmonisation.

1.62 "**Improvement Plan**" has the meaning set forth in Section 4.4(c)(i).

1.63 "**Incyte Agreement**" means that certain Global Collaboration and License Agreement between MacroGenics and Incyte Corporation effective as of October 24, 2017 as may be amended or restated from time to time.

1.64 "**IND**" means an Investigational New Drug application, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.65 "**Indemnifying Party**" means the Party that is obligated to indemnify the Indemnitee under Section 12.

1.66 "**Indemnitee**" means either the Zai Indemnitee or the MacroGenics Indemnitee, as applicable.

1.67 "**Independent Ethics Committee**" or "**IEC**" means an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects, all to the extent required by the Applicable Laws and Regulations or by the applicable Regulatory Authority. The legal status, composition, function, operations and regulatory requirements pertaining to IEC may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

1.68 "**Indication**" means a separate and distinct disease, disorder or medical condition in humans or non-human animals classified as a three-character category in International Statistical Classification of Diseases and Related Health Problems (or "**ICD**") 10-CM published by the World Health Organization, for which a Product can be used to diagnose, treat or prevent, which use is the subject of a separate Regulatory Filing to support a Regulatory Approval for such use.

1.69 "**Informed Assent Form**" or "**IAF**" means an agreement to participate by subjects who are not able to give consent, either because they are minors or because they are legally incompetent.

1.70 "**Informed Consent Form**" or "**ICF**" means a document that outlines a patient's rights during participation in a clinical trial. It also discusses the potential risks and benefits associated with participation, including all available data on previous studies. The ICF must be signed by the patient or authorized caregiver before entrance is granted into a study.

1.71 "**In-License Party**" has the meaning set forth in Section 9.7(a).

1.72 "**Investigational Review Board**" or "**IRB**" means in accordance with 45 C.F.R. 46, Protection of Human Subjects (Revised November 13, 2001) and 21 C.F.R. 45, Subpart C, IRB Functions and Operations, (as amended June 18, 1991 and other applicable regulations), an independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of the subjects involved in a clinical trial. It may also be referred to as an IEC in accordance with ICH E6, Section 1.27.

1.73 "**Jointly Owned IP**" has the meaning set forth in Section 13.1(c).

1.74 "**Jointly Owned Patents**" has the meaning set forth in Section 13.2(b)(i).

1.75 "**Jointly Owned Product Patents**" means those Jointly Owned Patents that solely and exclusively Cover (i.e., that do not also Cover the composition of matter of, or the method of using, any other product) (a) the composition of matter of a Product, or (b) the method of using such Product as a therapeutic, prophylactic or diagnostic, in each case ((a) and (b)) in the Territory, but excluding all Jointly Owned Patents that Cover MGA012 (including its use), in whole or in part (including as a component of a Combination Regimen).

1.76 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 2.1(h)(i)(1).

1.77 "**Joint Commercialization Committee**" or "**JCC**" has the meaning set forth in Section 2.1(h)(ii)(1).

1.78 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.1 (a).

1.79 "**Know-how**" means (a) any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, 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 and (b) any proprietary biological, chemical or physical materials.

1.80 "**Licensed Compound**" means, individually, Margetuximab, MGD013 and HER2 Trident, as context requires (and collectively, referred to as "**Licensed Compounds**").

1.81 "**License Payment**" means each of the Upfront Payment, milestone payments under Section 7.2 and royalty payments under Section 7.3 (collectively the "**License Payments**")

1.82 "**Licensing Transaction**" has the meaning set forth in Section 10.3(d)(ii)(C).

1.83 "[***]" means that certain License Agreement by and between [***] effective as of [***] as may be amended or restated from time to time.

1.84 "**Losses**" has the meaning set forth in Section 12.1.

1.85 "**MacroGenics Indemnitee**" has the meaning set forth in Section 12.1.

1.86 "**MacroGenics Licensed Know-how**" means the Know-how (excluding any Patents) that is Controlled by MacroGenics as of the Effective Date or MacroGenics or any of its Affiliates at any time during the Term, that is: (a) related to a Licensed Compound, or the Combination Regimen that includes [***] and (b) necessary or reasonably useful for Zai to exercise the rights licensed to it pursuant to this Agreement or to perform its obligations under this Agreement with respect to the Territory. "MacroGenics Licensed Know-how" shall specifically exclude any Know-how l[***].

1.87 "**MacroGenics Licensed Patents**" means the Patents in the Territory Controlled by MacroGenics as of the Effective Date or MacroGenics or any of its Affiliates at any time during the Term that: (a) claim the composition of matter of a Licensed Compound or a Product, including in the Combination Regimen that includes [***] itself), (b) would be infringed by Developing or Commercializing a Licensed Compound or any Product, including as a component of the Combination Regimen ([***]) but for the license granted hereunder, (c) would be infringed by use of [***] in a Combination Regimen but for the license granted hereunder or (d) are otherwise necessary or reasonably useful for Zai to Develop and Commercialize Licensed Compounds and Products in accordance with this Agreement, including as a component of the Combination Regimen ([***]). The MacroGenics Licensed Patents [***]. "MacroGenics Licensed Patents" shall [***].

1.88 "**MacroGenics Licensed Technology**" means the MacroGenics Licensed Patents and the MacroGenics Licensed Know-how.

1.89 "**MacroGenics Licensed Trademarks**" means any and all Trademarks [***].

1.90 "**MacroGenics Outside Cost Share**" has the meaning set forth in Section 3.5(b).

1.91 "**MacroGenics Platform Patents**" means all MacroGenics Licensed Patents other than MacroGenics Product-Specific Patents.

1.92 "**MacroGenics Product-Specific Patent**" means each MacroGenics Licensed Patent that solely and exclusively Covers (i.e., that does not also Cover the composition of matter of, or the method of using, any other product): (a) the composition of matter of a Product, or (b) the method of using such Product as a therapeutic, prophylactic or diagnostic, in each case ((a) and (b)) in the Territory, but excluding all MacroGenics Licensed Patents that Cover [***], in whole or in part, (including as a component of a Combination Regimen).

1.93 "**MacroGenics Third Party Agreement**" means each of (i) the [***], (ii) the Incyte Agreement, (iii) the [***], (iv) such other license agreements between MacroGenics and its Third Party licensor under which MacroGenics in-licenses intellectual property from such Third Party for MacroGenics and/or its Affiliates and/or sublicensees to manufacture the Product and such license is necessary for MacroGenics and/or its Affiliates to manufacture and supply the Product to Zai under this Agreement (the agreements described in (i) through (iv), "**MacroGenics Required Third Party Agreements**") and (v) any Other Third Party Agreement between MacroGenics and its Third Party licensor that is entered into after the Effective Date and for which Zai elects to obtain a sublicense under Section 9.7 (the agreements described in (v), "**MacroGenics Other Third Party Agreements**") ((i) through (v), collectively referred to as the "**MacroGenics Third Party Agreements**").

1.94 "**Major Safety Issue**" means, with respect to a Product, any of the following: (a) an adverse safety profile of a Product, or receipt or generation by a Party of any safety, tolerability or other data, indicating or signaling, as measured by safety and efficacy evaluation criteria and methodology customarily used by a majority of clinicians conducting studies on similar products in the applicable region (including Region) or country (including Country), that such Product has or would have serious risks for medical applications in humans to require a recall, withdrawal, or similar action; or (b) any notice, information or correspondence received by a Party from a Regulatory Authority, or any action taken by a Regulatory Authority, in each case, indicates that Regulatory Approval is unlikely to be granted therefor or, if already granted, the Regulatory Approval therefor would likely be revoked or materially amended, or causes the Regulatory Approval therefor not to be granted or, if already granted, to be revoked or materially amended. In the event that MacroGenics, its Affiliates and their sublicensees of such Product discontinue the global Development, Manufacturing and Commercialization of such Product as a result of events or circumstances of the type described in (a) and/or (b) of this Section 1.93, such discontinuance shall be conclusive evidence that such events or developments are Major Safety Issues.

1.95 "**Manufacture**" or "**Manufacturing**" means all operations involved in the manufacturing (including process development activities, quality assurance and quality control testing (including test method development and in-process, release and stability testing, if applicable), storage, releasing, packaging and importation of a Licensed Compound or a Product) to supply Licensed Compounds and Product for Development under the Global Development Plan and Territory Specific Development Plan and Commercialization under the Commercialization Plan. For purposes of clarification "Manufacturing" is not included in Development or Commercialization.

1.96 **"**[***]**"** means the specific [***] for (including any associated Know-how Controlled by MacroGenics or any of its Affiliates necessary for the then-current process) the [***] at the time of the [***] described in Section 5.4(b) and as further developed by MacroGenics.

1.97 "**Margetuximab**" means the therapeutic Antibody which binds to the HER2/Neu receptor described in [***].

1.98 "**Margetuximab Product**" means a product that incorporates a biopharmaceutical form of Margetuximab as an active ingredient.

1.99 "**MGA012**" means the anti-PD-1 Antibody coded as "MGA012", as further described [***].

1.100 "**MGA012 Commercial Forecasts**" has the meaning set forth in Section 5.1(a).

1.101 "**MGD013**" means the therapeutic bi-specific molecule which binds to PD-1 and LAG-3 and which is generated from MacroGenics' proprietary DART® platform, as further described [***].

1.102 "**MGD013 Product**" means a product that incorporates a biopharmaceutical form of MGD013 as an active ingredient.

1.103 "[***]" means that certain [***], Inc. effective as of [***], as may be amended or restated from time to time.

1.104 "**Net Sales**" means the gross amount invoiced for Products sold by Zai or its Related Parties in the Territory initially and directly to Third Parties which are not Related Parties after deducting, if not previously deducted, from the amount invoiced, the following, in each case to the extent included in the gross invoice price:

(a) reasonable trade, quantity and cash discounts and rebates (including wholesaler inventory management fees), chargebacks, and retroactive price reductions or allowances actually allowed or granted from the billed amount;

(b) credits or allowances actually granted upon claims, rejections or returns of such sales of Products, including recalls and amounts credited or repaid because of retroactive price reductions specifically identifiable to the Product;

(c) taxes imposed on the production, sale, import, delivery or use of the Product (including sales, use, excise or value added taxes but excluding income taxes), duties or other governmental charges (including charges for product testing required for importation) levied on or measured by the billing amount when included in billing, as adjusted for rebates and refunds; and

(d) costs incurred for importing (including transportation, freight and insurance, and warehousing in the Territory).

Such amounts shall be determined from the books and records of Zai or its Related Party, maintained in accordance with International Financial Reporting Standards (IFRS) or such similar accounting principles, consistently applied. Zai further agrees, in determining such amounts, it shall use Zai's then-current standard procedures and methodology, including Zai 's then-current standard exchange rate methodology for the translation of foreign currency sales into US Dollars or, in the case of Sublicensees, such similar methodology, consistently applied. Without limiting the generality of the foregoing, non-invoiced transfers or dispositions of Product for charitable, compassionate use, promotional (including samples, in amounts reasonably customary in the industry), non-clinical, clinical, or regulatory purposes shall be excluded from Net Sales, as will sales or transfers of Product among a Party and its Related Parties unless such Party or Related Party is the end user of such Product, but rather the Net Sales shall be deemed to have arisen upon the subsequent sale or transfer of Product to Third Parties.

If Zai or any of its Related Parties sells a 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: (i) 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 (ii) 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 MacroGenics' 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 Related Parties, 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 MacroGenics' mutual agreement of the fair market value of the Licensed Component and each of the Other Component(s) included in such Combination Product.

1.105 "**Other Jointly Owned Patents**" means all Jointly Owned Patents other than Jointly Owned Product Patents.

1.106 **"Other Third Party Agreement**" has the meaning set forth in Section 9.7(a).

1.107 "[***]" means all [***] Development and Regulatory Approval of the Product [***] but [***] Development and Regulatory Approval of the Product [***] the Territory and [***]) Development Costs incurred by or on behalf of Zai, MacroGenics or a Related Party outside the Territory in connection with the conduct of the Development Plan in support of the Development of the Licensed Compounds and Products for the Territory in accordance with such Development Plan.

1.108 "**Patent(s)**" means (a) all patents and patent applications in any country (including Country), region (including Region) or supranational jurisdiction and (b) any provisionals, substitutions, divisions, continuations, continuations in part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like, of any such patents or patent applications.

1.109 "**Patent Prosecution**" means the responsibility for (a) preparing, filing, prosecuting, and pursuing registration of, applications (of all types) for any Patent (b) for maintaining any Patent, and (c) for managing any interference or opposition proceeding relating to the foregoing.

1.110 **"Payment Taxes"** means VAT and income taxes withholding required under Applicable Law to be paid to a tax authority in the Territory.

1.111 "**Permitted Subcontractors**" has the meaning set forth in Section 3.7.

1.112 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.113 "**Phase I Clinical Trial**" means a human clinical trial, or the relevant portion of such trial, of a Product in patients in any country (including Country or Region) in accordance with GCP that generally provides for the first introduction into humans of a Product and intended to determine safety, metabolism and pharmacokinetic properties and clinical pharmacology of a Product in health patients, or that would otherwise satisfy the requirements of Applicable Laws and Regulations for such country in which such human clinical trial is conducted, such as 21 C.F.R. § 312.21(a), relating to human clinical trials conducted in the United States, or any successor regulation thereto or foreign equivalents.

1.114 "**Phase II Clinical Trial**" means a human clinical trial, or the relevant portion of such trial, conducted in patients with a Product, in accordance with GCP and intended to demonstrate efficacy and a level of safety in the particular Indication tested, as well as to obtain a preliminary Indication of the unit or daily dosage regimen required, or that would otherwise satisfy the requirements of Applicable Laws and Regulations of the country (including Country or Region) in which such human clinical trial is conducted, such as 21 C.F.R. § 312.21(b), relating to human clinical trials conducted in the United States, or any successor regulation thereto or foreign equivalents.

1.115 "**Phase III Clinical Trial**" means a human clinical trial, or the relevant portion of such trial, in any country that is conducted in accordance with GCPs and the results of which are intended to be used as a pivotal study to establish both safety and efficacy of a Product as a basis for a BLA submitted to the FDA, CFDA or the appropriate Regulatory Authority of such other country (including Country or Region), or that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(c), or any successor regulation thereto or foreign equivalents.

1.116 "**Phase IV Clinical Trial**" means a human clinical trial conducted after the Regulatory Approval of a Product in a country (including Country or Region), which trial is conducted (a) voluntarily to enhance scientific knowledge of such Product (e.g., for expansion of product labeling or dose optimization); or (b) conducted due to a request or requirement of a Regulatory Authority of a country (including Country or Region).

1.117 "**PRC**" means the People's Republic of China, which for purposes of this Agreement, excludes the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan.

1.118 "**Product**" means, individually, each of Margetuximab Product, MGD013 Product and HER2 Trident Product, including in each case, as a component of a Combination Regimen, and collectively, the "**Products**".

1.119 "**Product Brand**" has the meaning set forth in Section 4.2.

1.120 "**Qualified CMO**" has the meaning set forth in Section 5.4.

1.121 "**Region**" means individually and collectively Hong Kong Special Administrative Region, and Macau Special Administrative Region.

1.122 "**Registration Trial**" means the first clinical trial which is designed to support Regulatory Approval for the Product in a Country or Region in the Territory.

1.123 "**Regulatory Approval**" means a BLA approval from the relevant Regulatory Authority in a region (including Region) or country (including Country) to market and sell a Product in such region or country.

1.124 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the conduct of clinical trials or the manufacturing, marketing, reimbursement or pricing, as applicable, of a Product, including in the United States, the FDA and in the PRC, the CFDA, and any successor governmental authority having substantially the same function.

1.125 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including INDs, BLAs, NDAs, and 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 Product.

1.126 "**Related Party**" means, with respect to a Party, its Affiliates and (Sub)licensees.

1.127 "**Requesting Party**" has the meaning set forth in Section 8.2.

1.128 "[***]" has the meaning set forth in Section 5.4.

1.129 "[***]" has the meaning set forth in Section 5.4.

1.130 "[***]" has the meaning set forth in Section 5.4.

1.131 "**Rolling Net Sales**" has the meaning set forth in Section 5.4.

1.132 "[***]" has the meaning set forth in Section 5.4(a).

1.133 "[***] **Period**" has the meaning set forth in Section 5.4(a).

1.134 "**Royalty Term**" means, with respect to sales of a Product in the Territory, on a Country-by-Country and Region-by-Region basis, the time period beginning on the First Commercial Sale of such Product in the Territory and expiring on the latest of the following dates:

(a) the [***] of the date of First Commercial Sale of the Product in the applicable Country or Region, as the case may be;

(b) the expiration in the Territory of the last-to-expire MacroGenics Licensed Patent having a Valid Claim Covering the composition, Manufacture, use, sale or importation of the Product in the applicable Country or Region, as the case may be; or

(c) the expiration of the latest Data Exclusivity Period for the Product in the applicable Country or Region, as the case may be.

1.135 "**SIAC**" has the meaning set forth in Section 14.3.

1.136 "**Site Regulatory Package**" or "**SRP**" means a set of investigational site-specific regulatory documents such as, to the extent required by the applicable Regulatory Authority: Form FDA 1572 (or an equivalent document used in a region (including Region) or country (including Country) in the Territory that identifies any relationships that pose a potential conflict of interest for an investigator or other person whose responsibilities are critical to conduct of a clinical trial), principal investigator curriculum vitae, signed protocol signature page, site-specific ICF/IAF (back-translated into English if the local language is other than English), investigator brochure, clinical trial agreement, clinical trial approval, IRB/IEC approval, study site qualification documents, privacy requirements (e.g., HIPAA), IRB/IEC membership, and other country (including Country)-specific or region (including Region)-specific requirements.

1.137 "**SOPHIA**" means the Phase III Clinical Trial entitled "*A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients With HER2+ Metastatic Breast Cancer Who Have Received Prior Anti-HER2 Therapies and Require Systemic Treatment*" ongoing as of the Effective Date, as the protocol for such clinical trial may be amended or updated from time to time.

1.138 "**Study Material(s)**" means Licensed Compounds, MGA012 and Product formulated in accordance with the applicable specifications as adopted by MacroGenics and laws, rules and regulations of the United States and in the Territory (a) for preclinical activities, and (b) for administration to subjects in Clinical Trials.

1.139 "**Sublicensee**" means a Third Party that is granted a sublicense under the licenses granted to a Party under this Agreement, as permitted under this Agreement.

1.140 "**Term**" has the meaning set forth in Section 15.1.

1.141 "[***]" or "[***]" means Manufacture of Margetuximab by Zai, in the Territory, either itself or through a Qualified CMO, solely for Commercialization of Margetuximab Products (including as part of a Margetuximab Combination Regimen) by Zai, its Affiliates and Sublicensees in the Field in the Territory under this Agreement (but for clarity, (x) no other Licensed Compounds or Products and (y) not outside of the Field or outside of the Territory). [***] shall exclude product/quality release which shall be conducted by MacroGenics.

1.142 "[***]" has the meaning set forth in Section 5.4(b).

1.143 "**Territory**" means the PRC, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan.

1.144 "**Territory Development Costs**" has the meaning set forth in Section 3.6(a).

1.145 "**Territory Specific Development Plan**" means the written plan for Development of the Licensed Compounds and Products in the Field in the Territory that is primarily intended to support Regulatory Approval of the Product in the Territory (and, for clarity, not outside the Territory) and not otherwise included within the Global Development Plan.

1.146 "**Territory Subjects Enrolled**" means that portion of the Total Subjects Enrolled in the Territory for the applicable Clinical Trial.

1.147 "**Third Party**" means an entity other than (a) Zai and its Affiliates, and (b) MacroGenics and its Affiliates.

1.148 "**Total Amount**" has the meaning set forth in Section 7.4(b).

1.149 "**Total Manufacturing Cost**" has the meaning set forth in Section 5.4.

1.150 "**Total Subjects Enrolled**" means, with respect to a given Clinical Trial, the total number of study subjects enrolled in such Clinical Trial worldwide.

1.151 "**Trademark(s)**" means all trade names, logos, common law trademarks and service marks, trademark and service mark registrations and applications throughout the world.

1.152 "**Trademark Prosecution**" means the responsibility for (a) preparing, filing, and seeking registration of, trademark applications (of all types) for any Trademark, (b) for maintaining any Trademark, and (c) for managing any interference or opposition proceeding relating to the foregoing.

1.153 "**Triggered Third Party Payments**" is defined in Section 9.7(c).

1.154 "**United States**" or "**US**" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

1.155 "**US Dollars**" means United States Dollars, the lawful currency of the US.

1.156 "**Valid Claim**" means a claim of: (a) an issued and unexpired Patent included within the MacroGenics Licensed Patents in a country (including Country or Region) which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed 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 pending patent application that has been filed in good faith and that has not been cancelled, withdrawn, or abandoned and has not been pending for more than [***] years from the earliest priority date, provided that, if a claim ceases to be a Valid Claim by reason of the foregoing subclause (b), then such claim shall again be deemed a Valid Claim in the event such claim subsequently issues.

1.157 "**Zai Audit**" has the meaning set forth in Section 4.4(f).

1.158 "**Zai Indemnitees**" has the meaning set forth in Section 12.2.

1.159 "**Zai Licensed Know-how**" means all Know-how (excluding any Patent) Controlled by Zai or any of its Affiliates as of the Effective Date or at any time during the Term that is: (a) related to a Licensed Compound, Product or Combination Regimen (including MGA012 as a component of a Combination Regimen) and (b) incorporated or used by Zai or its Affiliates in connection with the Development, Manufacture or Commercialization of the Licensed Compounds or Products (including as part of a Combination Regimen) in the Territory; and (c) necessary or reasonably useful for MacroGenics to exercise the rights licensed to or retained by it under this Agreement or perform its obligations under this Agreement. The term Zai Licensed Know-how shall also be deemed to include Zai's interest in any Know-how jointly owned pursuant to Section 13.1(c).

1.160 "**Zai Licensed Patents**" means any and all Patents Controlled by Zai or any of its Affiliates at any time during the Term that: (a) claim or cover any data, result or invention conceived, created or reduced to practice in the course of conducting the Collaboration solely by or on behalf of Zai or any of its Affiliates specifically in relation to a Licensed Compound, Product or Combination Regimen (including in relation to MGA012 as a component of a Combination Regimen) and (b) Zai's interest in any Patent jointly owned pursuant to Section 13.1(c).

1.161 [***]" has the meaning set forth in Section 5.4(b).

1.162 "[***]" means [***] [***].

2. GOVERNANCE

2.1 Joint Steering Committee

(a) **Membership**. The Parties hereby establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"), to coordinate and oversee activities on which the Parties collaborate under this Agreement. The JSC shall consist of [***] representatives from each Party. [***] shall [***] the initial chairperson of the JSC. Thereafter, the role of chairperson shall [***]. Each Party may replace its appointed JSC representatives at any time upon reasonable written notice to the other Party. The initial representatives and chair of the JSC shall be established within [***] days after the Effective Date. The chair shall have the responsibility to call regular meetings, circulate meeting agendas at least [***] days prior to each regular JSC meeting, draft minutes for each JSC meeting and circulate such minutes for both Parties' written approval. The chair shall have no other authority or special voting power.

(b) **Responsibilities**. The responsibilities of the JSC shall be:

(i) to provide a vehicle by which the Parties may share information regarding the overall strategy for the Collaboration;

(ii) review, discuss and approve each of the Global Development Plan (with respect to the regulatory activities, non-clinical and clinical Development activities under the Global Development Plan that are to be conducted in the Territory (the "**Territory Specific Activities**")), Territory Specific Development Plan, Commercialization Plan, and updates or amendments thereto and

to share and discuss the progress of activities under each of the Global Development Plan and Territory Specific Development Plan [***];

(iii) to facilitate the exchange of information between the Parties with respect to the activities hereunder and to establish procedures for the efficient sharing of information necessary for the Parties to fulfill their respective responsibilities with respect the Collaboration;

(iv) to share and discuss the data generated by or on behalf of the Parties in the course of performance towards the goals set forth in the Global Development Plan, Territory Specific Development Plan and Commercialization Plan, respectively;

(v) to coordinate Development and Commercialization strategies, allocate resources and set timelines, in each case to facilitate the activities under the Global Development Plan, Territory Specific Development Plan and Commercialization Plan, respectively;

(vi) to establish an overall regulatory strategy for Products in the Territory that is consistent with and complements the worldwide regulatory strategy being implemented by MacroGenics for the Products;

(vii) to create any subcommittees (including the JDC and JCC) as agreed in writing by both Parties, to oversee the activities of such subcommittees, and to seek to resolve any issues that such subcommittees cannot resolve;

(viii) to establish an overall strategy for the filing, prosecution and maintenance of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks and Zai Licensed Patents in the Territory and Patent and Trademark term extensions; and

(ix) to perform such other functions as expressly set forth in this Agreement or as appropriate to further the purposes of this Agreement, as determined by the Parties.

(c) **Decision-Making**. The JSC shall make decisions [***], with each Party's representatives collectively having [***] and at least [***] representative from each Party present.

(d) **Deadlocks; Final Decision-Making Authority**. In the event the JSC cannot reach an agreement regarding any matter within the JSC's authority for a period of [***] days (a "**Deadlock**"), then either Party may [***], and if a Party makes an election to refer a matter to the Executive Officers, the Executive Officers shall [***]. If the Executive Officers are unable to reach consensus on any such matter within [***] days after its submission to them, the Deadlock shall be resolved in accordance with the provisions of this Section 2.1(d):

(i) Except for those Deadlocks set forth in Section 2.1(d)(ii) for which [***] shall have the final decision-making authority, [***] shall have the final decision-making authority with respect to all Deadlocks, including regarding:

(1) Manufacturing of Licensed Compounds, MGA012 or Products. [***] will use Commercially Reasonable Efforts to mitigate and minimize any adverse effect such decision may have on the Development, Regulatory Approval or Commercialization of the Licensed Compounds or

Products in the Territory. In making such decision [***] will in good faith [***] countries and regions, [***] (if impacted) in which the Licensed Compound or Products are being Developed or Commercialized and [***] shall not make any decision that will require [***] to take any action that is inconsistent with any requirement or recommendation of any Regulatory Authority in the Territory or prevent [***] from taking any action required by Regulatory Authority in order to obtain or maintain Regulatory Approval for the Product in the Territory;

(2) global Development of Licensed Compounds, MGA012 and Products, including the conduct of all Global Clinical Trials; and

(3) global Commercialization of Licensed Compounds, MGA012 and Products.

(ii) [***] shall have the final decision-making authority on all Deadlocks pertaining solely and specifically to any of the following: (A) Development and regulatory activities (subject to [***] right to [***] (an any [***])) [***], including for each Clinical Trial conducted [***] and the regulatory strategy and plan for obtaining Regulatory Approval of the Product [***], in each case, included in the [***] under the Global Development Plan and the Territory Specific Development Plan, and (B) Commercialization activities (consistent with the Global Branding Strategy for such Product in accordance with Section 4.2) of the Licensed Compounds and Products in the Field [***], provided that such decision under the foregoing (A) or (B) shall not have any material adverse effect on the Development, Regulatory Approval, Manufacture or Commercialization of the Licensed Compounds, MGA012 or Products [***].

All disputes that are not subject to the decision making authority of the Parties under Section 2.1(c)(i) and (ii), shall be subject to binding arbitration in accordance with Section 14.

Notwithstanding Section 2.1(d)(i) or (ii), no exercise of a Party's unilateral decision-making authority on any such matters may, without the other Party's prior written consent, be used to (a) make a determination as to whether a particular milestone or other criteria has been achieved or that any if its obligations under this Agreement has been fulfilled, (b) amend or add to such Party's consent or approval rights or otherwise expand or reduce its obligations provided under this Agreement, (c) impose any requirements that the other Party take or decline to take any action that would result in a violation of Applicable Laws and Regulations or any agreement with any Third Party (including any MacroGenics Third Party Agreements) or the infringement of intellectual property rights of any Third Party, (d) make a decision that is expressly stated to require the consent or approval of the other Party, (e) otherwise conflict with this Agreement or (f) increase the other Party's obligations (including payment obligations) or reduces the other Party's rights under this Agreement without such other Party's written consent.

(e) **JSC Meetings**. JSC meetings shall be held [***], or on any other schedule mutually agreed by the Parties. With the consent of the representatives of each Party serving on the JSC, other representatives of each Party may attend meetings as non-voting observers (provided such non-voting observers have confidentiality obligations to such Party that are at least as stringent as those set forth in this Agreement). A JSC meeting may be held either in person or by audio, video or internet teleconference with the consent of each Party. Meetings of the JSC shall be effective only if at least [***] of each Party is present or participating. Each Party shall be responsible for all of its own expenses of participating in the

JSC meetings. The Parties shall alternate hosting the in-person meeting, and the Party hosting is responsible for preparing and circulating the minutes of the JSC meetings.

(f) **Duration of JSC**. The JSC shall continue to exist until the first to occur of (a) the Parties mutually agreeing in writing to disband the JSC or (b) termination of this Agreement in accordance with the terms hereof.

(g) **Limitations**. The JSC shall have no authority other than that expressly set forth in this Section 2.1 and, specifically, shall have no authority (a) to amend or interpret this Agreement, or (b) to determine whether or not a breach of this Agreement has occurred.

(h) **Subcommittees**. Any Subcommittee (including the JDC and JCC) established by the JSC hereunder shall be composed of [***]. Each Party may replace its subcommittee representatives upon written notice to the other Party. All decisions of a Subcommittee shall be made by unanimous vote, with each Party's representatives having one vote. In the event the Parties are unable to reach a unanimous vote with respect to a matter, such matter shall be referred to the JSC for resolution.

(i) **Joint Development Committee**.

(1) **General**. Within [***] days of the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or the "**JDC**") to oversee (1) the day-to-day Development of the Licensed Compounds and Products and the execution of the Global Development Plan and Territory Specific Development Plan, (2) the progress of the Regulatory Approvals and Regulatory Submissions for the Licensed Compounds and Products, (3) to share information regarding proposed Clinical Trial sites in the Territory, and (4) such other Development related activities delegated to it by the JSC. Each Party shall appoint three [***] to the JDC, each of whom shall be an officer or employee of the applicable Party having sufficient knowledge regarding Development of the Licensed Compounds and Products.

(2) **Meetings**. While the Parties are developing and conducting Clinical Trials for Licensed Compounds and Products in the Territory, the JDC shall meet at least [***] per Calendar Quarter. The Parties shall endeavor to schedule meetings of the JDC at least [***] months in advance.

(ii) **Joint Commercialization Committee**.

(1) **General**. Within [***] days of initiating a Registration Trial, the Parties shall establish a joint commercialization committee (the "**Joint Commercialization Committee**" or the "**JCC**") to oversee and coordinate (1) the day-to-day Commercialization of the Licensed Compounds and Products in the Territory and the execution of the Commercialization Plan, including review of branding, marketing strategy, Product positioning, pricing and reimbursement strategy (to the extent legally permissible), (2) the progress of Commercialization activities for the Licensed Compounds and Products, and (3) such other Commercialization related activities delegated to it by the JSC. Each Party shall appoint [***] representatives to the JCC, each of whom shall be an officer or employee of the applicable Party having sufficient knowledge regarding Commercialization of the Licensed Compounds and Products.

(2) **Meetings**. While the Parties are Commercializing Licensed Compounds and Products in the Territory, the JCC shall meet at least [***] per Calendar Quarter. The Parties shall endeavor to schedule meetings of the JCC at least [***] months in advance.

3. **DEVELOPMENT**

3.1 **Zai Responsibilities**. Zai shall use Commercially Reasonable Efforts to Develop Products in the Territory in accordance with this Agreement, the Global Development Plan and Territory Specific Plan with the goal of achieving Regulatory Approval of Products in the Territory. Zai shall use Commercially Reasonable Efforts to conduct all activities described in the Global Development Plan and Territory Specific Plan. Zai shall not Develop any combination of Margetuximab Product or [***] (in each case, solely in accordance herewith) unless otherwise mutually agreed by the Parties, and any Clinical Trial to be conducted hereunder [***] in each instance. Notwithstanding the foregoing, either Party may propose to develop a Combination Regimen in the Territory using [***] that is [***] and such development shall be subject to the mutual agreement of the Parties, which agreement shall not be unreasonably withheld. Specifically, [***] shall not unreasonably withhold such consent provided that (a) Zai has used Commercially Reasonable Efforts to develop the Combination Regimen utilizing [***], (b) Zai has commenced [***] for a Margetuximab Product in accordance with Exhibit C, and (c) there exists a [***] such that development of [***] for at least [***] months or the nature of such issue makes it improbable for it to be resolved in less than [***] months.

3.2 Without limiting Section 3.1, in the Territory:

(a) Zai 's responsibilities shall include, using Commercially Reasonable Efforts to conduct the following activities: (i) conducting all Clinical Trials (other than [***]) required for Regulatory Approval of Products in the Territory, (ii) as soon as reasonably practicable after the Effective Date conducting an [***], (iii) the submission of all INDs in the Territory; (iv) interaction with the Regulatory Authorities in the Territory; (v) translation of necessary documents required for Regulatory Approval in the Territory; (vi) recruiting, qualifying and establishing Clinical Trial sites for the Territory, including the preparation, collection, review, approval and translation of all documentation (including Site Regulatory Packages, as applicable) required by Regulatory Authorities for the participating Clinical Trial sites in the Territory, (vii) monitoring of all clinical trial sites in the Territory for Clinical Trials that are part of the Territory Specific Development Plan or for the Territory Specific Activities under the Global Development Plan; and (viii) providing reasonable assistance to MacroGenics with submissions to and interactions with the FDA and other Regulatory Authorities outside of the Territory at MacroGenics' request and expense; provided, however, that with respect to the provision of data, information and materials, such obligation to assist shall not require Zai to generate any data not within its possession or control; and

(b) Zai shall use Commercially Reasonable Efforts to support other additional Development activities responsive to unique regulatory or commercial requirements in the Territory as set forth in the Territory Specific Development Plan or under the Global Development Plan.

3.3 **Development Plans.** The Development of the Product in the Territory under this Agreement shall be governed by the Global Development Plan and Territory Specific Development Plan, which may be revised from time to time in accordance with this Section 3.3. During the Term, the Global Development Plan and Territory Specific Development Plan shall contain in reasonable detail the major

Development and regulatory activities conducted by or on behalf of Zai (or its Affiliates or Sublicensees), including those necessary to (i) with respect to the Territory Specific Activities under the Global Development Plan, conduct the [***] in Section 3.2(a)(ii) above, (ii) seek Regulatory Approval and progress clinical Development for (A) Margetuximab [***], (B) Margetuximab [***] in the Territory, and (C) [***] Clinical Trials that include [***], in each case of (A) through (C) in the Territory and subject to review and change as set forth in Section 3.3(b), and (iii) the estimated timelines for achieving such activities until such Regulatory Approval in each Country or Region in the Territory has been obtained. In accordance with Section 2.1(b)(ii), the JDC shall review and submit to the JSC for approval, and the JSC shall review and approve the Global Development Plan and each Territory Specific Development Plan and any updates or amendments to the Global Development Plan or a Territory Specific Development Plan. The initial Global Development Plan and Territory Specific Development Plan are attached hereto as Exhibit C. To the extent the Development activities and Clinical Trials contemplated under 3.3(ii) are not included under the Global Development Plan, such Development activities and Clinical Trials shall be included under the Territory Specific Development Plan, unless otherwise mutually agreed by the Parties in writing. For clarity, Zai shall not be permitted to exercise its unilateral decision-making authority under Section 2.1(d)(ii)(A) to reduce or eliminate Zai's obligations to conduct the Development activities and Clinical Trials contemplated by the foregoing 3.3.

(a) **Review of Development**. The JDC shall review the progress of the conduct of the Global Development Plan and Territory Specific Development Plan at each meeting of the JDC.

(b) **Review of the Global Development Plan and Territory Specific Development Plan**. On no less than [***], the JDC shall review the Global Development Plan with respect to its conduct in the Territory and Territory Specific Development Plan, as appropriate, and recommend any amendment, and any changes (which for the Global Development Plan shall be limited to its conduct in the Territory) to such plans based on development, regulatory and commercialization considerations in the Territory consistent with Zai's using Commercially Reasonable Efforts, which shall be submitted to and subject to the approval by the JSC. Once approved by the JSC, the Parties agree that any such updated Global Development Plan or Territory Specific Development Plan shall supersede and replace, as applicable, the then-current Territory Specific Development Plan and Global Development Plan with respect to the Territory.

3.4 **MacroGenics Responsibilities**. As between the Parties, MacroGenics (itself or through its Affiliates or licensees) shall use Commercially Reasonable Efforts for Developing the Products outside of the Territory and completing and funding (or having completed and funded) [***] Trident. Without limiting the foregoing, MacroGenics' responsibilities shall include, either by itself or through its Affiliates or licensees, using Commercially Reasonable Efforts (a) to conduct [***] in such Clinical Trial; and (b) to conduct those Development activities assigned to MacroGenics under the Global Development Plan or Territory Specific Development Plan. MacroGenics agrees to provide reasonable assistance to Zai with submissions to and interactions with the CFDA and other Regulatory Authorities necessary to obtain Regulatory Approval for the Products in the Territory at [***].

3.5 **Conduct of Development**. Zai shall use Commercially Reasonable Efforts to conduct the Development activities under the Territory Specific Development Plan and those Development activities allocated to Zai under the Global Development Plan (including the Territory Specific Activities) and to achieve the Development goals as described in those Territory Specific Activities under the Global Development Plan and Territory Specific Development Plan. All such activities shall be conducted in

compliance with: (a) the terms and conditions of this Agreement; (b) the Global Development Plan and Territory Specific Development Plan, as updated from time to time; (c) all applicable GLP, GCP and applicable cGMP requirements, including those specified by the ICH; and (d) all Applicable Laws and Regulations. MacroGenics shall conduct its activities under this Agreement in compliance with: (a) the terms and conditions of this Agreement; (b) the Global Development Plan, as updated from time to time; (c) all applicable GLP, GCP and applicable cGMP requirements, including those specified by the ICH; and (d) all Applicable Laws and Regulations.

3.6 **Development Costs**.

(a) **Territory Specific**. Zai shall be responsible for all [***] with the conduct of (i) the [***] under the Global Development Plan or (ii) the Territory Specific Development Plan, including in each case ((i) and (ii)) the applicable cost of the [***] (the "**Territory Development Costs**"). Costs for [***] MacroGenics to Zai are addressed in Section 5.1(c).

(b) **Outside Territory**. Zai shall be responsible for the [***], and, as between the Parties, MacroGenics shall be responsible for all [***] other than the [***] (the "[***]").

(c) **Reconciliation/Reimbursement**. Within [***] days after [***], MacroGenics shall submit to a finance officer designated by MacroGenics and a finance officer designated by Zai (the "**Finance Officers**") a report setting forth a good faith estimate of the Outside Development Costs and Territory Development Costs it incurred in [***]. Within [***] days following the end of such quarter, MacroGenics shall update such report to reflect the final amount of Outside Development Costs and Territory Development Costs incurred by it in [***]. Such report shall specify in reasonable detail all such costs and shall include reasonably detailed supporting documentation, and, any additional documentation reasonably requested by Zai shall be promptly provided. Within [***] days after [***], Zai shall notify MacroGenics in writing if it disagrees with the calculation of such payments owed to MacroGenics by Zai along with a detailed explanation thereof, and within [***] following Macrogenics' receipt of such notice from Zai, the Finance Officers shall promptly confer and attempt to resolve in good faith the amount of the reimbursement payment owed to MacroGenics by Zai, such that all Territory Development Costs and the [***] are borne [***] and the MacroGenics Outside Cost Share for [***] is borne [***]. With respect to each such reimbursement payment owed to MacroGenics, Zai shall (or any of its Affiliates shall) submit such payment to MacroGenics (or any of its designated Affiliates) within [***] Business Days after the end of such [***] period. In the event of any disagreement with respect to the calculation of any such payment under this Sections 3.6(c), any undisputed portion of such payment shall be paid in accordance with the foregoing timetable specified in this Section 3.6(c), and the remaining, disputed portion shall be paid within [***]after the date [***]. In addition, following the Effective Date, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit each Party to close its books in a periodic timely manner. For the avoidance of doubt, no cost or expense shall be counted more than once in calculating Territory Development Costs and Outside Development Costs, even if such costs or expense falls into more than one of the cost categories that comprise [***].

3.7 **Subcontractors.** Each Party shall have the right to engage Third Party contractors to perform any portion of its obligations under this Agreement (each such subcontractor, a "**Permitted Subcontractor**"), provided, however, [***]. Any such Permitted Subcontractor engaged by Zai hereunder

shall be required to agree in writing to be bound by terms regarding maintaining the confidentiality of proprietary information that are no less stringent than those contained in this Agreement and regarding ownership of intellectual property that are consistent with those contained in this Agreement. Zai's use of Permitted Subcontractors shall not relieve it of any of its obligations pursuant to this Agreement.

3.8 **Clinical Trial Data**. All Clinical Data generated under this Agreement, including under the Territory Specific Development Plan or the Global Development Plan, shall be [***]. [***] by Applicable Laws and Regulations, shall [***]) to [***] all of [***] Clinical Data. [***] shall provide a copy of all such Clinical Data to [***] promptly following generation thereof, but in any event, on a schedule reasonably agreed by the JSC.

3.9 **Information and Cooperation**. In addition to the obligations under Section 3.8, each Party shall use Commercially Reasonable Efforts to reasonably cooperate with the other Party in relation to the work under this Agreement and keep the other Party informed of its Development and Commercialization (including promotional) activities reasonably related to the work under this Agreement, and shall provide to the other Party, as appropriate, regular summary updates. If reasonably necessary for a Party to perform its work under this Agreement or to exercise its rights under this Agreement, or in the case of MacroGenics, to further the Development, including clinical or regulatory programs, or Commercialization of a Licensed Compound, or a Product outside the Territory (or inside the Territory in connection with a Global Clinical Trial) or MGA012 inside or outside the Territory, that Party may request that the other Party provide more detailed information and data regarding the updates it earlier provided, and the other Party shall promptly provide the requesting Party with information and data as is reasonably available and reasonably related to the work under this Agreement. Neither Party is required to generate additional data or prepare additional reports (except to the extent required to comply with safety reporting requirements under Applicable Laws and Regulations) to comply with the foregoing obligation. All such reports, information and data provided shall be subject to Section 10.1.

3.10 **MacroGenics' Development in Territory and Global Clinical Trials**. MacroGenics shall not have the right to conduct non-clinical Development and clinical Development (in connection with Global Clinical Trials) in the Field in the Territory which are not specified in the Global Development Plan without Zai's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) ("**MacroGenics Territory Activities**"). If so consented by Zai, MacroGenics shall control and be responsible for conducting such MacroGenics Territory Activities, including the interaction with Regulatory Authority in the Territory in connection therewith, and all associated Development Costs incurred by MacroGenics in the conduct of such Development shall be borne [***] by [***].

4. COMMERCIALIZATION

4.1 **Overview.** [***] shall have [***] (subject to Sections 2.1(c) and (d)) for [***] of the Commercialization of Products in the Territory [***], including developing and executing a plan for commercial launch, obtaining all required approvals from Regulatory Authorities for Commercialization (including reimbursement activities), marketing and promotion, booking sales and distribution and performance of related services, providing customer support, including handling medical queries, and performing other related functions. Zai shall use Commercially Reasonable Efforts to Commercialize the Products. [***] shall [***] Commercialization activities at regular meetings of the JSC as contemplated by Section 2.1(e). As between Zai and MacroGenics, Zai shall [***] Products in the Territory, and shall

have [***] Products in the Territory. [***] shall [***] in connection with all such Commercialization activities in the Territory. [***] shall provide [***] in the Territory within [***] days after such [***] [***] shall have [***] the Commercialization of Products [***] at [***], including obtaining all required approvals from Regulatory Authorities for Commercialization (including reimbursement activities), marketing and promotion, booking sales and distribution and performance of related services, providing customer support, including handling medical queries, and performing other related functions.

4.2 **Product Labeling; Promotional Materials.** Zai shall reasonably cooperate with MacroGenics and its designees to establish a global branding strategy for the Products worldwide. Zai shall Commercialize the Products in the Territory under the worldwide brand and consistent with the global branding strategy, in each case, specified by MacroGenics (the "**Product Brand**" and "**Global Branding Strategy**", respectively), except to the extent such branding is not practicable in the Territory or not permitted by any applicable Regulatory Authority in the Territory, in which case MacroGenics and Zai shall agree on an alternate Territory specific Product Brand or MacroGenics may make an adjustment to the Global Branding Strategy, as MacroGenics deems appropriate. Except for the depiction of trademarks, logos and other symbols that are intended to identify MacroGenics' as a company or the manufacturer or owner of a Product, Zai shall be responsible for designing and supplying the printable artworks of Product labeling in electronic version and promotional materials for the Products for the Territory. Zai shall be responsible for how and the manner in which Products shall be presented and described in the Territory to the medical community in any promotional materials for a Product intended to be disseminated in the Territory, and the placement of the name and logos of Zai therein, in each case as permitted by Applicable Law and consistent with the Product Brand and labeling for the Products approved by the applicable Regulatory Authority, and consistent with the Global Branding Strategy.

4.3 **Sales and Distribution**

(a) **Orders and Sales**. [***] shall [***] handling all returns, order processing, invoicing and collection, distribution, and inventory and receivables for the Products throughout the Territory. [***] shall have the [***] establishing and modifying the terms and conditions with respect to the sale of the Products in the Territory, including any terms and conditions relating to or affecting the price at which the Products shall be sold, discounts available to any Third Party payers (including managed care providers, indemnity plans, unions, self-insured entities, and government payer, insurance or contracting programs), any discount attributable to payments on receivables, distribution of the Products, and credits, price adjustments, or other discounts and allowances to be granted or refused; provided, however, that Zai shall act in good faith when doing the foregoing.

(b) **Pricing**. [***] shall [***] pricing of the Products in the Territory, with the understanding that Zai shall also be solely responsible for preparing and implementing the reimbursement strategy for the Products in the Territory. MacroGenics shall, subject to any restrictions imposed under Applicable Laws and Regulations, use reasonable efforts to provide all the data deemed necessary by MacroGenics and within its possession or control so as to support any application by Zai for desired medical reimbursement rates in the Territory.

4.4 **Compliance**. Each Party shall comply with the terms of this Agreement and all Applicable Laws and Regulations relating to activities performed or to be performed by such Party (or its Affiliates, contractor(s) or Sublicensee(s)) under or in relation to the Commercialization of the Products pursuant to this Agreement. Notwithstanding the foregoing, Zai agrees, on behalf of itself, its officers, directors and

employees and on behalf of its Affiliates, agents, representatives, consultants, and Permitted Subcontractors (together with Zai, the "**Zai Representatives**") that for the performance of its obligations hereunder:

(a) The Zai Representatives shall not directly or indirectly pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything else of value, to: (i) any Government Official in order to influence official action; (ii) any Person (whether or not a Government Official) (a) to influence such Person to act in breach of a duty of good faith, impartiality or trust ("**Acting Improperly**"), (b) to reward such Person for Acting Improperly, or (c) where such Person would be Acting Improperly by receiving the money or other thing of value; (iii) any other Person while knowing or having reason to know that all or any portion of the money or other thing of value shall be paid, offered, promised or given to, or shall otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or (iv) any Person to reward that Person for Acting Improperly or to induce that Person to Act Improperly.

(b) The Zai Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(c) Zai and the other Zai Representatives shall comply with the Anti-Corruption Laws and shall not take any action that shall, or would reasonably be expected to, cause either Party (or its Affiliates) to be in violation of any such laws. In furtherance of the foregoing, Zai acknowledges and confirms the following:

(i) Zai has reviewed its internal programs in relation to the Anti-Corruption Laws and the ability of the Zai representatives to adhere to such laws in performance of its obligations hereunder in advance of the signing of this Agreement and warrants that it and the other Zai Representatives can and shall continue to comply with such Anti-Corruption Laws in performance of its obligations hereunder and further represents and warrants that should either Party identify in writing to the other Party any measures that should be reasonably taken to improve Zai Representatives' compliance with such Anti-Corruption Laws for the performance of its obligations hereunder (the "**Improvement Plan**"), Zai shall use Commercially Reasonable Efforts to implement such Improvement Plan within [***] (which shall in any event not be in excess of [***] calendar months) from the date the Improvement Plan is delivered to the receiving Party. In the absence of the full implementation by Zai of such Improvement Plan within [***] calendar month period, MacroGenics shall be entitled to terminate this Agreement, upon written notice to Zai with immediate effect, to be relieved of any obligations, and to seek compensation from Zai;

(ii) To the best of Zai's and its Affiliates' knowledge after reasonable diligence, no Zai Representative that shall participate or support Zai's performance of its obligations hereunder has, directly or indirectly, (x) paid, offered or promised to pay, or authorized the payment of any money; (y) given, offered or promised to give, or authorized the giving of anything else of value; or (z) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((x), (y) and (z)), in violation of the Anti-Corruption Laws during the [***] preceding the date of this Agreement.

(iii) To the best of Zai 's and its Affiliates' knowledge, none of its intellectual property rights, technology, contracts, materials, or licenses or other assets that are the subject of this

Agreement, other than those provided by or on behalf of MacroGenics, were procured in violation of any Anti-Corruption Laws.

(d) Zai, on behalf of itself and the Zai Representatives, represents and warrants to MacroGenics that all information provided by Zai and the Zai Representatives to MacroGenics in any anti-bribery and corruption due diligence checklist, similar due diligence process performed by MacroGenics or its Affiliates or inquiry by MacroGenics related to Zai 's or the Zai Representatives compliance with Anti-Corruption Laws is true, complete and correct in all material respects at the date it was provided and that any material changes in circumstances relevant to the answers provided in such exercise shall be promptly disclosed to MacroGenics.

(e) Zai shall promptly provide MacroGenics with written notice of the following events: (i) Upon becoming aware of any actual, alleged, or potential breach or violation by Zai or any Zai Representative of any representation, warranty or undertaking set forth in this Section 4.4; or (ii) Upon receiving a formal notification that it is the target of a formal investigation by a government authority for any violation of any Anti-Corruption Law or upon receipt of information from any of the Zai Representatives that any of them is the target of a formal investigation by a government authority for a violation of any Anti-Corruption Law.

(f) For [***] years following the expiration or earlier termination of the Agreement, Zai shall for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly this Section 4.4 permit MacroGenics, its Affiliates, any auditors of any of them and any government authority to have reasonable access to any premises of Zai or other Zai Representatives used in connection with this Agreement, together with a right to reasonably access personnel and records that relate to this Agreement ("**Zai Audit**"). Zai shall provide or procure that the Zai Representatives shall provide all co-operation as reasonably requested by MacroGenics for the purposes of the Zai Audit, with the understanding that MacroGenics shall be responsible for all costs and fees of any Zai Audit and MacroGenics shall procure that any auditor enters into a confidentiality agreement consistent with the confidentiality provisions elsewhere in this Agreement in all material respects.

(g) On the occurrence of any of the following events:

(i) MacroGenics becomes aware of, whether or not through a Zai Audit, that Zai (or any other Zai Representative) is in breach or violation of any representation, warranty or undertaking in Section 4.4 or of the Anti-Corruption Laws; or

(ii) Notification is received by MacroGenics that a suspected or actual violation of an Anti-Corruption Law has occurred by Zai or any other Zai Representative;

MacroGenics shall have the right, in addition to any other rights or remedies under this Agreement or to which MacroGenics may be entitled in law or equity, to take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by MacroGenics or any of its Affiliates of the Anti-Corruption Laws, including by requiring that Zai agrees to and uses Commercially Reasonable Efforts to implement any curative actions requested by MacroGenics. In the event that Zai refuses to agree to all of the curative actions requested by MacroGenics (and provided that MacroGenics has (x) provided Zai with an explanation in reasonable detail as to why MacroGenics considers such actions necessary, (y) given Zai a reasonable opportunity to review and comment upon the proposed actions and to provide its view as to

the necessity or usefulness of these to address the event concerned, and (z) considered such comments in good faith), MacroGenics shall be entitled to terminate this Agreement in its entirety with immediate effect. Any termination of this Agreement pursuant to this Section 4.4 shall be treated as a termination for breach by Zai of this Agreement and the consequences of termination shall apply and additionally: (1) subject to the accrued rights of the Parties prior to termination, MacroGenics shall have no liability to Zai for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (2) any amounts that would otherwise be payable to Zai pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under Applicable Laws and Regulations.

(h) Zai shall be responsible for any breach of any representation, warranty or undertaking in this Section 4.4 or of the Anti-Corruption Laws by any Zai Representative.

(i) MacroGenics may disclose the terms of this Agreement or any action taken under this Section 4.4 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of Zai and the payment terms, to any government authority if MacroGenics determines, upon advice of counsel, that such disclosure is necessary.

4.5 **Commercialization Diligence**

(a) **Prior to Submission of First BLA**. For each Product under Development, prior to the submission of the first BLA to the first Regulatory Authority in the Territory, Zai shall submit to the JCC for review and submission to the JSC for review and approval, a written summary plan for the Commercialization in the Territory for each such Product under Development, as well as updates and amendments thereto. Thereafter, Zai shall regularly report on its Commercialization activities at meetings of the JSC. Such reports shall cover subject matter at a level of detail similar to that which Zai affords its senior executives with respect to similar Zai products. All such plans and information shall be presented for discussion purposes, and Zai agrees to consider in good faith any comments or suggestions MacroGenics may make with respect to Commercialization of Products.

(b) **Following Regulatory Approval**. Zai shall use Commercially Reasonable Efforts to Commercialize each Product in the Territory after Regulatory Approval for such Product is obtained.

5. MANUFACTURE AND SUPPLY

5.1 **Supply of Products**

(a) **Responsibility**. MacroGenics shall be responsible for the Manufacture, either by itself or through one or more Third Parties selected by MacroGenics at its sole discretion, of (i) all Licensed Compounds, MGA012 and Product required for the Clinical Trials described in the Global Development Plan and Territory Specific Development Plan, (ii) subject to Section 5.4, all commercial supplies of Product required by Zai for the Commercialization of Products in the Territory, and (iii) either (A) [***], in accordance with the terms and conditions of the [***], to make [***] a reasonably sufficient quantity based on demand, or (B) solely in the event that [***] the Manufacture and supply of [***], to make supply of [***]available in a reasonably sufficient quantity based on demand, in each case ((A) and (B)) in the Territory for the Commercialization of the Combination Regimen in the Territory after the Regulatory

Approval of such Combination Regimen in the Territory, in each case ((i) through (iii)) in accordance with this Section 5.1, except as the Parties may otherwise agree in writing. The Parties agree and acknowledge that subsection (iii) above shall not be construed as requiring MacroGenics to guarantee the [***] to Zai's requirement, either to Zai for clinical use or for sale in the Territory by [***] or any other [***], but shall be construed as requiring MacroGenics to endeavor to fulfill [***] provided by Zai for use in clinical development and/or pursuant to the Commercial Supply Agreement ("[***]"). In the event of a [***], MacroGenics shall [***] to fulfill a [***] as if MacroGenics was [***].

(b) **Supply Agreements**. Within [***] months after the Effective Date, the Parties shall enter into negotiations for a supply agreement governing the clinical supply of Product to Zai for its requirements of Product for Development hereunder in the Territory. Within [***] months after the Effective Date, the Parties shall enter into negotiations for a supply agreement governing the clinical supply of MGA012 to Zai for its requirements of MGA012 in the conduct of the Development hereunder of Licensed Compounds and Products solely as a component of a Combination in the Territory (which supply agreement will be subject to the Incyte Agreement). Within [***] months (but no later than [***] months) prior to the projected commercial launch date of the Product in any Country or Region in the Territory, the Parties shall negotiate and enter into a supply agreement governing the commercial supply of Product to Zai for its requirements of Product for Commercialization in the Territory (the "**Commercial Supply Agreement**"), with such Commercial Supply Agreement including pricing, payment, and delivery terms consistent with the provisions set forth in Sections 5.1(c) and 5.1(d). The supply agreements shall provide other customary terms and conditions, such as acceptance and rejection procedures, forecast and order procedures, release documentations and audit rights by Zai and for MacroGenics and Zai to discuss and agree upon a Third Party supplier for Products in the event of certain material supply failures (as determined in accordance with criteria to be mutually agreed by the Parties thereunder). In addition, the Commercial Supply Agreement shall include further provisions for the commercial supply of Product in the Territory, including procedures for the MGA012 Commercial Forecasts.

(c) **Price; Payment**.

(i) The price of (A) clinical quantities of Licensed Compounds and Product ordered by Zai under Section 5.1(a)(i) for use under the Territory Specific Activities under the Global Development Plan shall be equal to [***] of MacroGenics' Fully-Burdened Manufacturing Costs, (B) clinical quantities of Licensed Compounds and Product for use ordered by Zai under Section 5.1(a)(i) for use under a Territory Specific Development Plan, or commercial quantities of Product ordered by Zai under Section 5.1(a)(ii), shall be equal to [***] of MacroGenics' Fully-Burdened Manufacturing Costs for such Licensed Compounds and Products (subject to adjustment in accordance with Section 5.4 or Section 5.5 below, as applicable). MacroGenics' supply of clinical quantities of MGA012 pursuant to Section 5.1(a)(i) shall be at no cost to Zai.

(ii) All payments due hereunder to MacroGenics shall be paid to MacroGenics in US Dollars no later than [***] days following the receipt of the applicable invoice.

(d) **Delivery**. Unless otherwise agreed by the parties in writing, all shipments shall be shipped [***].

5.2 **Manufacturing Specifications**. All Study Materials and commercial supplies of Product shall be manufactured in accordance with the specifications (i) determined by MacroGenics, (ii) subject to Section 5.3, consistent with those Territory specific specifications required by the applicable Regulatory Authority in the Territory provided by Zai to MacroGenics in writing, and (iii) in compliance with all regulatory requirements and all Applicable Laws and Regulations, as further set forth in the supply agreements and related quality agreements.

5.3 **Change of Manufacturing Process**. MacroGenics shall reasonably inform Zai of developments in matters of process development and Manufacture of Products, and shall consult with Zai with respect to the development and Manufacture processes of Products adopted by MacroGenics to the extent necessary to obtain Regulatory Approval(s) of the same in the Territory, all as described in further detail in the supply agreements and quality agreements. In addition, MacroGenics shall implement changes required by Regulatory Authority in the Territory to the extent commercially practicable, provided that Zai shall bear any and all incremental costs resulting from any changes to the manufacturing specifications required by the applicable Regulatory Authority in the Territory but not by any of the Regulatory Authorities outside the Territory, and the supply agreements and quality agreements shall provide the mechanism for such implementation. In the event it is not commercially practicable for MacroGenics or its supplier to implement a change required by a Regulatory Authority in the Territory, the Parties shall explore the potential engagement of another Third Party supplier to implement a Manufacturing process that incorporates such required change. Each Party shall promptly notify the other Party of any information that may impact approvability or regulatory status (before or after approval) of Products of which it is aware and reasonably believes may impact the regulatory status before or after Regulatory Approval of a Product or Combination Regimen in the Territory.

5.4 **Margetuximab Manufacturing Cost Control**.

With respect to the commercial supply of Margetuximab hereunder, from and after the date that is [***] months from [***], in the event that both (i) the [***]of (A) the [***] for Margetuximab supplied by or on behalf of MacroGenics to Zai hereunder [***] (B) the[***] of such Margetuximab during the corresponding period (such Net Sales the "**Rolling Net Sales**") (such [***], the "[***]") is [***]than [***] (the "[***]"), and (ii) Zai reasonably, and in good faith, believes that either [***] or a [***] reasonably acceptable to both Parties (a "[***]") in the Territory is able to [***] equivalent (including, in quantity, quality and form) at a [***] that is at least [***] than MacroGenics' [***] for commercial supply of Margetuximab, as reasonably demonstrated by Zai via delivery to MacroGenics of competent written [***] documentation showing that [***] or such [***] has historically (within the most recent three (3) year period) [***] consistent with the foregoing at such [***], then Zai shall provide MacroGenics with written notice of such belief along with such documentation (the "[***] **Notice**"), then MacroGenics may [***] (in accordance with Section 5.4(a) below) and, to the extent applicable, Zai may [***] (in accordance with Section 5.4(b) below). For purposes hereof, "**Total Manufacturing Cost**" means [***].

(a) [***]. For each instance in which the [***] is achieved as contemplated in this Section 5.4 above, MacroGenics shall have the option (in its sole discretion) to elect, to subsequently (i)

reduce the royalty payable by Zai pursuant to Section 7.3 on Net Sales of Margetuximab Manufactured and supplied by MacroGenics to Zai under this Agreement by [***], or (ii) in lieu of any royalty payable by Zai pursuant to Section 7.3 for such Margetuximab, supply Margetuximab to Zai at [***] (the "[***]"). MacroGenics may exercise the [***], if at all, by providing written notice of such exercise to Zai within [***] days of the date of MAcroGenics receipt of such RMA Threshold Notice ("[***] **Period**"). Such written notice shall specify whether MacroGenics is electing the means under (i) or (ii) under this Section 5.4(a) to reduce the Rolling Margetuximab Cost and if the means under (i) is elected, the initial amount by which MacroGenics shall reduce the royalty payable to Zai. MacroGenics shall subsequently have the right to adjust such reduction by providing [***] days prior written notification to Zai prior to such adjustment.

(b) [***]. Subject to Section 5.4(d), in the event that (i) MacroGenics does not exercise the [***] prior to the expiration of the [***] Period or (ii) if MacroGenics timely exercises the [***] set forth in Section 5.4(a)(ii) but the [***] is [***], then Zai shall have the option ("[***]") to conduct [***]. Zai may exercise the [***], if at all, by providing written notice of such exercise to MacroGenics [***]. Such written notice shall specify whether [***] elects that it or its [***] or both, as applicable, the **"**[***]**"**) will conduct [***] pursuant to the [***].

(c) **Activities Post** [***]**.** If Zai exercises the [***] in accordance with Section 5.4(b), MacroGenics and Zai shall use Commercially Reasonable Efforts to conduct the activities necessary or useful to [***] to conduct [***] using the [***] as soon as practicable, including performance of a [***] pursuant to a mutually agreed [***] and budget whereby [***] would transfer (to the extent not previously transferred) the [***] to the [***]. Following the initial [***], MacroGenics shall use Commercially Reasonable Efforts to disclose and/or make available to Zai any [***] (to the extent not previously transferred) that comes into existence from time to time and to the extent used in the [***]. Zai would bear [***] of all costs and expenses of such [***] pursuant to this Section 5.4(c). MacroGenics hereby grants to [***] a non-exclusive, non-transferable license, with right to sublicense solely to its Affiliates or a [***], to the [***] (and any Patents Controlled by MacroGenics that claim or cover the [***]) to [***] and [***] in the Field in the Territory, which license shall become effective only upon exercise of the [***]. At MacroGenics' request (at its sole discretion and election), the Parties will negotiate and enter into a [***] pursuant to which [***] would undertake Commercially Reasonable Efforts to [***] (or [***]would cause its [***]) [***], its [***] and licensees' [***] (and [***]) on commercially reasonable terms. Such [***] shall provide for supply of [***] (and [***]) to MacroGenics by Zai based on [***] of its [***] (as such definition is applied to Zai *mutatis mutandis*) and other commercially reasonable terms that are generally consistent with the [***]. For clarity, in the event Zai exercises the [***], after Zai has established a [***] of the [***] for the [***] and [***] after the completion of a [***] to Zai, MacroGenics shall have no further obligations under this Agreement to [***] to [***] hereunder, including pursuant to Section 5.1(a)(ii).

(d) **First Change of Control of Zai**. Notwithstanding the foregoing, Zai's rights under Sections 5.4(b) and 5.4(c) shall terminate upon the First Change of Control of Zai if at such time Zai has not exercised the [***].

5.5 **Third Party Obligations; MacroGenics Third Party Agreements.** All licenses and other rights granted to Zai under this Agreement are subject to the rights and obligations of MacroGenics under the MacroGenics Third Party Agreements. Zai will comply with all applicable provisions of the MacroGenics Third Party Agreements and Zai agrees to (and shall cause its Related Parties to) timely perform and take such actions as may be required to allow MacroGenics to comply with its obligations thereunder, including to provide to MacroGenics such information and reports as it reasonably requires, comply with reasonable requests for access to Zai's (and its Related Parties') records or facilities or otherwise cooperate with MacroGenics, including with respect to any financial and regulatory reporting, audit and payment obligations under each MacroGenics Third Party Agreement, insofar as they pertain to a Licensed Compound, MGA012 or any Product or Zai's (and its Related Parties') activities hereunder. Zai shall pay its share of Triggered Third Party Payments in accordance with Section 7.5.

6. REGULATORY

6.1 **Overview.** Zai shall develop an overall regulatory strategy and plan for obtaining Regulatory Approval of the Product in the Territory to be included in the Global Development Plan and Territory Specific Development Plan and approved by the JSC.

6.2 **Regulatory Submissions**.

(a) MacroGenics or its designee shall hold and own all Regulatory Submissions as set forth in Section 9.1(e), and Zai shall promptly provide all original copies of Regulatory Submissions (including all updates thereof) to MacroGenics.

(b) Zai shall be responsible for in MacroGenics' or its designee's name, at [***], (x) the filing and obtaining all Regulatory Submissions, (y) responding to inquiries and correspondence from the Regulatory Authorities responsible for regulatory matters in the Territory, and (z) the monitoring of all clinical experiences through the pharmacovigilance exchange between the Parties and submission of all required reports throughout clinical Development and Commercialization, in each case as required by Regulatory Authority in the Territory and in compliance with all Applicable Laws and Regulations. MacroGenics shall be responsible for providing to Zai any revisions to the investigator's brochure and CMC information required for regulatory submissions and responses to Regulatory Authorities in the Territory. MacroGenics (or its designee) shall have a right to participate (and Zai may otherwise request MacroGenics to participate) in meetings with the Regulatory Authorities if it is reasonably likely that there would be discussions on the agenda about (i) the Product beyond the scope of Zai's Development of the Product in the Territory (e.g., CMC matters, data from clinical trials MacroGenics conducted) or (ii) MGA012. Each Party shall provide information to the other Party as necessary and reasonably consult with the other Party regarding any filings, and regarding significant or material notices, actions or requests from or by Regulatory Authorities. Each Party shall, at the other Party's request, review and comment on filings, submissions, and responses to Regulatory Authorities related to any Product.

6.3 **Right of Reference.** MacroGenics hereby grants to Zai a right of reference to all Regulatory Submissions pertaining to the Product and MGA012 (solely in connection with the Combination Regimen) in the Field in the Territory to the extent necessary for Zai to Develop and Commercialize the Products (including as part of the Combination Regimen) in accordance with this Agreement, including obtaining and maintaining Regulatory Approval of the Products (including as part of the Combination Regimen) in Field in the Territory in accordance with this Agreement.

6.4 **Records of Correspondence with Regulatory Authorities**. Following each substantive communication (whether by phone or in person) with a Regulatory Authority regarding matters arising under this Agreement, Zai shall prepare a record of such meeting in accordance with its standard business practices (e.g., written minutes) and provide to MacroGenics a copy of such record. Zai's occasional inadvertent failure to provide such record to MacroGenics shall not itself be deemed a material breach of this Agreement, and Zai shall provide such record to MacroGenics promptly after discovery of such inadvertent failure, provided that the foregoing shall not relieve Zai from, and Zai shall be responsible (at [***]) for, any and all liability and costs incurred by or on behalf of MacroGenics and its Affiliates as a result of such failure.

6.5 **Safety Management Plan**. The Parties shall conduct in good faith and agree upon a safety management plan ("**SMP**"), which will detail the Clinical Trial specific responsibilities, processes and other matters to ensure that adverse event notification and reporting requirements meet current health agency regulations and guidelines worldwide, as further detailed in Exhibit D. Zai shall cause its Related Parties and Permitted Subcontractors to submit all such information, data and reports required under the SMP directly to MacroGenics (or its designee) as applicable.

7. PAYMENTS

7.1 **Upfront Payment**.

(a) Within [***] days after the Effective Date, Zai shall pay to MacroGenics Twenty Five Million US Dollars (US$25,000,000) (the "**Upfront Payment**"), which shall be [***].

(b) In the event that MacroGenics does not obtain Regulatory Approval of Margetuximab in the United States (using the SOPHIA results and other pertinent data) by December 31, 2020, then [***].

7.2 **Development Milestone Payments**.

(a) On a Product-by-Product basis, Zai shall pay to MacroGenics the milestone payments listed below for the first achievement of the corresponding milestone event, which in each case shall be non-refundable, and non-creditable. For clarity, there shall be only three Products for the purpose of the payment provisions under this Agreement, and all products comprising Margetuximab shall be deemed a single Product, all Products comprising MGD013 shall be deemed a single Product and all products comprising [***] Trident shall also be deemed a single Product. Each milestone payment shall be payable only once under this Agreement for the applicable Product, or, if applicable to Margetuximab Product, MGD013 Product and [***] Trident Product, once for each such Product.

Milestone Event	Milestone Payment
(i)[***]	[***]
(ii)[***]	[***]

(iii)[***]	[***]	
(iv)[***]	(A)[***]	[***]
	(B)[***]	[***]
	(C)[***]	[***]
(v)[***]	(A)[***]	[***]
	(B)[***]	[***]
	(C)[***]	[***]
(vi)[***]	(A)[***]	[***]
	(B)[***]	[***]
	(C)[***]	[***]
	(D)[***]	[***]
(vii)[***]	[***]	
(viii)[***]	[***]	
(ix)[***]	[***]	
(x)[***]	[***]	[***]
	[***]	[***]
	[***]	[***]

* For clarity, in the event that no patients are dosed in a Clinical Trial that would otherwise be subject to the foregoing milestones, then the next equivalent Clinical Trial where the applicable milestone criteria are met will be used for purposes of such milestone hereunder.

(b) Zai shall provide written notification to MacroGenics of the achievement by or on behalf of Zai or its Related Party of each of the milestones described in Sections 7.2(a)(i), (ii), (iii), (vii), (viii), (ix) and (x) within [***] Business Days after such achievement. MacroGenics shall provide written notification to Zai of the achievement of each of the milestones described in Sections 7.2(a)(iv), (v) and (vi) within [***] Business Days after such achievement. In addition, MacroGenics shall provide Zai with a complete list of milestone payments subject to payment under Section 7.6(a) for MacroGenics Required Third Party Agreements and Section 7.6(b) for Triggered Third Party Payments under the MacroGenics Other Third Party Agreements, and Zai shall provide written notification to MacroGenics of the achievement of each such milestone event by or on behalf of Zai or its Related Party.

7.3 **Product Royalties**. Zai shall pay to MacroGenics a royalty at the rate determined [***]. After the Royalty Term for a particular Product in a particular Country or Region, subject to Section 7.7, the license granted to Zai under this Agreement for such Product in such Country or Region shall otherwise become perpetual, irrevocable, fully paid and royalty free.

7.4 **Royalty Adjustments.** The following adjustments shall be made, on a Product-by-Product, Country-by-Country and Region-by-Region basis, to the royalties payable pursuant to Section 7.3, provided that in no event shall the aggregate [***].

(a) **Biosimilar Product Market Effect**. If there is no longer a Valid Claim within the MacroGenics Licensed Patents covering a given Product in a Country or Region in the Territory, then Zai may [***].

(b) [***]. On a Product-by-Product basis, and with respect to a Margetuximab Product for so long as the [***] has not occurred pursuant to Section 5.4(b), in the event that [***] (such sum, the "**Total Amount**") is [***] (the "[***]" and [***], the "[***]"), then [***]. For clarity with respect to a Margetuximab Product, (i) in the event MacroGenics exercises the [***] under Section 5.4(a)(ii), then this Section 7.4(b) shall no longer apply; and (ii) upon the occurrence of the [***] pursuant to Section 5.4(c), then [***].

7.5 **Royalty Floor**. In no event shall the royalty reductions available to Zai to under this Agreement, collectively or individually, reduce the royalties payable to MacroGenics for a given Calendar Quarter to less than [***] or [***] of the amount otherwise payable under Section 7.3 with respect to an applicable Product.

7.6 **Payments For Third Party Agreements**

(a) **MacroGenics Required Third Party Agreements**. MacroGenics shall be responsible for all payments to MacroGenics' other parties under the MacroGenics Required Third Party Agreements. Zai shall reimburse MacroGenics for such payments according to the following percentages:

(i) Royalties based on Net Sales of Products in the Territory: [***].

(ii) Payments, including license maintenance fees and milestone payments, that result from activities or events other than (i): [***].

(b) **Other Third Party Agreements**. In the event that a Party owes the other Party any Triggered Third Party Payments to the other Party, such Party shall reimburse the other Party at least [***] days prior to the applicable payment date for such Triggered Third Party Payment specified under the applicable Other Third Party Agreement. Such Party's obligation under this Section 7.6(b) with respect to the payment of Triggered Third Party Payments under a given MacroGenics Other Third Party Agreement or Other Third Party Agreement for which MacroGenics elects to obtain a sublicense pursuant to Section 9.7 shall terminate upon termination of the In-License Party's obligation to pay such Triggered Third Party Payments under the terms of such MacroGenics Other Third Party Agreement or Other Third Party Agreement.

7.7 **Payment of Milestones**. All payments based on milestone achievements shall be due and payable within [***] days after the event for which the payment is due, subject to any shorter deadline that is set forth in the applicable Other Third Party Agreement.

7.8 **Reports; Payments**

(a) **Net Sales Quarterly Reports**. During the Term, following the First Commercial Sale of a Product in the Territory, Zai shall furnish to MacroGenics:

(i) a quarterly written report for the Calendar Quarter showing the Net Sales of all Products subject to royalty payments sold by Zai and its Related Parties in the Territory during the reporting period and the royalties payable under this Agreement; and

(ii) a quarterly report for the Calendar Quarter showing the Triggered Third Party Payments, Zai's royalties payable to Third Parties on Net Sales made during such Calendar Quarter and any royalty adjustments taken by Zai pursuant to Section 7.4, with such detail as shall reasonably allow MacroGenics to determine the basis for such quarterly costs.

(b) **Submission and Payment Schedule**

(i) Reports under this Section 7.8 shall be due on the [***] Calendar Day following the close of each Calendar Quarter.

(ii) Royalties (including those within the Triggered Third Party Payments) shown to have accrued by each report shall, unless otherwise specified under this Agreement, be due and payable [***] days after the date such report is due.

7.9 **Payment Exchange Rate**. All payments to be made by Zai to MacroGenics under this Agreement shall be made in US Dollars by bank wire transfer in immediately available funds to a bank account in the United States designated in writing by MacroGenics. For invoices that Zai shall forward to MacroGenics, Zai shall use an exchange rate as published by the *Wall Street Journal* as of the close of business on the last business day of the preceding month, or such other source as the Parties may agree in writing. Zai shall take all possible steps to ensure all payments are made to MacroGenics under this Agreement, including by paying from non-Territory sources.

7.10 **Taxes**. All taxes applicable to the Development, Manufacture, Commercialization, use, import, distribution or sale of Products in the Territory or assessable on any payments made by Zai to MacroGenics under this Agreement shall be paid by [***], subject to the following:

(a) **License Payments**. Zai shall deduct or withhold from the License Payments made to MacroGenics [***]. Zai shall furnish to MacroGenics appropriate evidence of the payment (including official receipts) of all Payment Taxes or other amount required by Applicable Laws and Regulations. Zai shall use Commercially Reasonable Efforts to obtain any credits or refunds available for VAT taxes paid by Zai. MacroGenics shall reimburse Zai for [***].

(b) **Other Payments Due To MacroGenics**. [***] shall bear [***] of the Payment Taxes due for payments due to [***], other than License Payments. [***] shall ensure by the payment of additional amounts to [***] that [***] receives the full amount due for each such payment as set forth under this Agreement as if no deduction or withholding of such taxes had taken place.

8. **Record Keeping and Inspections and Audits**

8.1 **Records**

(a) **Research, Development, Manufacturing and Commercialization Activities.** Each Party shall maintain appropriate records of: (i) all research, Development, Manufacturing and Commercialization events and activities conducted by it or on its behalf related to a Product (including as part of the Combination Regimen), and all costs in connection therewith, as applicable; and (ii) all significant information generated by it or on its behalf in connection with Development of Licensed Compounds and Products (including as part of the Combination Regimen) under this Agreement, in each case in accordance with such Party's usual documentation and record retention practices, provided, that, without limiting the foregoing, Zai shall be required to maintain appropriate records of all information generated by it or on its behalf in connection with the use of MGA012 and research and Development of Licensed Compounds and Products related thereto under this Agreement. Such records shall be in sufficient detail to properly reflect, in good scientific manner, all significant work done and results of studies and trials undertaken, and further shall be at a level of detail appropriate for patent and regulatory purposes. Upon the reasonable request of a Party, the other Party shall make such records available to the requesting Party. Each Party shall cause its Related Parties and Permitted Subcontractors to comply with this Section 8.1(a).

(b) **Records for Zai Payments**. Without limiting the foregoing under Section 8.1(a), Zai shall keep complete and accurate records in sufficient detail to (i) ensure that MacroGenics receives the full amount of royalties payable to it under Section 7.3 and Triggered Third Party Payments payable under Section 7.5, and (ii) reasonably allow MacroGenics to determine the basis for the MacroGenics Outside Cost Share. At the reasonable request of MacroGenics, Zai shall make such records available to MacroGenics.

(c) **MacroGenics' FBMC and Development Costs**. MacroGenics shall keep complete and accurate records with such detail as shall reasonably allow Zai to determine the basis for such FBMC, the Territory Development Costs and the [***]. At the reasonable request of Zai, MacroGenics shall make such records available to Zai.

8.2 **Audit Rights**. Upon the written request of a Party ("**Requesting Party**") with reasonable advance notice and not more than [***] in each Calendar Year, the other Party shall permit an independent certified public accounting firm of internationally recognized standing selected by Requesting Party and reasonably acceptable to the other Party, at [***], to have access during normal business hours to such of the records as may be reasonably necessary to verify the that the correct amounts have been paid to such Party under this Agreement during any Calendar Year ending not more than [***] months prior to the date of such request. The accounting firm shall disclose to the Requesting Party only whether the reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Requesting Party in connection with this audit right. This right to audit shall remain in effect throughout the life of this Agreement and for a period of [***] years after the termination of this Agreement (and thereafter until [***]).

8.3 **Discrepancies**. If such accounting firm identifies a discrepancy, the other Party shall pay Requesting Party the amount of the discrepancy within [***] days of the date Requesting Party delivers to the other Party such accounting firm's written report so concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Requesting Party unless the underpayment by the other Party exceeded [***] of the amount owed for such Calendar Year, in which case the other Party shall pay to Requesting Party the reasonable fees charged by such accounting firm.

8.4 **Confidentiality**. Each Party shall treat all information of the other Party subject to review under this Section 8 in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party and any applicable Related Parties, obligating it or them to retain all such information in confidence pursuant to such confidentiality agreement.

9. LICENSES

9.1 License to Zai.

(a) **Licensed Compounds and Products**. Subject to the terms and conditions of this Agreement, MacroGenics hereby grants to Zai an exclusive, royalty-bearing license (or sublicense, as applicable), with the right to grant sublicenses (subject to Section 9.1(d)), under the MacroGenics Licensed Technology and the MacroGenics Licensed Trademarks to conduct the Development (subject to MacroGenics' reserved rights to conduct Development under Section 9.1(g)) activities allocated to Zai under the Global Development Plan and Territory Specific Development Plan, and to Commercialize and otherwise distribute, sell, offer for sale and import Products in the Field in the Territory during the Term. For clarity, except to the extent expressly set forth in Section 5.4 with respect to Margetuximab, Zai shall not have the right to Manufacture the Licensed Compounds or Product (including as part of any Combination Regimen), but the foregoing license under this Section 9.1(a) does include the right to sell, offer for sale, and import Products in the Field in the Territory that have been Manufactured using the [***] [***] Controlled by MacroGenics or its Affiliates Covering the Manufacture of the Licensed Compounds or Products (including as part of any Combination Regimen, [***]).

(b) Subject to the terms and conditions of this Agreement, MacroGenics hereby grants to Zai an exclusive, royalty-bearing license (or sublicense, as applicable), with the right to grant sublicenses (subject to Section 9.1(d)), under the MacroGenics Licensed Technology to utilize MGA012 in the conduct of the Development (subject to MacroGenics' reserved rights to conduct Development under Section 9.1(g)) activities allocated to Zai under the Global Development Plan and Territory Specific Development Plan of Licensed Compounds and Products solely as a component of a Combination Regimen, which for clarity shall include the conduct of one or more Combination Regimen Study(ies), and, following Regulatory Approval of such Combination Regimen, to market and promote such Combination Regimen (which right to market and promote shall be co-exclusive with MacroGenics) in accordance with the approved label in the Field in the Territory during the Term.

(c) Notwithstanding anything to the contrary hereunder, with respect to any MacroGenics Licensed Technology which MacroGenics Controls pursuant to the license granted to MacroGenics from Incyte under the Incyte Agreement, the foregoing sublicenses granted to Zai under Sections 9.1(a) and (b) shall be non-exclusive.

(d) **Sublicensees**. In no event shall Zai grant any sublicense to any of the rights granted to it pursuant to Section 9.1(a) without MacroGenics' prior written consent, not to be unreasonably withheld. Each sublicense granted by Zai shall be in writing and consistent with this Agreement and subject thereto, and Zai shall remain responsible to MacroGenics for the compliance of each such Sublicensee with the terms and conditions of this Agreement, including, with respect to the financial and other obligations due under this Agreement. Zai shall provide a complete copy of each such sublicense (and all amendments or restatements thereof) to MacroGenics so that MacroGenics can confirm Zai's compliance with the foregoing, with reasonable redactions solely to the extent (i) pertaining to technology and products that are not licensed under this Agreement other than (A) products that bind or affect a PD-1 receptor, (B) products that bind or affect a HER2 receptor, or (C) technology and products that related to the foregoing (A) or (B), and (ii) with respect to (i), not necessary to determine Zai's compliance with this Agreement. Each sublicense granted by Zai under this Agreement shall permit the conversion of such sublicense to a direct license with MacroGenics at MacroGenics' sole option (and discretion) in the event this Agreement is terminated and, upon such conversion, MacroGenics shall be responsible for all former obligations of Zai under such sublicense. Zai shall include in each such sublicense a requirement obligating such Sublicensee to cooperate with MacroGenics.

(e) **Regulatory Approvals**. MacroGenics or its designee shall own and hold all Regulatory Submissions, subject to the requirements of Section 6.2. Zai hereby assigns, transfers and conveys (and to the extent a present assignment is prohibited by Applicable Laws and Regulations, shall assign) to MacroGenics all of Zai's (and its Affiliates' and Sublicensees') right, title and interest in and to such Regulatory Submissions.

(f) **Limitations**. During the Term, Zai shall not (either by itself, or with or through a Related Party or Third Party) (i) Develop or Commercialize any Product, (ii) utilize any Clinical Data or (iii) practice the MacroGenics Licensed Technology, in each case ((i), (ii) and (iii)) outside of the scope of this Agreement.

(g) **MacroGenics Retained Rights**. MacroGenics shall retain the following: (i) the right to Manufacture or have Manufactured MGA012, the Licensed Compounds and Products in the Territory; (ii) all rights to conduct non-clinical Development in the Territory and clinical Development in

the Territory in connection with a Global Clinical Trial; and (iii) all rights not otherwise granted to Zai inside and outside the Territory. For clarity, notwithstanding the licenses granted to Zai pursuant to Section 9.1, no right or license is granted by MacroGenics to Zai under the MacroGenics Licensed Technology or MacroGenics Licensed Trademarks with respect to any compound or product covered by such MacroGenics Licensed Technology or MacroGenics Licensed Trademarks, including without limitation, any Other Component of a Combination Product, other than the Licensed Compounds and Products solely in accordance with Section 9.1(a) and use of MGA012 solely in accordance with Section 9.1(b).

9.2 **License to MacroGenics**. Zai hereby grants to MacroGenics a royalty-free (except as set forth below in this Section 9.2 and in Section 15.6 upon certain termination of this Agreement), worldwide, perpetual, irrevocable license, with the right to grant sublicenses (through multiple tiers), under the Zai Licensed Patents and Zai Licensed Know-how that is incorporated into any Product by Zai as part of its activities under this Agreement to develop, make, have made, use, sell, offer for sale and import Licensed Compounds, Products, Combination Regimens, MGA012 or products containing or incorporating MGA012 (whether as a monotherapy, multi-therapy, combination or otherwise), in all cases without any obligation to obtain Zai's prior consent. The license granted pursuant to this Section 9.2 shall be non-exclusive in the Territory solely to permit MacroGenics to conduct activities assigned to it under the Territory Specific Development Plan or Global Development Plan, exclusive (even as to Zai and its Affiliates) in the rest of the world outside the Territory and in the Territory with respect to MGA012 or products containing or incorporating MGA012 (whether as a monotherapy, multi-therapy, combination or otherwise). For clarity, the license granted to MacroGenics under this Section 9.2 shall (a) not include the right to any compound proprietary to Zai, its Affiliates or (Sub)licensees by reason of such compounds being included in a combination product or Combination Regimen with a Licensed Compound or MGA012, and (b) be subject to the Triggered Third Party Payments in the event any such Zai Licensed Patents and/or Zai Licensed Know-How are subject to an Other Third Party Agreement for which MacroGenics elects to obtain a sublicense under pursuant to Section 9.7. The license granted to MacroGenics under this Section 9.2 shall survive expiration or termination of this Agreement, subject to MacroGenics' continuing payment of any such Triggered Third Party Payments. In the event that both (x) the Agreement is terminated by Zai pursuant to Section 15.3 (but MacroGenics does not exercise its option in accordance with Section 15.6(a)(iii)(2)), and (y) prior to the effective date of such termination (as contemplated in the foregoing (x)), the Parties have enrolled in the Territory under the Territory Specific Activities or Territory Specific Plan greater than [***] of [***] and/or greater than [***], then MacroGenics agrees to pay to Zai, on a Country-by-Country and Region-by-Region basis in the Territory, a royalty at a rate of [***] of [***] during the Royalty Term, which royalty shall further be subject to Section 7.4 (in which case Net Sales, Royalty Term and Section 7.4 shall be applied mutatis mutandis, provided that, for clarity, subsection (b) of the defined Royalty Term shall be based on the Zai Licensed Patents and not the MacroGenics License Patents.

9.3 **Clinical Data Licenses**. Subject to the terms and conditions of this Agreement (particularly Section 9.1(g)(ii)), MacroGenics hereby grants to Zai an exclusive, royalty-free, license, with the right to grant sublicenses, during the Term to use all (a) Clinical Data and (b) other data Controlled by MacroGenics, in each case as necessary or reasonably useful for Zai to exercise its rights or fulfill its obligations under this Agreement solely with respect to the Development and Commercialization of Licensed Compounds and Products (including as part of the Combination Regimen) in the Field in the Territory hereunder. At Zai's request, MacroGenics shall provide a copy of the foregoing Clinical Data (not already in Zai's possession) on a schedule reasonably acceptable to Zai.

9.4 **Negative Covenant**. Each Party covenants that, except to the extent Third Parties generally are lawfully permitted to do so without a granted license from or other contractual right with the other Party, it shall not use or practice any of the other Party's intellectual property rights licensed to it under this Section 9 except for the purposes expressly permitted in the applicable license grant.

9.5 **No Implied Licenses**. Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

9.6 **Diversion**

(a) Each Party hereby covenants and agrees that it shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold Products, including via the Internet or mail order, to any Third Party, address or Internet Protocol address in the other Party's territory.

(b) If any of the Products are diverted into the other Party's territory (the "**Unauthorized Territory**") for use (excluding use by or on behalf of MacroGenics, its Affiliates and licensees for MacroGenics Territory Activities) or sale therein ("**Unauthorized Activity**"), the following shall apply: (i) if such Products were diverted by an identifiable customer, distributor, employee, consultant or agent of the source Party (each an "**Unauthorized Person**") then, upon the request of the other Party, the source Party shall not sell such Products to, or allow the sale of such Products by, such Unauthorized Person (including by requiring the discontinuation of sales of such Product or enforcement of contractual obligations against such Unauthorized Person) for the remaining Term and shall use Commercially Reasonable Efforts to buy back all such Products from such Unauthorized Person within [***] business days of such request from the other Party; or (ii) the source Party shall use Commercially Reasonable Efforts to investigate the location of such diverted Products and buy them back; but, if and to the extent that, the source Party elects not to, or is unable to, buy back the applicable diverted Products, then the other Party may, in its sole discretion, buy back the applicable diverted Products, and the source Party shall reimburse the other Party for all reasonable costs incurred by such other Party in connection with the buy-back or lost sales of any such diverted Products.

9.7 **Other Third Party Agreements**.

(a) If after the Effective Date, either Party enters into a license agreement in which it would Control (in the case of MacroGenics, other than under the MacroGenics Required Third Party Agreements) any Patents or Know-how licensed from a Third Party that would fall under the definitions of MacroGenics Licensed Patents or MacroGenics Licensed Know-how (in the case of MacroGenics), or Zai Licensed Patents or Zai Licensed Know-how (in the case of Zai), (each, an "**Other Third Party Agreement**"), then such Party (the "**In-License Party**") shall promptly notify the other Party in writing of the terms and conditions of such Other Third Party Agreement, including a description of such Patents or Know-how, any restrictions on use, obligations required to be undertaken by, or otherwise applicable to, any (sub)license and any Triggered Third Party Payment that would be payable if the other Party elects to obtain a sublicense under such Patents or Know-how.

(b) Unless the other Party agrees in writing to be responsible for, and subject to all of the applicable terms of the Other Third Party Agreement to the extent that would be applicable to the rights (sub)licensed hereunder to such Party (including to reimburse the In-License Party for all Triggered Third Party Payments), then MacroGenics Licensed Patents or MacroGenics Licensed Know-how (in the case of

MacroGenics as the In-License Party), or Zai Licensed Patents or Zai Licensed Know-how (in the case of Zai as the In-License Party) shall not include such Patents or Know-how in-licensed pursuant to such Other Third Party Agreement.

(c) **"Triggered Third Party Payment**" means, with respect to an Other Third Party Agreement for which a Party elects to obtain a sublicense under this Section 9.7, [***] of any payments that the In-License Party would be obligated to pay the Third Party licensor of such Other Third Party Agreement in connection with the grant of a sublicense to the other Party, including [***] payable by the In-License Party pursuant to such Other Third Party Agreement.

9.8 **Future MacroGenics Required Third Party Agreements**. Subject to any written contractual obligations with a Third Party, MacroGenics shall keep Zai apprised of any negotiations it undertakes after the Effective Date to enter into a MacroGenics Required Third Party Agreement which if executed, would require Zai to reimburse MacroGenics under Section 7.5(a) for payments made by MacroGenics under such MacroGenics Required Third Party Agreement, provide Zai the opportunity to comment on the terms and conditions being negotiated for such MacroGenics Required Third Party Agreement and shall consider any such comments provided by Zai in good faith. Within [***] days after the execution of such MacroGenics Required Third Party Agreement, MacroGenics shall provide a copy of such executed MacroGenics Required Third Party Agreement; provided that MacroGenics shall have the right to redact Confidential Information from such copy that is not relevant to Zai's obligation to reimburse MacroGenics according to Section 7.5(a) for costs incurred by MacroGenics under such MacroGenics Required Third Party Agreement.

10. CONFIDENTIALITY; PUBLICATION

10.1 Nondisclosure Obligation

(a) **Definition and Restrictions**. All Confidential Information disclosed by one Party to the other Party at any time, including before the Effective Date or after the expiration or termination of this Agreement, shall be maintained in confidence by the receiving Party and shall not be disclosed by the receiving Party to any Third Party or used by the receiving Party for any purpose except as set forth herein without the prior written consent of the disclosing Party, during the Term and for a period of [***] years thereafter; provided that, with respect to Confidential Information that is confidential information of a Third Party, including with regard to MGA012, to which a Party has an obligation of confidentiality or non-use under an agreement with such Third Party, including the Incyte Agreement, the confidentiality and non-use obligations in this Agreement shall (A) further include such additional confidentiality and non-use obligations as such Party is required to undertake with respect to such confidential information pursuant to such Third Party agreement, and (B) continue beyond such [***] year period for so long as such Party is required to maintain such confidential information as confidential pursuant to such Third Party agreement (including a MacroGenics Third Party Agreement), including the Incyte Agreement. The following shall not be deemed Confidential Information for purposes of the restrictions set forth in this Section 10.1(a):

(i) Information that is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

(ii) Information that is or becomes part of the public domain through no wrongful act or fault on the part of the receiving Party;

(iii) Information that is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; and

(iv) Information that is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.

(b) **Combinations**. Any combination of features or disclosures shall not be deemed to fall within the exclusions set forth in Section 10.1(a) merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

(c) **Permitted Disclosures**. Notwithstanding the restrictions set forth in Section 10.1(a), the receiving Party may disclose Confidential Information of the other Party to:

(i) governmental or other regulatory agencies in order to obtain Patents or to gain or maintain approval to conduct clinical trials or to market Products, but such disclosure may be only to the extent reasonably necessary to obtain Patents or authorizations; or

(ii) as the receiving Party deems necessary to be disclosed, to its Affiliates, agents, consultants, or other Third Parties for the Development, Manufacture (with respect to MacroGenics permitted disclosures, provided that this shall additionally apply to [***] with respect to its [***] solely in the event Zai exercises its option to [***] pursuant to Section 5.4(b)) or Commercialization of Product(s), or in connection with a licensing transaction or contractual obligation related to such Product(s) or loan, financing or investment or acquisition, merger, consolidation or similar transaction (or for such entities to determine their interest in performing such activities or to determine their rights and obligations as a result of completing such transactions) or in order to perform its obligations or exercise its rights under this Agreement, in each case on the condition that any Third Parties, other than Regulatory Authorities, to whom such disclosures are made agree to be bound by confidentiality and non-use obligations substantially similar to those contained in this Agreement; provided that the term of confidentiality and non-use applicable to such Third Parties shall be no less than [***] years (but of shorter duration if [***]; provided that with respect to any Confidential Information of MacroGenics hereunder that MacroGenics informed Zai in writing at or prior to the time of disclosure to Zai that such Confidential Information (either in itself or as a category of information) constitutes confidential information under the Incyte Agreement such shorter duration may not be less than [***] years) from the date of disclosure to them, provided further, that with respect to Confidential Information of a Party that constitutes (a) a trade secret, such confidentiality and non-use obligations shall apply for so long as such information constitutes a trade secret under Applicable Laws and Regulations, or (b) confidential information of a Third Party, such confidentiality and non-use obligations shall apply for so long as such Party is required to keep such information confidential under such Third Party agreement (including a MacroGenics Third Party Agreement), but only if such Party informs the other Party in writing of such additional obligations and identifies to the other Party at the time of disclosure the information subject to such additional obligations. Without limiting the foregoing or remainder of this Section 10.1, with respect to Confidential Information of MacroGenics disclosed to Zai

hereunder that at the time of disclosure to Zai, MacroGenics identifies such confidential information as a trade secret under the Incyte Agreement, prior to Zai disclosing such trade secret to a Third Party (to the extent permitted hereunder), Zai must expressly contractually bind the Third Party to obligations to keep the trade secret confidential to the extent protected as a trade secret under Applicable Laws and Regulations.

(d) **Disclosure Required by Judicial or Administrative Process.** If a Party is required by judicial or administrative process to disclose Confidential Information of the other Party that is subject to the non-disclosure provisions of this Section 10.1, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 10.1, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including obtaining an order of confidentiality, to ensure the continued confidential treatment of such Confidential Information, including, by using not less than the same level of efforts to secure such confidential treatment of such information as it would to protect its own Confidential Information of like nature from disclosure.

(e) **Obligations Upon Termination.** Upon the termination or expiration of this Agreement, or upon the earlier request of either Party, the receiving Party shall return to the disclosing Party, all of the disclosing Party's Confidential Information, including all copies thereof, provided that the receiving Party may retain one copy for archival purposes, and provided further, that a receiving Party shall not be required to destroy electronic files containing such Confidential Information of the disclosing Party that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information, and any such retained copies shall continue to be subject to the confidentiality and non-use obligations in accordance with this Agreement.

10.2 **Publication**

(a) **Publication of Results**. Zai and MacroGenics each acknowledge the other Party's interest in publishing the results of its activities under the Collaboration in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. The JSC shall establish procedures for review of publications related to the Collaboration, ensuring that, except for disclosures permitted pursuant to Section 10.1, either Party and its employees wishing to make a publication related to work performed under this Agreement shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least [***] days prior to submission for publication or for presentation. Publications related to Global Clinical Trials conducted by MacroGenics or its Affiliates or permitted licensees in which the majority of patients reside outside the Territory shall not be subject to this Section 10.2, provided that MacroGenics shall use commercially reasonable efforts to provide Zai with a copy of such proposed written publication prior to publication thereof for Zai's review (but not approval).

(b) **Review of Publications and Presentations**

(i) The reviewing Party shall have the right (a) to propose modifications to the publication or presentation for patent reasons, trade secret reasons, or for purposes of removing the

Confidential Information of the reviewing Party, or (b) to request a reasonable delay in publication or submission for presentation in order to protect trade secret or patentable information.

(ii) If the reviewing Party requests the removal of the reviewing Party's Confidential Information or a delay, the publishing Party shall remove such Confidential Information and if requested by the reviewing Party delay submission for publication or submission for presentation for a period of [***] days to enable patent applications protecting such Party's rights in such Confidential Information to be filed in accordance with Section 13 below.

(iii) Upon expiration of such [***] days and satisfaction of any other conditions imposed by the JSC, the publishing Party shall be free to proceed with the publication or submission for presentation.

(iv) Upon request of the Party seeking publication, the reviewing Party shall consider expediting the time frames set forth in this Section 10.2.

(v) If the reviewing Party requests modifications to the publication or submission for presentation, the publishing Party shall edit such publication to prevent disclosure of the Confidential Information of the reviewing Party.

10.3 **Publicity; Use of Names**

(a) **Press Releases**. The Parties shall issue the press release included in this Agreement as Exhibit F announcing the execution of this Agreement. A Party may issue any subsequent press release relating to this Agreement or activities conducted hereunder upon prior written approval of the other Party, such approval not to be unreasonably withheld or delayed; provided, however, that no approval of the other Party shall be required if a subsequent press release or securities filing solely discloses the information that (1) a milestone under this Agreement has been achieved or any payments associated therewith have been received; (2) the filing or approval of a BLA generally has occurred (provided, however, that specific dates of filing shall not be disclosed); (3) initiation of any clinical trial; and (4) commercial launch of a Product or any information that has previously been approved and disclosed as permitted by this Section 10.3(a). In the case of items (1) to (4) of the preceding sentence, the disclosing Party shall provide the other Party a copy of such proposed disclosures at least [***] business days prior to the proposed release and consider in good faith any comments the other Party may make, where practicable, and in light of any reporting obligations of such disclosing Party under Applicable Laws and Regulations, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any other governmental agency.

(b) **No Other Use of Company Names**. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter without the prior express written permission of the other Party.

(c) **Approved Press Releases**. In addition and notwithstanding anything to the contrary herein, (a) if the relevant text of a proposed press release has already previously been reviewed and approved for disclosure by the other Party then such text may be disclosed or republished in such proposed press release provided that the Party issuing such press release provides notice to the other Party of such press release at least [***] business days prior to the issuance of such press release, where

practicable, and (b) if the relevant text of a proposed public announcement such as a corporate presentation or comments to analysts or investors has already previously been reviewed and approved for disclosure by the other Party (whether in the form of an approved press release or prior approved presentation materials, Q&A script or the like) then such text may be included in such proposed public announcement (but not a press release) without resubmission and review by the other Party.

(d) **Existence of Agreement**

(i) **No Disclosure**. Neither Party shall disclose the existence or terms of this Agreement pursuant to a press release or otherwise except as provided in this Section 10.3(d).

(ii) **Permitted Disclosures**

(A) Notwithstanding the terms of this Section 9.7(c), either Party shall be permitted to disclose the existence and terms of this Agreement and the conduct of the Collaboration under this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with Applicable Laws and Regulations, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any other governmental agency. The disclosing Party shall take reasonable and lawful actions to avoid or minimize the degree of such disclosure.

(B) Either Party may also disclose the existence and terms of this Agreement to its attorneys, accountants and advisors, and to potential acquirors, in connection with a potential acquisition or other change of control transaction and to existing and potential investors or lenders of such Party, as a part of their due diligence investigations, or to potential licensees or to potential and current permitted assignees in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement and to use such confidential information solely for the purpose of the contemplated transaction.

(C) Each Party may also disclose the existence and terms of this Agreement pursuant to transactions related to the research, Development, Manufacture or Commercialization or exploitation of a Licensed Compound, MGA012 or any Product ("**Licensing Transactions**"), in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement and to use such confidential information solely for the purpose of the contemplated transaction. The transactions described in Section 10.3(d)(ii)(B) shall not be deemed Licensing Transactions for purposes of this Section 10.3(d)(ii)(C).

11. REPRESENTATIONS AND WARRANTIES

11.1 **Representations and Warranties of MacroGenics**. MacroGenics represents and warrants to Zai that, as of the Effective Date:

(a) it has the full right, power and authority to enter into this Agreement, to perform the Collaboration, and to grant the licenses contemplated under Section 9, and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any contractual obligation or court or administrative order by which MacroGenics is bound;

(b) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by MacroGenics as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;

(c) for purposes of Sections 1.86 and 1.87, no Affiliates of MacroGenics' exist as of the Effective Date.

(d) it Controls the right, title and interest in and to the MacroGenics Licensed Patents and MacroGenics Licensed Know-how, and has the right to grant to Zai the licenses under such MacroGenics Licensed Patents and MacroGenics Licensed Know-how that it purports to grant hereunder and has not granted any Third Party rights under such MacroGenics Licensed Patents and MacroGenics Licensed Know-how that would interfere or be inconsistent with Zai's rights hereunder;

(e) to its knowledge, except for those licensed or sublicensed under the MacroGenics Third Party Agreement, the MacroGenics Licensed Patents and MacroGenics Licensed Know-how are not subject to any other Third Party agreements or existing royalty or other payment obligations to any Third Party;

(f) to its knowledge, the issued Patents in the MacroGenics Licensed Patents are valid and enforceable;

(g) there are no action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing by any Third Party that challenges or threatens the validity or enforceability of any of the MacroGenics Licensed Patents. In the event that MacroGenics receives written notice of any such action or proceeding, it shall notify Zai in writing; and

(h) there are no action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing by any Third Party (and it is not aware of any grounds therefor) that alleges the use of the MacroGenics Licensed Patents or the development, manufacture, commercialization, and use of the Products would infringe intellectual property rights of any Third Party (and it has not received any notice alleging such an infringement). In the event that MacroGenics receives written notice of any such action or proceeding, it shall notify Zai in writing.

11.2 **Representations and Warranties of Zai**. Zai represents and warrants to MacroGenics that as of the Effective Date:

(a) it has the full right, power and authority to enter into this Agreement, to perform the Collaboration, to grant the licenses granted hereunder, and the fulfillment of its obligations and performance of its activities hereunder do not materially conflict with, violate, or breach or constitute a default under any contractual obligation or court or administrative order by which Zai is bound;

(b) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Zai as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained; and

(c) no Zai Licensed Patents or Zai Licensed Know-how exist as of the Effective Date that are or would be (i) necessary for the Development, Manufacture or Commercialization of or (ii)

incorporated into, in each case ((i) and (ii)) the Licensed Compounds or Products (including the Combination Regimen).

11.3 **Covenant**. Each Party hereby covenants to the other Party that it will not, and will not permit its Affiliates, (Sub)licensees or anyone acting on its or their behalf to, grant or otherwise convey to any Third Party any rights that would interfere or be inconsistent with such other Party's rights hereunder.

11.4 **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, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

12. INDEMNIFICATION

12.1 **By Zai**. Zai agrees to indemnify and hold harmless MacroGenics, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**MacroGenics 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**") first arising after the Effective Date to the extent arising from (a) activities by Zai or any of its Related Parties or Permitted Subcontractors with respect to the research, Development, use, Manufacture (in the event it becomes entitled to do so Section 5.4), Commercialization, import, distribution, or sale of Licensed Compounds or Products or any other exercise of their rights or performance of their obligations hereunder, (b) the use by Zai or any of its Related Parties or Permitted Subcontractors of the MacroGenics Licensed Patents or MacroGenics Licensed Know-how, (c) the [***] of Zai, or (d) Zai's breach of this Agreement, except to the extent such Losses arise out of any of MacroGenics Indemnitee's [***] of this Agreement.

12.2 **By MacroGenics**. MacroGenics agrees to 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) activities by MacroGenics or any of its Related Parties or Permitted Subcontractors with respect to the research, Development, use, Manufacture, Commercialization or sale of Products for the purpose of Commercialization or sale of Products by MacroGenics or its Related Parties (which for clarity, excludes Zai, its Affiliates and Sublicensees), (b) the [***] of MacroGenics, (c) the use by MacroGenics or any of its Related Parties or Permitted Subcontractors of the Zai Licensed Patents or Zai Licensed Know-how, or (d) MacroGenics' breach of this Agreement, except to the extent such Losses arise out of any of Zai Indemnitee's [***] of this Agreement.

12.3 **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 Section 12.

12.4 **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, provided such settlement would not subject the Indemnitee to an injunction or otherwise adversely impact any of the Indemnitee's rights under this Agreement or constitute an admission of guilt or wrongdoing by the Indemnitee, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld.

12.5 **Notice**. The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Section 12.1 or Section 12.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

12.6 **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. Provided, however, that such permission shall not be required if such settlement does not involve (a) any admission of legal wrongdoing by the other Party's Indemnitee(s), or (b) the imposition of any equitable relief against the other Party's Indemnitee(s).

12.7 **Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.7 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN SECTION 10.

13. INVENTIONS; PATENT PROVISIONS

13.1 Ownership of Intellectual Property

(a) Ownership of MacroGenics IP. As between MacroGenics and Zai, MacroGenics shall remain the sole and exclusive owner of all MacroGenics Licensed Patents, MacroGenics Licensed Trademarks and MacroGenics Licensed Know-how that exist as of the Effective Date.

(b) Ownership of Zai IP. As between Zai and MacroGenics, Zai shall remain the sole and exclusive owner of all Zai Licensed Patents and Zai Licensed Know-how that exists as of the Effective Date.

(c) Ownership of IP Generated under the Collaboration. MacroGenics shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting the Collaboration solely by MacroGenics, its Affiliates or its or its Affiliates' respective consultants or subcontractors, together with all intellectual property rights therein. Zai shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting the Collaboration solely by Zai or its Affiliates or its or its Affiliates' respective consultants or subcontractors, together with all intellectual property rights therein. MacroGenics and Zai shall jointly own

all data, results and inventions, whether patentable or not, conceived or reduced to practice jointly by MacroGenics (or its Affiliates or its or its Affiliates' respective consultants or subcontractors) on one hand and Zai (or its Affiliates or its or its Affiliates' respective consultants or subcontractors) on the other hand ("**Jointly Owned IP**"), together with all intellectual property rights therein, with each Party owning an undivided half interest and the right to exploit without the duty of accounting or seeking consent from the other Party to the extent to be permitted under Applicable Laws and Regulations.

13.2 **Patent and Trademark Filing, Prosecution and Maintenance**

(a) **Overall Strategy**. The JSC shall establish an overall strategy for the filing, prosecution and maintenance of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks, Jointly Owned Patents and Zai Licensed Patents in the Territory.

(b) **Prosecution**

(i) The responsibility for Patent Prosecution and Trademark Prosecution related to a Patent or Trademark that is within the MacroGenics Licensed Patents and MacroGenics Licensed Trademarks or the Zai Licensed Patents that is owned solely by a Party shall be the responsibility of such Party, except that (A) Zai shall have the right (but not the obligation), at its election and cost and expense, to file, prosecute and maintain, in the name of MacroGenics, MacroGenics Product-Specific Patents (but for clarity, excluding MacroGenics Platform Patents) and MacroGenics Licensed Trademarks in the Territory, (B) MacroGenics shall have the right (but not the obligation), at its election and cost and expense, to file, prosecute and maintain, in the name of Zai, Zai Licensed Patents that are specific to the Product (i.e., do not Cover any product that is not a Product, such Zai Licensed Patents, the "**Zai Product-Specific Patent**") (within the scope of the exclusive license granted by Zai to MacroGenics pursuant to Section 9.2) outside the Territory. In accordance with Section 13.2(b)(v) below, MacroGenics shall be responsible for undertaking the Patent Prosecution with respect to Patents jointly owned by the Parties (the "**Jointly Owned Patents**") outside the Territory and Zai shall be responsible for undertaking the Patent Prosecution with respect to Jointly Owned Patents in the Territory, and each shall do as directed by the JSC.

(ii) In the event that Zai elects not to undertake the Patent Prosecution for the MacroGenics Product-Specific Patents in the Territory, Zai shall notify MacroGenics at least [***] days before any such patent rights would become abandoned or otherwise forfeited, and MacroGenics shall have the right (but not the obligation), at its sole cost and expense, to undertake the Patent Prosecution of such MacroGenics Product-Specific Patents. Thereafter, any MacroGenics Product-Specific Patents that are the subject of such opt-out notice by Zai shall cease to be MacroGenics Licensed Patents for all purposes under this Agreement, including for purposes of the license granted by MacroGenics to Zai under Section 9.1. In the event that MacroGenics elects not to undertake the Patent Prosecution for the Zai Product-Specific Patents outside the Territory, MacroGenics shall notify Zai at least [***] days before any such patent rights would become abandoned or otherwise forfeited, and Zai shall have the right (but not the obligation), [***], to undertake the Patent Prosecution of such Zai Product-Specific Patents outside the Territory. With respect to Jointly Owned Patents, in the event that the prosecuting Party elects not to undertake the Patent Prosecution for the Jointly Owned Patents in the Territory (with respect to Zai) or outside the Territory (with respect to MacroGenics), the prosecuting Party shall notify the non-prosecuting Party at least [***]days before any such patent rights would become abandoned or otherwise forfeited, and the previously non-prosecuting Party shall have the right (but not the obligation), to undertake the Patent Prosecution of such Jointly Owned Patents in such territory and become the

prosecuting Party therefor. The right to assume Patent Prosecution of a MacroGenics Product-Specific Patent, Zai Product-Specific Patent or Jointly Owned Patent shall not apply in the event such a patent application would become abandoned or otherwise forfeited as a result of the prosecuting Party (x) discontinuing Patent Prosecution of such patent application but also filing a continuation application claiming the same invention or (y) settling an opposition to obtain a license to a competing patent.

(iii) The prosecuting Party shall keep the JSC and the other Party informed of the status of all matters affecting Patent Prosecution and Trademark Prosecution of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks and Jointly Owned Patents in the Territory, and the Zai Product-Specific Patents outside the Territory, including providing a copy of all patent applications filed hereunder and any material correspondence from or with any governmental authorities (including the applicable patent office) to the JSC and the other Party in sufficient time to allow for review and comment by the non-prosecuting Party, and timely consulting with the non-prosecuting Party and its patent counsel on the strategy and content of submissions to such governmental authorities in advance of any submissions. Timely advice and suggestions of the non-prosecuting Party and its patent counsel shall be taken into consideration in good faith by the prosecuting Party and its patent counsel in connection with such filing. With respect to the MacroGenics Product-Specific Patents, Zai (if the prosecuting Party) shall pursue in good faith all reasonable claims requested by MacroGenics for the Territory.

(iv) Any dispute regarding Patent Prosecution and Trademark Prosecution of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks, Zai Product-Specific Patent (outside the Territory only) or Jointly Owned Patents that cannot be resolved by intellectual property counsel of the Parties, shall be resolved by the JSC.

(v) Without limiting the generality of the foregoing, MacroGenics shall prosecute and maintain Jointly Owned Patents outside the Territory and Zai shall prosecute and maintain Joint Owned Patents in the Territory, and each prosecuting Party shall instruct its counsel to provide copies of correspondence and filings directly to the other Party and otherwise permit the other Party to participate with the prosecuting Party in any of the activities of such counsel with respect to the Patent and Trademark Prosecution of such Jointly Owned Patents. Before taking any material step in the Patent Prosecution or Jointly Owned Patents, the prosecuting Party and its counsel shall allow the other Party a reasonable opportunity to comment on the action proposed to be taken, and agrees to incorporate in such filings all reasonable comments of the other Party. All Patent Prosecution of Jointly Owned Patents shall be in the names of both MacroGenics and Zai.

(vi) Zai's rights and obligations under this Section 13.2 with respect to MarcoGenics Licensed Patents are secondary to and shall be subject to any Third Party rights and obligations under the applicable MacroGenics Third Party Agreements.

(c) **Patent and Trademark Invalidations**. The JSC shall decide whether and how to undertake activities intended to invalidate pending or issued Third Party Patents in the Territory that cover the composition, use or manufacture of Licensed Compounds or Products.

13.3 **Costs of Patent and Trademark Prosecution**

(a) **Costs.** All out-of-pocket costs for Patent Prosecution and Trademark Prosecution of a Party's solely owned Patent or Trademark and for maintaining a Party's solely

owned Patent or Trademark shall be [***], except that [***] of all out-of-pocket costs for Patent Prosecution of the MacroGenics Platform Patents in the Territory shall be borne by [***] and [***] borne by [***]. All out-of-pocket costs for Patent Prosecution of Jointly Owned Patents and for maintaining Jointly Owned Patents in the Territory shall be [***]. In the event Zai assumes the responsibility to conduct the Patent Prosecution of MacroGenics Product-Specific Patents and MacroGenics Licensed Trademarks in the Territory under Section 13.2(b)(i)(A), the costs of such activities conducted by or on behalf of Zai shall be borne [***]. In the event MacroGenics assumes the responsibility to conduct the Patent Prosecution of the Zai Product-Specific Patents outside the Territory under Section 13.2(b)(i)(B), the costs of such activities conducted by or on behalf of MacroGenics shall be borne [***].

13.4 **Patent and Trademark Prosecution Cooperation**. With respect to all Patent Prosecution and Trademark Prosecution related to pending or issued Patents and Trademarks included in MacroGenics Licensed Patents in the Territory, MacroGenics Licensed Trademarks in the Territory or Zai Product-Specific Patents outside the Territory, each Party shall:

(a) execute all further 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 and Trademark Prosecution responsibilities;

(c) cooperate, if necessary and appropriate, with the other Party in gaining Patent and Trademark term extensions; and

(d) endeavor in good faith to coordinate its efforts under this Agreement with the other Party to minimize or avoid interference with the Patent Prosecution and Trademark Prosecution of the other Party's Patents and Trademarks.

13.5 **Enforcement**

(a) **Notice**. Each Party shall promptly provide, but in no event later than [***] days, the other with written notice reasonably detailing any known or alleged infringement in the Territory (or with respect to Zai Licensed Patents or Jointly Owned Patents, inside the Territory or outside the Territory) of any Patent or Trademark owned by the other Party and subject to a license under this Agreement. The notifying Party will provide the other Party with all evidence available to it supporting its belief of such infringement.

(b) **Enforcement of Intellectual Property Rights**

(i) Except as expressly set forth in this Section 13.5, the sole owner (as between the Parties) of a Patent, Trademark, Know-how or Confidential Information shall have the exclusive right to institute and direct legal proceedings against any Third Party believed to be infringing

such Patent or Trademark or misappropriating or otherwise violating such Know-how or Confidential Information.

(ii) Zai shall have the initial right (but not the obligation) to institute and direct legal proceedings in the Territory against any Third Party believed to be infringing in the Territory MacroGenics Product-Specific Patents and Product-specific claims within other MacroGenics Licensed Patents (in each case within the scope of the exclusive license granted by MacroGenics to Zai under this Agreement) or Jointly Owned Product Patents, in each case that Covers a Product (excluding MGA012) sold within the Territory. Zai agrees to discuss the foregoing in good faith with MacroGenics. If Zai (x) does not initiate any action against such violation of such MacroGenics Product-Specific Patents, Product-specific claims within other MacroGenics Licensed Patents or Jointly Owned Product Patents solely with respect to Products (excluding MGA012) in the Territory, including by commencement of a lawsuit against the accused person if necessary or obtain settlement thereof (in accordance with this Agreement), within [***] months after receiving notice of such infringement of such MacroGenics Licensed Patents, Product-specific claims within other MacroGenics Licensed Patents or Jointly Owned Product Patents, or (y) if such action is initiated within such period, ceases to pursue or withdraws from such action, then in each case ((x) and (y)) MacroGenics shall be entitled (but shall not be obligated) to take all actions reasonably necessary to abate such violation in the Territory, including commencement of a lawsuit against the accused Third Party if necessary.

(iii) [***] shall have the first right (but not the obligation) to institute and direct legal proceedings against any Third Party believed to be infringing Zai Product-Specific Patents and Product-specific claims within other Zai Licensed Patents (within the scope of the exclusive license granted by Zai to MacroGenics under this Agreement) outside the Territory or Other Jointly Owned Patents outside the Territory. [***] agrees to discuss the foregoing in good faith with [***]. If [***] (x) does not initiate any action against such violation of the Zai Product-Specific Patents or Product-specific claims within other Zai Licensed Patents outside the Territory or Other Jointly Owned Patents outside the Territory, as applicable, including by commencement of a lawsuit against the accused person if necessary or obtain settlement thereof (in accordance with this Agreement), within [***] months after receiving notice of such infringement of such Zai Product-Specific Patents or Product-specific claims within other Zai Licensed Patents or Other Jointly Owned Patents, or (y) if such action is initiated within such period, ceases to pursue or withdraws from such action, then in each case ((x) and (y)) [***] shall be entitled (but shall not be obligated) to take all actions reasonably necessary to abate such violation outside the Territory with respect to the Zai Product-Specific Patents or Product-specific claims within other Zai Licensed Patents or outside the Territory with respect to the Other Jointly Owned Patents, including commencement of a lawsuit against the accused Third Party if necessary.

(iv) All amounts recovered from enforcement of any such rights by either Party in the Territory (or with respect to Zai Product-Specific Patents or Product-specific claims within other Zai Licensed Patents outside the Territory or Jointly Owned Patents in the Territory or outside the Territory) relating to the intellectual property licensed under this Agreement shall be first used to reimburse each Party's costs and expenses incurred in connection with such action, and any remainder of such recovery, other than amounts recovered as lost profits, shall be retained by (i) Zai if Zai is the Party instituting the action, provided that any remainder retained by Zai shall be treated as Net Sales and shall be subject to Zai 's royalty payment obligations at the applicable rate specified in Section 7.3; (ii) shared between MacroGenics and Zai [***] if MacroGenics is the Party instituting the action during the Term in the Territory where MacroGenics has the first right to enforce, or retained by MacroGenics if MacroGenics is

the Party instituting the action during the Term in the Territory where MacroGenics exercised its backup right to enforce; and (iii) MacroGenics if MacroGenics is the Party instituting the action with respect to a Zai Product-Specific Patent or Product-specific claims within other Zai Licensed Patents (A) during the Term or (B) after the Term and has exercised its option under Section 15.6(a)(iii)(2) or Zai terminates this Agreement for MacroGenics' breach under Section 15.2, provided that any remainder retained by MacroGenics shall be treated in the same as Net Sales were treated during the Term and shall be subject to MacroGenics royalty payment obligations or Third Party Triggered Payments, to the extent applicable, at the applicable rate specified in Section 15.6(a)(iii)(2) or 15.6(b)(ii).

(c) **Cooperation in Enforcement Proceedings**. For any action by a Party pursuant to subsection (b) above, in the event that such Party is unable to initiate or prosecute such action solely in its own name, the other Party shall join such action voluntarily and shall execute all documents necessary for such Party to initiate, prosecute and maintain such action. If either Zai or MacroGenics initiates an enforcement action pursuant to Section 13.5(b), then the other Party shall cooperate to the extent reasonably necessary and at the first Party's sole expense (except for the expenses of the non-controlling Party's counsel, if any). Upon the reasonable request of the Party instituting any such action, such other Party shall join the suit and can be represented in any such legal proceedings using counsel of its own choice. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof.

(d) **Status; Settlement**. The Parties shall keep each other informed of the status of and of their respective activities regarding any enforcement action pursuant to Section 13.5(b). Neither Party shall settle any litigation or legal proceeding in the Territory to enforce MacroGenics Licensed Patents against a Third Party selling a Product that binds to or otherwise affects the HER2/Neu receptor (with respect to a Margetuximab Product), or [***] (with respect to a [***] Trident Product) or MacroGenics Licensed Trademarks without the other Party's written authorization. Zai will not enter into any settlement of any action described in this Section 13.5 that admits to the invalidity, unpatentability, narrowing of scope or unenforceability of the MacroGenics Licensed Patents or the Jointly Owned Patents in any manner, incurs any financial liability on the part of MacroGenics or requires an admission of liability, wrongdoing or fault on the part of MacroGenics, in each case without MacroGenics' prior written consent. MacroGenics will not enter into any settlement of any action described in this Section 13.5 that admits to the invalidity, unpatentability, narrowing of scope or unenforceability of the Zai Licensed Patents or the Jointly Owned Patents in any manner, incurs any financial liability on the part of Zai or requires an admission of liability, wrongdoing or fault on the part of Zai, in each case without Zai's prior written consent.

13.6 **Defense**

(a) **Notice of Allegations**. Each Party shall notify the other in writing of any allegations it receives from a Third Party that the manufacture, production, use, development, sale, offer for sale, import or distribution of any Product or practice of any MacroGenics Licensed Technology or Zai Licensed Patents or Zai Licensed Know-how licensed by a Party under this Agreement or Jointly Owned Patents infringes the intellectual property rights of such Third Party in the Territory or with respect to the Zai Licensed Patents, Zai Licensed Know-how or Jointly Owned Patents outside the Territory. Such notice shall be provided promptly, but in no event after more than [***] Business Days, following receipt of such allegations.

(b) **Notice of Suit**. In the event that a Party receives notice that it or any of its Affiliates have been individually or collectively named as a defendant (or defendants) in a legal proceeding by a Third Party alleging infringement of a Third Party's Patents issued (i) in the Territory as a result of the manufacture, production, use, development, sale, offer for sale, import or distribution of Products or any MacroGenics Licensed Technology or Zai Licensed Patents or Zai Licensed Know-how licensed by a Party under this Agreement or Jointly Owned Patents, or (ii) outside the Territory as a result of the practice of any Zai Licensed Patents, Zai Licensed Know-how or Jointly Owned Patents, such Party shall immediately notify the other Party in writing and in no event notify such other Party later than [***] Business Days after the receipt of such notice. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof. In such event, the Parties shall agree how best to mitigate or control the defense of any such legal proceeding; provided however, that if either Party or any of its Affiliates have been individually named as a defendant in a legal proceeding relating to the alleged infringement of a Third Party's issued Patents in the Territory as a result of the manufacture, production, use, development, sale or distribution of Products, the other Party shall be allowed to join in such action, at its own expense.

(c) **Status; Settlement**. The Parties shall keep each other informed of the status of and of their respective activities regarding any litigation or settlement thereof initiated by a Third Party as contemplated under Section 13.6(a) or Section 13.6(b); provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this Section 13.6(c) may be undertaken by a Party without the consent of the other Party which consent shall not be unreasonably withheld, conditioned or delayed.

14. DISPUTE RESOLUTION

14.1 **Exclusive Dispute Resolution Mechanism**. The Parties agree that the procedures set forth in this Section 14 shall be the exclusive mechanism for resolving any Dispute between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder that is not resolved through good faith negotiation between the Parties. For the avoidance of doubt, this Section 14 shall not apply to any decision with respect to which a Party has final decision-making authority hereunder. Any Dispute, including Disputes that may involve the parent company, subsidiaries, or Affiliates under common control of any Party, shall be resolved in accordance with this Section 14.

14.2 **Resolution by Executive Officers**. Except as otherwise provided in this Section 14, in the event of any Dispute regarding the construction or interpretation of this Agreement or the rights, duties or liabilities of either Party hereunder, the Parties shall 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 such basis within [***] Business Days (unless otherwise agreed by the Parties) after being submitted to the JSC, either Party may, by written notice to the other Party, refer the Dispute to the Executive Officer of each Party for attempted resolution by good faith negotiation within [***] Business Days after such notice is received (unless otherwise agreed by the Parties). Each Party may, in its discretion, seek resolution of any and all Disputes that are not resolved under this Section 14.2 in accordance with Section 14.3.

14.3 **Arbitration**. If the Parties fail to resolve the Dispute pursuant to Section 14.2, and a Party desires to pursue resolution of the Dispute, the Dispute shall be referred to and finally resolved by arbitration administered by the Singapore International Arbitration Centre ("**SIAC**") in accordance with the Arbitration Rules of the Singapore International Arbitration Centre ("**SIAC Rules**") for the time being in force, which rules are deemed incorporated by reference in this clause. The seat of the arbitration shall be in Singapore, and the arbitration tribunal shall consist of three arbitrators, of whom each Party shall designate one in accordance with the appointment procedures provided in the SIAC Rules and the chairs shall be selected by the tribunal in accordance the SIAC Rules. The language of the arbitration shall be English.

14.4 **Costs of Dispute Resolution**. Each Party shall be solely responsible for the costs it incurs to resolve a Dispute except for the costs of engaging arbitrators which shall be [***].

15. TERMS AND TERMINATION

15.1 **Term.** Unless earlier terminated, this Agreement shall continue in effect until the expiration of the Royalty Term ("**Term**"), and thereafter Zai has no remaining payment obligations with respect to the Products pursuant to Section 7.3 above and MacroGenics shall have no further obligations hereunder.

15.2 **Termination for Cause**. This Agreement may be terminated as a whole, or in part with respect to [***] Trident Products or Margetuximab Products or Combination Regimens only, at any time during the Term upon written notice by either Party if the other Party is in material breach of its material obligations under this Agreement and, in each case, has not cured such breach within [***] days after notice requesting cure of the breach (other than for non-payment which shall be cured within [***] days). Notwithstanding the foregoing, in the event there is a good faith dispute as to whether such termination is appropriate, the termination shall not become effective unless and until such dispute is resolved in favor of the Party seeking such breach.

15.3 **Termination for Convenience**. At any time after the second (2nd) anniversary of the Effective Date, Zai may terminate this Agreement in its entirety for any or no reason upon [***] days' written notice to MacroGenics.

15.4 **Termination for Safety and End of Global Development.** MacroGenics may terminate this Agreement in its entirety or on a Product-by-Product or Region-by-Region basis upon [***] days' written notice if a Major Safety Issue has occurred with respect to a Product before First Commercial Sale of the Product in the Territory and MacroGenics, its Affiliates and other licensees have all discontinued the global Development, Manufacturing and Commercialization activities with respect to such Product and announced such discontinuation through a press release or other public announcement.

15.5 **Termination for Force Majeure**. This Agreement may be terminated at any time during the Term upon written notice by either Party in accordance with Section 16.1.

15.6 **Effect of Termination.**

(a) If MacroGenics terminates this Agreement pursuant to Section 15.2 for cause based on material breach by Zai, Section 15.4 or Section 15.5, or if Zai terminates this Agreement pursuant to Section 15.3 or 15.5:

(i) Zai shall pay any amounts due pursuant to Section 3.6 and Section 7 prior to the date of termination;

(ii) For the avoidance of doubt, the licenses and sublicenses granted to Zai under Sections 9.1(a) and 9.3 shall terminate;

(iii) The following shall apply:

(1) The license granted to MacroGenics under Section 9.2 shall survive;

(2) Zai hereby grants MacroGenics the exclusive option to convert the non-exclusive license granted to MacroGenics under Section 9.2 to an exclusive license and to expand such license to include the Territory by providing written notice to Zai of such election within [***] days of the effective date of termination of this Agreement. In the event that MacroGenics exercises its option hereunder within such [***] day period, then the non-exclusive license granted to MacroGenics by Zai pursuant to Section 9.2 shall automatically (without any further action required on the part of either Party) convert to an exclusive license and the license shall automatically encompass the Territory as of the effective date of such notice, and thereafter, MacroGenics agrees to pay to Zai, on a Country-by-Country and Region-by-Region basis in the Territory, a royalty at a rate of either (a) [***], if [***], or (b) [***], if [***] as contemplated by Section 9.2(b), in each case ((a) or (b)) of MacroGenics' Net Sales of Licensed Compounds and Products in the Territory during the Royalty Term, which royalty shall further be subject to Section 7.4 (in which case Net Sales, Royalty Term and Section 7.4 shall be applied mutatis mutandis, provided that, for clarity, that subsection (b) of the defined Royalty Term shall be based on the Zai Licensed Patents (for which MacroGenics maintains the exclusive license from Zai) and not the MacroGenics Licensed Patents); provided that in the event of a termination of this Agreement by Zai pursuant to Section 15.3, the foregoing royalty shall be in lieu of (and not in addition to) the royalty contemplated by Section 9.2.

(iv) Zai shall return to MacroGenics or its designee all Products (including all Licensed Compounds) and all MGA012 within its possession or control and arrange for the Zai Sublicensees to return to MacroGenics or its designee all Products (including all Licensed Compounds) and MGA012 within such Zai Sublicensees' possession or control;

(v) Zai shall cease to Develop and Commercialize all Licensed Compounds and Products (including all Combination Regimen and Combination Products), including immediately stopping enrollment of subjects (unless otherwise directed in writing by MacroGenics) into any Clinical Trial being conducted by the Parties and at MacroGenics' sole election either wind-down (including to cease administering Licensed Compounds or Products to Clinical Trial subjects and conducting Clinical Trial procedures on Clinical Trial subjects, to the extent medically advisable) or transition to MacroGenics

(or its designee) any Clinical Trial then be conducted by Zai, but in all cases in a timely manner and in accordance with all Applicable Laws and Regulations;

(vi) Zai shall cease all marketing and promotion of MGA012 as a component of a Combination Regimen, including as part of a Combination Product.

(vii) for the Products (including Licensed Compounds), Zai shall assign and promptly transfer to MacroGenics, [***], all of Zai's right, title and interest, if any, in and to (A) all Regulatory Submissions (such as Regulatory Approvals, INDs, BLAs, NDAs, and drug master files) and clinical trial agreements (to the extent assignable and not cancelled) for such Products(s), to the extent that MacroGenics elects to continue development of such Product(s); (B) all data, including clinical data, materials and information of any kind or nature whatsoever, in Zai 's possession or in the possession of its Affiliates or its or their respective agents related to such Product(s); (C) all trademarks related to such Products (if such termination occurs after approval of such trademark by a Regulatory Authority); and (D) all material information, and any other information reasonably requested and required by MacroGenics, relating to the manufacture of such Products;

(viii) all sublicenses under the rights granted pursuant to Section 9.1(b) shall terminate, unless converted to a direct license under Section 9.1(b) subject to terms and conditions to be agreed between MacroGenics and such sublicensee; and

(ix) MacroGenics shall revoke (and Zai shall allow revocation of) any powers of attorney for any MacroGenics Licensed Patents that Zai holds as of the time of such termination; and

(b) If Zai terminates this Agreement pursuant to Sections 15.2 for cause based on material breach by MacroGenics, the following shall apply; provided that MacroGenics' failure to supply Product or MGA012 to Zai (other than due to MacroGenics' gross negligence or willful misconduct) shall not constitute a material breach by MacroGenics:

(i) Section 15.6 (a) clauses (i), (ii), (v), (vi), (viii) and (ix) shall apply, clause (iv) shall apply subject to MacroGenics' payment to Zai for the Fully Burdened Manufacturing Costs for the Products transferred to MacroGenics thereunder, and clause (vii) shall apply subject to MacroGenics' payment to Zai in a commercially reasonable form and amount to be agreed by the Parties at the time of such termination as consideration for Regulatory Submissions, clinical trial agreements, data, materials, information and trademarks generated by or on behalf of Zai or its Affiliates or sublicensees under this Agreement and related to Products;

(ii) the license granted to MacroGenics under Section 9.2 shall survive (subject to MacroGenics' continuing payment of any Triggered Third Party Payments to Zai) and thereafter, MacroGenics agrees to pay to Zai, on a country-by-country basis outside the Territory, a royalty at a rate of [***], which royalty shall further be subject to Section 7.4 (in which case Net Sales, Royalty Term and Section 7.4 shall be applied mutatis mutandis, provided that, for clarity, that subsection (b) of the defined Royalty Term shall be based on the Zai Licensed Patents (for which MacroGenics maintains the exclusive license from Zai) and not the MacroGenics Licensed Patents).

15.7 **Survival**. The following provisions shall survive the termination or expiration of this Agreement for any reason: Sections 1, 3.8, 4.4(f), 4.4(g), 7.3, 7.8, 7.9, 7.10, 8, 9.2, 10.1, 10.3, 11.4, 12, 13.1, 14, 15.6, 15.7, 16. In addition, the other applicable provisions of Section 7 shall survive such expiration or termination of this Agreement in its entirety to the extent required to make final reimbursements, reconciliations or other payments incurred or accrued prior to the date of termination or expiration.

16. MISCELLANEOUS

16.1 **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 acts, omissions or delays in acting by any governmental authority or the other Party ("**Force Majeure**"). 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. In the event a Party is unable to perform its obligations under this Agreement due to Force Majeure for a period of [***] days, the other Party shall have the option of unilaterally terminating this Agreement upon providing [***] days written notice.

16.2 **Section 365(n) of the Bankruptcy Code**. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. The Parties agree that a Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against the licensing Party (such Party, the "**Involved Party**") under the U.S. Bankruptcy Code, the other Party (such Party, the "**Noninvolved Party**") shall be entitled to a complete duplicate of or complete access to (as such Noninvolved Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, provided the Noninvolved Party continues to fulfill its payment or royalty obligations as specified herein in full. Such intellectual property and all embodiments thereof shall be promptly delivered to the Noninvolved Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by the Noninvolved Party, unless the Involved Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Involved Party upon written request therefor by Noninvolved Party. The foregoing is without prejudice to any rights the Noninvolved Party may have arising under the U.S. Bankruptcy Code or other Applicable Laws and Regulations.

16.3 **Assignment**. Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, provided that each Party may assign its rights and obligations under this Agreement, without such consent from the other Party, to its Affiliate or any successor in interest in connection with the sale of all or substantially all of its assets or a sale of all or substantially of the business related to a Licensed Compound or a Product, or a merger, acquisition or other similar transactions. For the avoidance of doubt, the terms and conditions of this Agreement shall be binding on the permitted successors and assignees of each Party.

16.4 **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.

16.5 **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 MacroGenics, to:	9704 Medical Center Drive Rockville, MD 20850 [***]
with copy to: (which shall not constitute notice)	Goodwin Procter LLP Exchange Place 100 Northern Ave. Boston, MA 02210 [***]
if to Zai, to:	4560 Jinke Rd, Bldg. 1, 4/F Pudong, Shanghai, China, 201210 [***]

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 upon receipt.

16.6 **Applicable Law**. All questions of inventorship shall be determined in accordance with U.S. patent laws. In respect to all other Patent issues related to the enforceability or validity of a Patent, the laws of the jurisdiction in which the applicable Patent is filed or granted shall govern. Except as otherwise indicated, in all other respects, the right and obligations of the Parties under this Agreement shall be governed by and construed in accordance with the laws of [***].

16.7 **Entire Agreement; Amendments.** The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof, including the Collaboration and licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof, including the Collaboration and the licenses granted hereunder, are superseded by the terms of this Agreement, including the Existing CDA. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties

hereto. The "**Existing CDA**" means that certain Mutual Confidentiality Agreement between the Parties effective as of [***]. Any confidential information disclosed by the Parties pursuant to the Existing CDA shall be deemed to constitute Confidential Information under this Agreement.

16.8 **Headings.** The captions to the several Sections hereof are not a part of the Agreement, but are merely for convenience to assist in locating and reading the several Sections and Sections of this Agreement.

16.9 **Independent Contractors**. It is expressly agreed that MacroGenics and Zai shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MacroGenics 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.

16.10 **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.

16.11 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

16.12 **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.

16.13 **Counterparts**. The 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.

16.14 **Further Assurances**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

16.15 **Construction**. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". References to "Section" or "Sections" are references to the numbered sections of this Agreement, unless expressly stated otherwise. All dollars are United States Dollars. Unless the context otherwise requires, countries shall include territories. References to any specific law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement law thereto.

The Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Zai Lab (Shanghai) Co., Ltd.		**MacroGenics, Inc.**	
By:	/s/Tao Fu	By:	/s/Scott Koenig
Name:	Tao Fu	Name:	Scott Koenig
Title:	President	Title:	CEO

Chop/Corporate Seal:

Exhibit A

Application No.	Publication No.	Patent No.	Filing Date	Title
[***]	[***]	[***]	[***]	[***]

Country	Application No.	Publication No.	Patent No.
[***]	[***]	[***]	[***]

Exhibit B

MacroGenics Licensed Trademarks

[***]

Exhibit C

Global Development Plan and Territory Specific Development Plan

[***]

Exhibit D

SAFETY MANAGEMENT PLAN COMPONENTS

[***]

Exhibit E

Product Royalty Rates

Applicable Product	**Aggregate Net Sales threshold of the applicable Products in the Territory:**	**Then the Product Royalty Rate Percentage shall be (%):**
Margetuximab Products	On that portion of aggregate Net Sales in a Calendar Year less than [***]	[***]
	On the portion of Net Sales in a Calendar Year equal to or greater than [***] but less than [***]	[***]
	On that portion of Net Sales in a Calendar Year greater than [***]	20
MGD013 Products	All	[***]
[***] Trident Products	All	[***]

[***]

Exhibit F

Press Release

MacroGenics and Zai Lab Announce Exclusive Collaboration and License Agreement to Develop and Commercialize Margetuximab, MGD013 and TRIDENT™ Molecule in Greater China

- **Comprehensive collaboration across three MacroGenics' pipeline programs to accelerate and expand ongoing development**
- **Expand Zai Lab's late-stage clinical pipeline with margetuximab and obtain rights to first-in-class dual checkpoint inhibitor, MGD013**
- **Jointly conduct global studies across multiple indications, including HER2 positive gastric cancer with margetuximab**
- **MacroGenics to receive $25 million upfront cash payment and potential future milestones and royalties**

ROCKVILLE, MD, and SHANGHAI, China, Nov. 29, 2018 (GLOBE NEWSWIRE) – MacroGenics (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, and Zai Lab Limited (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, announced today that the companies have entered into an exclusive collaboration and license agreement involving three immuno-oncology (I-O) programs from MacroGenics' pipeline of product candidates:

- Margetuximab, an immune-optimized anti-HER2 monoclonal antibody currently being evaluated in Phase 3 metastatic breast cancer with anticipated topline results in the first quarter of 2019.
- MGD013, a first-in-class bispecific DART® molecule designed to provide coordinate blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies.
- An undisclosed multi-specific TRIDENT™ molecule in preclinical development.

Zai Lab obtains regional development and commercialization rights for these programs in mainland China, Hong Kong, Macau and Taiwan. Zai Lab 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, Zai Lab 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.

"We believe Zai Lab is an ideal partner to enable us to expand MacroGenics' global efforts to address patient populations with high unmet medical needs such as gastric cancer," said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. "Zai has a strong

track record of rapidly progressing the development of innovative product candidates in China and is well on its way to building its commercial platform. Zai is strongly positioned to take advantage of a growing pharmaceutical market in this region."

Dr. Samantha Du, Chief Executive Officer of Zai Lab said, "MacroGenics is a leader in the immuno-oncology field and we are thrilled to enter into this comprehensive strategic collaboration for a broad set of innovative assets. We believe we can build off the promising, previously reported results from MacroGenics' clinical studies of margetuximab in HER2-positive breast and gastric cancer, which are highly synergistic operationally with our other existing pipeline programs. We also look forward to working with MacroGenics in advancing MGD013, an exciting first-in-class I-O program that will help distinguish our pipeline and create combination opportunities with our other oncology assets. We believe this collaboration significantly increases the value of our oncology portfolio and is another step in establishing Zai as a leader in the field of innovative cancer treatments."

Under the terms of the agreement, MacroGenics will receive an upfront cash payment of $25 million and will be eligible to receive up to $140 million in potential development and regulatory-based milestone payments. In addition, Zai Lab would pay MacroGenics double-digit royalties on annual net sales of the assets, which may be subject to adjustment in specified circumstances.

Zai Lab to Host Webcast and Conference Call

Zai Lab will host a webcast and conference call to discuss the collaboration and license agreement on Thursday, November 29th, at 8:30 a.m. ET.

Zai Lab Investor Conference Call Details
Date: Thursday, November 29, 2018
Time: 8:30 a.m. EDT
Dial-In Details: 1-866-394-4355 (US); 1-314-888-4344 (International); 4006828609 (China)
Conference ID: 5874458

A live webcast and replay will be available on the Investor section of Zai Lab's website at http://ir.zailaboratory.com. A slide presentation will accompany the webcast and will also be available on Zai Lab's website.

About MacroGenics' Margetuximab Program

Margetuximab is an Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2, oncoprotein. HER2 is expressed by tumor cells in breast, gastric, and other solid tumor cancers, making it a key marker for biologic therapy. MacroGenics has completed enrollment of its pivotal Phase 3 SOPHIA study, which is evaluating the treatment of relapsed/refractory HER2-positive metastatic breast cancer patients. MacroGenics anticipates disclosure of topline PFS results from this trial in the first quarter of 2019. In addition to being studied in metastatic breast cancer, margetuximab is also being studied in combination with an anti-PD-1 agent in a Phase 2 clinical trial in gastric cancer, for which data was recently presented at the 2018 European Society of Medical Oncology (ESMO) Congress.

About MacroGenics' MGD013 Program

MGD013 is a first-in-class bispecific DART molecule designed to provide coordinate blockade of two immune checkpoint molecules expressed on T cells, PD-1 and LAG-3, for the potential treatment of a range of solid tumors and hematological malignancies. MacroGenics recently established the dose and schedule for MGD013 administration and has initiated dose expansion in up to nine tumor types.

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see MacroGenics' website at www.macrogenics.com. MacroGenics, the MacroGenics logo and DART and TRIDENT are trademarks or registered trademarks of MacroGenics, Inc.

About Zai Lab

Zai Lab is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. Zai Lab's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and addressing unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

MacroGenics' Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for MacroGenics, including statements about the company's strategy, future operations, clinical development of the company's therapeutic candidates, milestone or opt-in payments from the company's collaborators, the company's anticipated milestones and future expectations and plans and prospects for the company and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of MacroGenics' product candidates and other risks described in the company's filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent MacroGenics' views only as of the date hereof. MacroGenics anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing MacroGenics' views as of any date subsequent to the date hereof.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding business strategy, plans and objectives for future operations and other statements containing words such as "anticipates", “believes”, "expects", “plans” and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) Zai Lab’s ability to obtain additional future funding, (2) Zai Lab’s results of clinical and pre-clinical development of its drug candidates, (3) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab’s drug candidates, (4) Zai Lab’s ability to generate revenue from its drug candidates, and (5) other factors discussed in Zai Lab's Annual Report on Form 20-F for the fiscal year ended December 31, 2017 and its other filings with the Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab’s expectations and assumptions to change and undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing Zai Lab’s views as of any date subsequent to the date of this press release.

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Investors: Jill Steier
Burns McClellan, on behalf of Zai Lab
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Exhibit 10.18

FOURTH AMENDED AND RESTATED FOUNDER EMPLOYMENT AGREEMENT

THIS FOURTH AMENDED AND RESTATED FOUNDER EMPLOYMENT AGREEMENT ("**Agreement**") is made and entered into as of December 1, 2018 (the "**Effective Date**"), by and between Zai Lab Limited, a limited company incorporated under the laws of the Cayman Islands (the "**Company**"), and Samantha (Ying) Du, an individual (the "**Founder**").

WHEREAS, the Company and the Founder previously entered into that certain Third Amended and Restated Founder Employment Agreement dated as of November 10, 2017 (the "**Existing Agreement**"); and

WHEREAS, the Company and the Founder desire to amend and replace the Existing Agreement in its entirety with the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Employment**. The Founder's employment under the terms of this Agreement will commence as of the Effective Date and will continue until terminated in accordance with Section 4 (the "**Employment Period**").

1.1. Duties and Responsibilities. The Company agrees to employ the Founder as the Chairperson and Chief Executive Officer of the Company, to render such services and to perform such duties and responsibilities as are normally associated with and inherent in the aforementioned role and the capacity in which the Founder is employed, as well as such other duties and responsibilities as shall from time to time be assigned to the Founder by the Board of Directors of the Company (the "**Board**").

1.2. Acceptance of Employment. The Founder accepts such employment set out in Section 1.1 and agrees to faithfully perform and render the services required of the Founder under this Agreement. Except for reasonable vacations, absences due to temporary illness, and activities that may be mutually agreed to by the parties, the Founder shall devote substantially all of her time, attention and energies during normal business hours and such evenings and weekends as may be reasonably required for the discharge of her duties to the Company and the performance of the Founder's duties and responsibilities under this Agreement.

1.3. Positions with Subsidiaries/Affiliates. If requested by the Board and agreed upon by the Founder, the Founder agrees to serve without additional compensation if elected, nominated or appointed as an officer and/or director of the Company and any of the subsidiaries or affiliates of the Company and in one or more executive offices of any of the subsidiaries or affiliates of the Company, provided that the Founder is indemnified for serving in any and all such capacities pursuant to the indemnification provisions set forth in the bylaws of such subsidiaries and/or affiliates.

1.4. Conflicts of Interest. The Founder has reviewed with the Board the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Founder or her associate(s) in all such business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Founder 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. The Founder or 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 other company that may be directly competitive or directly in conflict with the Company until such interest is presented to the Board and the Board consents to such interest or employment. The Company further acknowledges and agrees that, subject to the prior written approval by a majority of the Board (which majority shall exclude the Founder if the Founder is a then-current member of the Board) and consistent with the terms of the Compliance Agreement (as defined below), the Founder may serve on the boards of directors and advisory boards of other companies which are not in direct competition or not in direct conflict with the Company and its subsidiaries and affiliates, provided that such service does not interfere with the performance of the Founder's duties hereunder. Notwithstanding any of the foregoing, the Founder's interest in, and affiliation with, Quan Venture Fund I, LP, and its affiliates is not deemed to conflict with her responsibilities to the Company or interfere with her performance of her duties hereunder.

2. **Reserved.**

3. **Compensation, Benefits and Expense Reimbursements**.

3.1. Base Salary. In consideration for the agreement of the Founder to be employed under this Agreement, during the Employment Term, the Founder shall receive from the Company an annual base salary (as it may be adjusted from time to time, the "**Base Salary**") of US$620,000, with the understanding that, at the sole discretion of the Company, up to an aggregate of (a) fifty percent (50%) of the Base Salary may be paid by the Company or one or more subsidiaries of the Company domiciled in the Cayman Islands (each such subsidiary, a "**Cayman Subsidiary**"), (b) thirty percent (30%) of the Base Salary may be paid by one or more subsidiaries of the Company domiciled in the People's Republic of China (each, a "**PRC Subsidiary**"), and (c) twenty percent (20%) of the Base Salary may be paid by one or more subsidiaries of the Company domiciled in the United States (each, a "**U.S. Subsidiary**"), in each case, pursuant to a short-form labor contract between the Founder and such Cayman Subsidiary, PRC Subsidiary, or U.S. Subsidiary, as applicable, identified by the Company, to the extent required by or desirable under applicable laws. The Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service or similar organization. The Company shall pay such Base Salary in arrears on the last working day (Monday to Friday) of each month in accordance with the standard payroll procedures of the Company (as they may be modified from time to time). The Base Salary will be subject to review by the Board or the Compensation Committee of the Board (the "**Compensation Committee**") and adjustments will be made by the Board or the Compensation Committee based upon its respective normal performance review practices.

3.2. Stock Options. During the Employment Period, the Founder may, from time to time, be entitled to receive options to purchase ordinary shares of the Company or its affiliates and other equity-based incentives as and when determined by the Board or the Compensation Committee, in its respective sole and exclusive discretion.

3.3. Bonus. During the Employment Period, the Founder may be entitled to receive an annual bonus with a target equal to 70% of the Base Salary (the "**Target Bonus**"), the actual amount of which shall be determined by the Board or the Compensation Committee in its respective 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. The Company's current practice, which is subject to change, is to pay annual bonuses to employees in January of the calendar year following the calendar year to which the annual bonus relates.

3.4. Fringe Benefits. During the Employment Period, the Founder will be entitled to 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, in its respective sole and exclusive discretion, it being understood that the Founder shall continue to receive the fringe benefits provided under the Existing Agreement.

3.5. Reimbursements. During the Employment Period, the Founder 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 Founder of appropriate documentation.

3.6. Deductions. Recognizing that the Founder is an employee for all purposes, the Company or a subsidiary of the Company shall deduct from any compensation payable to the Founder the sums which the Company or such subsidiary 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 or such subsidiary shall pay any amounts so deducted to the applicable governmental entities and agents entitled to receive such payments.

4. **Termination of Employment**.

4.1. Death or Disability. If the Founder dies during the Employment Period, the Founder's employment by the Company hereunder shall automatically terminate on the date of the Founder's death. If, during the Employment Period, the Founder 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 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 Founder's employment under this Agreement immediately upon giving her notice to that effect. In the case of a Disability, until the Founder becomes eligible for disability income under the Company's disability income insurance (if any) or until the Company terminates the Founder's employment in accordance with the foregoing, whichever occurs first, the Founder will be entitled

to receive compensation, at the rate and in the manner provided in Section 3.1, notwithstanding any such physical or mental disability. Termination pursuant to this Section 4.1 is referred to in this Agreement as a "**Death/Disability Termination**".

(a) Substitution. The Board may designate another employee to act in the Founder's place during any period of Disability suffered by the Founder during the Employment Period. Notwithstanding any such designation, the Founder shall continue to receive the Base Salary and benefits in accordance with Section 3 of this Agreement until the Founder becomes eligible for disability income under the Company's disability income insurance (if any) or until the termination of the Founder's employment, whichever occurs first.

(b) Disability Income Payments. While receiving disability income payments under the Company's disability income insurance, if any (the "Disability Payments"), the Founder shall remain entitled to receive the Base Salary under Section 3.1, which shall be reduced by any Disability Payments received by the Founder, and shall continue to participate in all other compensation and benefits in accordance with Sections 3.2, 3.3 and 3.4 until the date of the Founder's termination of employment.

(c) Verification of Disability. If any question arises as to whether during any period the Founder 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 Founder's duties and responsibilities hereunder, the Founder may, and at the request of the Company shall, submit to a medical examination by a physician selected by the Company to whom the Founder or the Founder's guardian has no reasonable objection to determine whether the Founder is so disabled and such determination shall for the purposes of this Agreement be conclusive of the issue. If such question arises and the Founder fails to submit to such medical examination, the Company's determination of the issue shall be binding on the Founder.

4.2. Termination by the Company for Cause. The Company, on recommendation from the Board (excluding the Founder if the Founder is a then current member of the Board), may terminate the employment of the Founder hereunder at any time during the Employment Period for Cause (as defined below) (such termination being referred to in this Agreement as a "**Termination for Cause**") by giving the Founder notice of such termination, upon the giving of which such termination shall take effect immediately. For the purpose of this Agreement, "**Cause**" means any one of the following grounds:

(a) repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the Founder's obligations and duties to or for the Company;

(b) the Founder's conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws;

(c) gross mismanagement by the Founder of the business and affairs of the Company or any subsidiary or affiliate of the Company which directly results in a material loss to the Company and for which the Company has reasonable proof was committed by the Founder;

(d) material violation of any material terms of this Agreement or the Compliance Agreement (as defined below); or

(e) a conclusive finding by an independent fact finder appointed by the Board of any willful misconduct, dishonesty or acts of moral turpitude by the Founder which is materially detrimental to the interests and well-being of the Company and its subsidiaries and affiliates, including, without limitation, harm to its business or reputation.

4.3. Termination by the Company without Cause. The Company, on recommendation from the Board (excluding the Founder if the Founder is a then-current member of the Board), may terminate the employment of the Founder hereunder other than for Cause at any time upon thirty (30) days advance written notice to the Founder (such termination being referred to in this Agreement as a "**Termination without Cause**").

4.4. Termination by the Founder for Good Reason. The Founder may terminate her employment hereunder at any time for Good Reason (as defined below) by giving the Company written notice of such termination, provided that such notice specifies: (a) the basis for termination and (b) the effective date of termination (such termination being referred to in this Agreement as a "**Termination for Good Reason**"). For purposes of this Agreement, the term "**Good Reason**" shall mean (i) any material diminution of the Founder'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 Founder of duties or responsibilities that are materially inconsistent with the Founder's then current position; (ii) any material breach of this Agreement by the Company which is not cured within ten (10) business day days after written notice thereof is given to the Company; or (iii) a relocation of the Founder (other than any relocation requested by the Founder) from the place of assignment of the Founder by the Company as of the Effective Date 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.

4.5. Termination by the Founder without Good Reason. The Founder may terminate her employment hereunder without Good Reason at any time upon reasonable notice by the Founder to the Board of no fewer than thirty (30) calendar days (such termination being referred to in this Agreement as a "**Termination without Good Reason**").

5. **Effect of Termination**.

5.1. Termination for Cause or without Good Reason.

(a) Upon the termination of the Founder's employment hereunder pursuant to a Termination for Cause or a Termination without Good Reason, neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries 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) reimbursement for any expenses for which the Founder has not been reimbursed as provided in Section 3.5, provided that that the Founder submits all such expenses and required supporting documentation within sixty (60) days of the effective date of such termination; and

(iii) any additional compensation as may be expressly required under applicable law.

(b) Final Compensation (other than any 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 Founder within thirty (30) days following the date of termination (or such shorter period required by law).

5.2. Termination upon Death or Disability.

(a) Upon the termination of the Founder's employment hereunder pursuant to a Death/Disability Termination, neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following:

(i) Final Compensation in accordance with Section 5.1; and

(ii) an aggregate amount equal to one (1) months' Base Salary plus an amount equal to one month of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder, payable in accordance with the Company's normal payroll practices, subject to Sections 5.5, 5.6 and 5.7.

(b) Notwithstanding anything to the contrary in any agreement between the Founder and the Company, upon a Death/Disability Termination, the Founder, or her beneficiaries or estate (as applicable), 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 Founder by the Company, subject to Sections 5.5 (in the case of a termination by the Company due to Disability), 5.6 and 5.7.

5.3. Termination without Cause or for Good Reason.

(a) Upon the termination of the Founder's employment hereunder pursuant to a Termination without Cause or a Termination for Good Reason, neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to eighteen (18) months' Base Salary;

(iii) an aggregate payment equal to eighteen (18) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder; and

(iv) a payment equal to a pro-rated Target Bonus (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 Founder 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.

(b) Subject to Sections 5.5, 5.6 and 5.7, 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 eighteen- (18) month period following the effective date of the termination of the Founder's employment, 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 Founder's employment.

(c) Notwithstanding anything to the contrary in any agreement between the Founder and the Company, upon a Termination without Cause or a Termination for Good Reason, the Founder 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 Founder by the Company, subject to Sections 5.5, 5.6 and 5.7.

5.4. Change in Control Termination.

(a) Upon the termination of the Founder'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 Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Enhanced Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to eighteen (18) months' Base Salary;

(iii) an aggregate payment equal to eighteen (18) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder; and

(iv) a payment equal to the sum of (x) six (6) months' Base Salary, (y) two times the Target Bonus and (z) six (6) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder.

(b) Subject to Sections 5.5, 5.6 and 5.7, other than Final Compensation, Enhanced Severance Payments will be paid as follows: (i) the amounts under Section 5.4(a)(ii) and Section 5.4(a)(iii) will be provided in the form of salary continuation, payable in equal installments in accordance with the Company's normal payroll practices during the eighteen- (18-) month period following the effective date of the termination of the Founder's employment, 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 Founder's employment, and (ii) the amount under Section 5.4(a)(iv) will be paid in a lump sum on the next regular pay day following the date on which the Release of Claims (as defined below) becomes effective and irrevocable.

(c) Notwithstanding anything to the contrary in any agreement between the Founder and the Company, upon a Change in Control Termination, the Founder 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 Founder by the Company, subject to Sections 5.5, 5.6 and 5.7.

(d) 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 Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company, except that any change in the ownership of the stock of the Company as a result of a private financing of the 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 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 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 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 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 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 Company's securities immediately before such transaction. With regard to any payment considered to be nonqualified deferred compensation under Section 409A (as defined below), to the extent applicable, that is payable upon a Change in Control, to avoid the imposition of an additional tax, interest or penalty under Section 409A (as defined below), no amount will be payable unless such change in control constitutes a "change in control event" within the meaning of Section 1.409A-3(i)(5) of the Treasury Regulations.

5.5. Conditions to Receipt of Severance. The receipt of any payments and benefits pursuant to Sections 5.2 – 5.4 (other than Final Compensation) is conditioned on the Founder signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release of Claims**"), provided that such separation agreement and 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 Founder will forfeit any rights to severance or benefits (other than Final Compensation) under this Agreement. In no event will severance payments or benefits (other than Final Compensation) be paid or provided under this Agreement until such Release of Claims becomes effective and irrevocable. If the sixty (60) day period following termination referred to herein extends through two (2) taxable years, to the extent required to comply with Section 409A, such amount will be paid in the second taxable year (but within the sixty (60) day period) following the Founder's termination.

5.6. Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time the Founder's employment terminates, the Founder 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 Founder's death; except (a) 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); (b) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (c) 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**"). 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).

5.7. 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 Founder 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 5.7, 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 5.7 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 Founder 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.

6. **Compliance Agreement**. The Founder 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.

7. **Standards of Conduct**. The Founder 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.

8. **Indemnification**.

8.1. Indemnification. In the event that (a) the Founder was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Founder's Corporate Status (as defined below) or (b) the Founder was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Founder's Corporate Status, the Founder shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by the Founder in connection with such Proceeding to the maximum extent permitted by applicable law (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, (ii) "**Corporate Status**" means the status of the Founder as an employee and/or director of the Company, as applicable, (iii) "**Expenses**" means all fees, costs and expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys' fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants, counsels and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) "**Liabilities**" means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

8.2. Advancement of Expenses. The Company agrees that the Company shall pay to the Founder all Indemnifiable Amounts incurred by the Founder in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Founder provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Founder is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

8.3. Limitation on Indemnification. The Founder shall not be entitled to any indemnification under this Section 8 if the Founder knowingly violated any duty, responsibility or obligation imposed under this Agreement, the Compliance Agreement or any Company policy.

8.4. Change in Law. To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Founder shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

9. **Representations and Warranties of the Company**. The Company represents and warrants to the Founder that the execution of this Agreement by the Company has been duly authorized by resolution of the Board.

10. **Representations and Warranties of the Founder**. The Founder represents and warrants to the Company that: (i) the Founder 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 Founder will not infringe any intellectual property rights including patent, copyright, trademark, trade secret or other proprietary right of any person; and (iii) the Founder will not use any trade secrets or confidential information for purposes other than for the furtherance of the business of the Company and will not use any trade secrets or confidential information owned by any third party.

11. **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 11.

12. **Dispute Resolution**. In the event the parties hereto are unable to settle a dispute between them regarding this Agreement through friendly consultation, such dispute shall be referred to and finally settled by arbitration administered by JAMS in accordance its Employment Arbitration Rules & Procedures (the "**Arbitration Rules**") in effect, which rules are deemed to be incorporated by reference into this Section 12 applying the laws of the State of New York, without regard to any principles of conflicts of laws that would result in the application of the laws of another jurisdiction. The arbitration tribunal shall consist of three (3) arbitrators to be appointed according to the Arbitration Rules (the "**Arbitration Board**"). The Arbitration Board shall decide any such dispute or claim strictly in accordance with the governing law specified in Section 14.5. Judgment upon any arbitral award rendered hereunder may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The costs and expenses of the arbitration, including the fees of the Arbitration Board, shall be borne equally by each party to the dispute or claim, and each party shall pay its own fees, disbursements and other charges of its counsel; provided that the

Arbitration Board shall have the right to allocate the costs and expenses between each party as the Arbitration Board deems equitable. Any award made by the Arbitration Board shall be final and binding on each of the parties that were parties to the dispute. The parties expressly agree to waive the applicability of any laws and regulations that would otherwise give the right to appeal the decisions of the Arbitration Board so that there shall be no appeal to any court of law for the award of the Arbitration Board, and a party shall not challenge or resist the enforcement action taken by any other party in whose favor an award of the Arbitration Board was given. Notwithstanding this agreement to arbitrate, the parties agree that either party may seek provision remedies such as a temporary restraining order or a preliminary injunction from a court of competent jurisdiction in aid of arbitration. As a material part of this agreement to arbitrate claims, the parties expressly waive all rights to a jury trial in court on all statutory or other claims. The parties acknowledge and agree that no claims will be arbitrated on a class action or collective action basis.

13. **Covenant Against Assignment**. The Founder may not assign any rights or delegate any of the duties of the Founder 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. **Miscellaneous**.

14.1. 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 or 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.

14.2. Time. Time is of the essence in performance of the rights and obligations under this Agreement.

14.3. Survival. The provisions set forth in Sections 5, 6, 8, 11, 12 and 14 of this Agreement (and any other provisions necessary to give effect to such provisions) shall survive the termination of this Agreement.

14.4. 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.

14.5. Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the State of New York, 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.

14.6. 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.

14.7. Entire Agreement; Amendments. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements or understanding among the parties with respect thereto, including, without limitation, the Existing Agreement. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

14.8. 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.

14.9. Severability. Subject to the provisions of Section 11 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.

14.10. 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 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.

14.11. Further Assurances. The Founder 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.

14.12. 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.

14.13. Interpretation of Agreement. This Agreement has been negotiated at arm’s length between persons knowledgeable in the matters dealt with in this Agreement. In addition, each party has been represented by experienced and knowledgeable legal counsel. Accordingly, any rule of law, or any legal decision that would require interpretation of any ambiguities in this Agreement against the party that has drafted it, is of no application and is waived.

14.14. 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.

14.15. No Third-Party Rights. Nothing in this Agreement is intended to grant to any third party (other than the parties' respective successors in title and permitted assigns) any right to enforce any term of this Agreement or to confer on any third party (other than the parties' respective successors in title and permitted assigns) any benefits under this Agreement. No person who is not a party to this Agreement shall have any right to enforce any term of this Agreement.

[*REMAINDER OF PAGE INTENTIONALLY LEFT BLANK*]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

ZAI LAB LIMITED	FOUNDER:
By: /s/Peter Wirth	By: /s/Samantha (Ying) Du
Peter Wirth Chairman, Compensation Committee	Samantha (Ying) Du
Address:	Address:
4560 Jinke Road, Bldg. 1, 4F Pudong, Shanghai, 201210, China	On File with the Company

SIGNATURE PAGE OF EMPLOYMENT AGREEMENT

Exhibit 10.19

AMENDED AND RESTATED EMPLOYMENT AGREEMENT
William Ki Chul Cho

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT ("**Agreement**") is made and entered into on March 22, 2019 (the "**Effective Date**"), by and between Zai Lab (Hong Kong) Ltd., a limited company incorporated under the laws of Hong Kong whose registered office is at Room 1902, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong (the "**Company**"), and William Ki Chul Cho, an individual (the "**Employee**") whose correspondence address is XXX and whose US passport number is XXX.

RECITALS

WHEREAS, the Company and its Affiliates are engaged in the business of researching, developing, manufacturing, commercialization of drug products in the pharmaceutical industry, including and without limitation to sales and marketing of both small molecule and large molecule therapeutics (the "**Business of the Group**");

WHEREAS, the Company and the Employee previously entered into that certain Employment Agreement, dated as of March 5, 2018 (the "**Existing Agreement**"); and

WHEREAS, the Company and the Employee desire to amend and replace the Existing Agreement in its entirety with the terms and conditions set forth in 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 and throughout the time for which the Employee's employment under this Agreement is not terminated, the Company agrees to continue the employment of the Employee and the Employee agrees to continue employment with the Company.

1.1. Employment by Company. The Company agrees to employ the Employee as the Chief Financial Officer of the Company. In addition, the Employee shall serve as the Chief Financial 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. The Employee shall report directly to the Chief Executive Officer of the Company and/or the Chief Executive Officer of the Parent Company or such other senior executive officer of the Company or Parent Company as designated by the Chief Executive Officer or the Board of Directors (the "**Board**") of the Parent Company.

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 activities that may be mutually agreed to by the parties and other absences consistent with the policies of the Company then in effect, the Employee shall devote his entire business time, attention and energies 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 and agreed upon by the Employee, 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 Affiliate, provided that the Employee is indemnified for serving in any and all such capacities pursuant to the indemnity provisions set forth in the bylaws of such Affiliate.

1.4. Conflicts of Interest. The Employee has reviewed with the Board the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Employee or his 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 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. The Company and the Parent Company further acknowledge and agree that, subject to the prior written approval by a majority of the Board (which majority shall exclude the Employee if the Employee is a then current member of the Board) and consistent with the terms of the Compliance Agreement (as defined below), the Employee may serve on the boards of directors and advisory boards of other companies which is not in direct competition or not in direct conflict with the Company or the Parent Company provided that such service does not interfere with the performance of the Employee's duties hereunder.

2. **PLACE OF PERFORMANCE**. The Employee shall discharge his responsibilities at such corporate locations of the Parent Company as is reasonably determined by the Chief Executive Officer of the Company and/or the Chief Executive Officer of the Parent Company. 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, the Employee shall receive from the Company an annual base salary (**"Base Salary"**) of US$400,000. This Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service organization, and will be payable in such installments as are applicable to employees of the Company at substantially the same service level as the Employee. 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 shall pay such Base Salary in arrears on the last working day (Monday to Friday) of each month in accordance with the standard payroll procedures of the Company. 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 Option. For the avoidance of doubt, the Employee acknowledges, agrees and confirms that (i) as of the date of this Agreement, the Employee has been granted, in accordance with the provisions of the Existing Agreement and the Parent Company's 2017 Equity incentive Plan (the "**Plan**"), (A) an option to purchase 400,000 American Depositary Shares ("**ADSs**") representing ordinary shares of the Parent Company (the "**Existing Option**"), as evidenced by that certain Option Agreement dated of [ ], 2018 and entered into by and between the Parent Company and the Employee (the "**Option Agreement**") and (B) 100,000 ADSs representing ordinary shares of the Parent Company (the "**Existing Restricted Stock Grant**"), as evidenced by that certain Restricted Stock Agreement dated as of [ ], 2018 and entered into by and between the Employee and the Parent Company (the "**Restricted Stock Agreement**"); (ii) this Agreement does not modify or otherwise supplement the terms and conditions pertaining to the Existing Option or the Existing Restricted Stock Grant; and (iii) the Employee has no further rights or claims to any additional options or equity incentive awards other than the Existing Option and the Existing Restricted Stock Grant. The Plan, the Option Agreement and the Restricted Stock Agreement are incorporated herein by reference.

3.3 Bonuses.

3.3.1 Annual Bonus. During the Employment Period, the Employee may be eligible to receive an annual bonus with a target equal to 40% of the Base Salary (the "**Target Bonus**"), the actual amount of which shall be determined by the Board or the Compensation Committee in its respective 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.

3.3.2 Sign-on Bonus. The Employee will be eligible to receive a cash payment of US$300,000 (the "**Sign-On Bonus**") on the seven-month anniversary of his continuous employment with the Company (calculated as of a start date of March 5, 2018), 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 March 5, 2018, 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 prior to the third anniversary of March 5, 2018, he 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 for 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 him for or on behalf of the Company in the performance of his 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 him mentally or physically incapable of performing the services required to be performed by him under this Agreement for a period of ninety (90) consecutive days or longer, or for 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 him 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 Section 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, on recommendation from the Board, 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) repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the Employee's obligations and duties in the Company;

(ii) the Employee's conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws;

(iii) gross mismanagement by the Employee of the business and affairs of the Company or any subsidiary of the Company which directly results in a material loss to the Company and for which the Company has reasonable proof was committed by the Employee;

(iv) material violation of any material terms of this Agreement or the Compliance Agreement (as defined below); or

(v) a conclusive finding by an independent fact finder appointed by the Board for any willful misconduct, dishonesty or acts of moral turpitude by the Employee which is materially detrimental to the interests and well-being of the Company and its subsidiaries, including, without limitation, harm to its business or reputation.

6. **TERMINATION WITHOUT CAUSE BY THE COMPANY**. The Company, on recommendation from the Board, 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. The termination of service under this Section 6 will take effect upon the giving of reasonable advance notice of not less than thirty (30) calendar days.

7. **TERMINATION BY THE EMPLOYEE.**

7.1 Without Good Reason. The Employee may terminate his 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.

7.2 With Good Reason. The Employee may terminate his 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 (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; (b) any material breach of the Agreement by the Company which is not cured within ten (10) business day days after written notice thereof is given to the Company; or (c) a relocation of the Employee (other than any relocation requested by 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 his 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 "**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) 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 his beneficiary or estate will have any further rights or claims against the Company or any 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 his 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 (3rd) anniversary of March 5, 2018, or (ii) for twelve (12) months if such termination occurs on or following the third (3rd) anniversary of March 5, 2018, (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 (3rd) anniversary of March 5, 2018, or (ii) for twelve (12) months if such termination occurs on or following the third (3rd) anniversary of March 5, 2018, 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 his 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 Sections 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 Sections 8.5, 14 and 15.

8.4.4 For purposes of this Agreement, "**Change in Control**" means the occurrence of any of the following:

(a) 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;

(b) 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

(c) 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 (c), 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 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 himself 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. **INDEMNIFICATION**.

11.1 Indemnification. In the event that (a) the Employee was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Employee's Corporate Status (as defined below) or (b) the Employee was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Employee's Corporate Status, the Employee shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by the Employee in connection with such Proceeding (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, (ii) "**Corporate Status**" means the status of the Employee as an employee and/or director of the Company, as

applicable, (iii) "**Expenses**" means all fees, costs and expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys' fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants, counsels and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) "**Liabilities**" means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

11.2 Advancement of Expenses. The Company agrees that the Company shall pay to the Employee all Indemnifiable Amounts incurred by the Employee in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Employee provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Employee is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

11.3 Limitation on Indemnification. The Employee shall not be entitled to any indemnification under this Section 11 if the Employee knowingly violated any duty, responsibility or obligation imposed under this Agreement, the Compliance Agreement or any Company policy.

11.4 Change in Law. To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Employee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

12. **REPRESENTATIONS AND WARRANTIES OF THE COMPANY**. The Company represents and warrants to the Employee that the execution of this Agreement by the Company has been duly authorized by resolution of the Board.

13. **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; and (iii) the Employee will not use any Trade Secrets or Confidential Information for purposes other than for the furtherance of the interests of the Company or any of its Affiliates and will not use any trade secrets or confidential information owned by any third party.

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. **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 16.

17. **DISPUTE RESOLUTION.** In the event the parties hereto are unable to settle a dispute between them regarding this Agreement through friendly consultation, such dispute shall be referred to and finally settled by arbitration at the Hong Kong International Arbitration Centre in accordance with the UNCITRAL Arbitration Rules (the "**UNCITRAL Rules**") in effect, which rules are deemed to be incorporated by reference into this Section 17 applying the laws of Hong Kong, without regard to its principles of conflicts of laws. The arbitration tribunal shall consist of three (3) arbitrators to be appointed according to the UNCITRAL Rules (the "**Arbitration Board**"). The language of the arbitration shall be English. The Arbitration Board shall decide any such dispute or claim strictly in accordance with the governing law specified in Section 19.5. Judgment upon any arbitral award rendered hereunder may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The costs and expenses of the arbitration, including the fees of the Arbitration Board, shall be borne equally by each party to the dispute or claim, and each party shall pay its own fees, disbursements and other charges of its counsel; provided that the Arbitration Board shall have the right to allocate the costs and expenses between each party as the Arbitration Board deems equitable. Any award made by the Arbitration Board shall be final and binding on each of the parties that were parties to the dispute. The parties expressly agree to waive the applicability of any laws and regulations that would otherwise give the right to appeal the decisions of the Arbitration Board so that there shall be no appeal to any court of law for the award of the Arbitration Board, and a party shall not challenge or resist the enforcement action taken by any other party in whose favor an award of the Arbitration Board was given.

18. **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.

19. **MISCELLANEOUS**.

19.1 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.

19.2 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.

19.3 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.

19.4 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.

19.5 Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of Hong Kong, 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.

19.6 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.

19.7 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 or understanding among the parties with respect thereto, including, without limitation, that certain offer letter dated as of January 4, 2018 and the Existing Agreement. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

19.8 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.

19.9 Severability. Subject to the provisions of Section 16 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.

19.10 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 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.

19.11 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.

19.12 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.

19.13 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.

19.14 Interpretation of Agreement. This Agreement has been negotiated at arm's length between persons knowledgeable in the matters dealt with in this Agreement. In addition, each party has been represented by experienced and knowledgeable legal counsel. Accordingly, any rule of law, or any legal decision that would require interpretation of any ambiguities in this Agreement against the party that has drafted it, is of no application and is waived.

19.15 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.

19.16 No Third-Party Rights. Nothing in this Agreement is intended to grant to any third party (other than the parties' respective successors in title and permitted assigns) any right to enforce any term of this Agreement or to confer on any third party (other than the parties' respective successors in title and permitted assigns) any benefits under this Agreement. No person who is not a party to this Agreement shall have any right under the Contracts (Rights of Third Parties) Ordinance (Chapter 623 of the Laws of Hong Kong) to enforce any term of this Agreement.

[*REMAINDER OF PAGE INTENTIONALLY LEFT BLANK*]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

COMPANY:

ZAI Lab (HK) Limited

By: /s/ Samantha Du
Print Name: Samantha Du
Title: CEO

Address:

4560 Jinke Road
Pudong New Area
Shanghai, China 201210
Attention: Chief Executive Officer
Facsimile:
E-mail:

EMPLOYEE:

William Ki Chul Cho

/s/ William Ki Chul Cho

Address: XXX

E-Mail: XXX

Exhibit 10.22

SECONDED AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS SECONDED AMENDED AND RESTATED EMPLOYMENT AGREEMENT ("**Agreement**") is entered into on December 28, 2019 and made effective as of December 1, 2018 (the "**Effective Date**"), by and between Zai Lab (US) LLC, a Delaware limited liability company (the "**Company**"), and Harald Reinhart, an individual whose primary address is XXX (the "**Employee**").

WHEREAS, Zai Lab (Hong Kong) Ltd, an Affiliate (as defined below) of the Company ("**Zai Lab Hong Kong**"), and the Employee previously entered into that certain Employee Agreement dated as of May 7, 2017, as amended by that certain Amendment dated as of August 30, 2017 (the "**Amendment**" and, together, the "**Existing Agreement**"); and

Whereas, the Company and the Employee desire to amend and replace the Existing Agreement in its entirely with the terms and conditions set forth in this 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**. The Employee's employment under the terms of this Agreement will commence as of the Effective Date and will continue until terminated in accordance with Section 4 (the "**Employment Period**").

1.1. Duties and Responsibilities. The Company agrees to employ the Employee as the Chief Medical Officer, Autoimmune and Infectious Diseases of the Company and the Chief Medical Officer, Autoimmune and Infectious Diseases of Zai Lab Limited, an exempted company organized under the laws of the Cayman Islands and the ultimate parent corporation of the Company (the "**Parent Company**"), to render such services and to perform such duties and responsibilities as are normally associated with and inherent in the aforementioned role and the capacity 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. The Employee shall report directly to the Chief Executive Officer of the Company and/or the Chief Executive Officer of the Parent Company or such other senior executive officer of the Company as designated by the Chief Executive Officer or the Board of Directors (the "**Board**") of the Parent Company.

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 substantially all of his 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 Company and the performance of the Employee's duties and responsibilities under this Agreement.

1.3. Positions with Affiliates. If requested by the Company or the Parent Company, the Employee agrees to serve without additional compensation if elected, nominated or appointed as an officer and/or director of the Company and any of the subsidiaries, parents or other affiliates of the Company (collectively, "**Affiliates**") and in one or more executive offices of any of the Affiliates of the Company, provided that the Employee is indemnified for serving in any and all such capacities pursuant to the indemnification provisions set forth in the bylaws of such affiliates.

1.4. Conflicts of Interest. The Employee has reviewed with the Company the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Employee or his associate(s) in all such business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Employee agrees to review with the Company 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. Except with respect to the Employee's affiliation with Allphase Pharma Consulting, LLC, as set forth in Schedule 1 to the Existing Agreement (the "**Permitted Arrangement**"), which same Schedule 1 shall be appended to this Agreement, the Employee or his 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 other company that may be directly competitive or directly in conflict with the Company until such interest is presented to the Board and the Board consents to such interest or employment. The Company further acknowledges and agrees that, subject to the prior written approval by a majority of the Board (which majority shall exclude the Employee if the Employee is a then current member of the Board) and consistent with the terms of the Compliance Agreement (as defined below), the Employee may serve on the boards of directors and advisory boards of other companies which is not in direct competition or not in direct conflict with the Company provided that such service does not interfere with the performance of the Employee's duties hereunder.

2. **Place of Performance.** The Employee shall perform services on a remote basis, with the understanding that the Company may require that the Employee travel in furtherance of the business of the Company 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, which will include periodic trips to the Company's headquarters in Shanghai, China.

3. **Compensation, Benefits and Expense Reimbursements**.

3.1. Base Salary. In consideration for the agreement of the Employee to be employed under this Agreement, effective as of the Effective Date and during the Employment Period, the Employee shall receive from the Company an annual base salary (as it may be adjusted from time to time, the "**Base Salary**") of US$400,000. The Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service or similar 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 shall pay such Base Salary in arrears on the last working day (Monday to Friday) of each month in accordance with the standard payroll procedures of the Company (as they may be modified from time to time). The Base Salary will be subject to review by the Board or the Compensation Committee of the Board (the "**Compensation Committee**") and adjustments will be made by the Board or the Compensation Committee based upon its respective normal performance review practices.

3.2. Stock Options. Subject to the terms of the 2017 Stock Incentive Plan (the "**Plan**") of Parent Company, the Employee shall be granted an option to purchase 50,000 ordinary shares of the Parent Company (the "**Option**") at an exercise price equal to the fair market value of an American Depository Share (or ADS) representing Ordinary Shares of the Parent Company on the date of grant, which shall be the closing price of an ADS on the NASDAQ Global Market on the date of grant or, if no closing price is reported for the date of grant, the closing price on the immediately preceding date on which a closing price was reported. The Option so granted shall vest in accordance with the vesting schedule set out in the Additional Option Agreement (as defined below). The Option will be subject to the terms, definitions and provisions of the Plan and the stock option agreement by and between the Employee and the Parent Company on or after the Effective Date (the "**Additional Option Agreement**"). The Employee acknowledges, agrees and confirms that the Employee has previously been granted options to purchase up to an aggregate of 166,000 Ordinary Shares of the Parent Company in accordance with the provisions of the Existing Agreement, as evidenced by those certain Option Agreements entered into by and between the Parent Company and the Employee on May 12, 2017 and on September 20, 2017 (the "**Existing Options**"), and that (i) this Agreement (and the Additional Option Agreement) does not modify or otherwise supplement the terms and conditions pertaining to the Existing Options and (ii) that Employee has no further rights or claims to any additional options or equity incentive awards other than, pursuant to the Existing Options and the Option as provided under this Section 3.2.

3.3. Bonus. The Employee may be eligible to receive an annual bonus with a target equal to 30% of the Base Salary for services provided in fiscal year 2018 and for the remainder of any annual period during the Employment Period (the "**Target Bonus**"). The actual amount of which shall be determined by the Board or the Compensation Committee in its respective 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.

3.4. 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, in its respective sole and exclusive 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 him for or on behalf of the Company in the performance of his duties hereunder upon presentation by the Employee of appropriate documentation. 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 or a subsidiary of the Company shall deduct from any compensation payable to the Employee the sums which the Company or such subsidiary 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 or such subsidiary shall pay any amounts so deducted to the applicable governmental entities and agents entitled to receive such payments.

4. **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 him mentally or physically incapable of performing the services required to be performed by him 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 him 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 3.1, notwithstanding any such physical or mental disability. Termination pursuant to this Section 4.1 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 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 occurs first.

4.3. Disability Income Payments. While receiving disability income payments under the Company's disability income insurance, if any (the "Disability Payments"), 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, 3.4 and 3.5 until the date of the Employee's termination of employment.

(a) Verification of Disability. If any question arises 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 arises and the Employee fails to submit to such medical examination, the Company's determination of the issue shall be binding on the Employee.

4.4. Termination by the Company for Cause. The Company may terminate the employment of the Employee hereunder at any time during the Employment Period for Cause (as defined below) (such termination being referred to in this Agreement 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 Agreement, "**Cause**" means any one of the following grounds, as determined by the Board in its reasonably judgment:

(a) 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;

(b) the Employee's commission of a felony, or any crime involving fraud, moral turpitude or misrepresentation or violation of applicable securities laws;

(c) 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;

(d) the Employee's material 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; or

(e) 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.

4.5. Termination by the Company without Cause. The Company may terminate the employment of the Employee hereunder at any time during the Employment Period without "Cause" (such termination referred to in this Agreement as a "**Termination without Cause**").

4.6. Termination by the Employee for Good Reason. The Employee may terminate his employment hereunder at any time for Good Reason (as defined below) by giving the Company written notice of such termination, provided that such notice specifies: (a) the basis for termination and (b) the effective date of termination (such termination being referred to in this Agreement as a "**Termination for Good Reason**"). For purposes of this Agreement, the term "**Good Reason**" shall mean (i) 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; (ii) any material breach of this Agreement by the Company which is not cured within ten (10) business day days after written notice thereof is given to the Company; or (iii) a relocation of the Employee (other than any relocation requested by the Employee) from the place of assignment of the Employee by the Company as of the Effective Date 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.

4.7. Termination by the Employee without Good Reason. The Employee may terminate his employment hereunder without Good Reason (such termination being referred to in this Agreement as a "**Termination without Good Reason**") at any time upon reasonable notice by the Employee to the Board of no fewer than thirty (30) calendar days; provided that the Company may elect to waive all or any portion of such notice period).

5. **Effect of Termination**.

5.1. Termination for Cause or without Good Reason.

(a) Upon the termination of the Employee's employment hereunder pursuant to a Termination for Cause or a Termination without Good Reason, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries 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) reimbursement for any expenses for which the Employee has not been reimbursed as provided in Section 3.5, provided that 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 but unused vacation time as of the effective date of such termination.

(b) Final Compensation (other than any 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).

5.2. Involuntary Termination. Upon the termination of the Employee's employment hereunder pursuant to an Involuntary Termination, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, or any of its Affiliates under this Agreement except to receive:

(a) Final Compensation in accordance with Section 5.1; and

(b) an aggregate amount equal to one (1) months' Base Salary plus an amount equal to one month of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Employee, payable in accordance with the Company's normal payroll practices, subject to Sections 5.5, 5.6 and 5.7; and

(c) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 3.5.

5.3. Termination without Cause or for Good Reason.

(a) 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to twelve (12) months' Base Salary; and

(iii) an aggregate payment equal to twelve (12) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Employee; and

(iv) a payment equal to pro-rated Target Bonus. (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**").

(b) Subject to Sections 5.5, 5.6 and 5.7, 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 effective date of the termination of the Employee's employment, 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.

5.4. Change in Control Termination.

(a) 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Enhanced Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to twelve (12) months' Base Salary;

(iii) an aggregate payment equal to twelve (12) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Employee; and

(iv) a payment equal to the Pro-rated Bonus.

(b) Subject to Sections 5.5, 5.6 and 5.7, other than Final Compensation, Enhanced Severance Payments will be paid as follows: the amounts under Section 5.4(a)(ii) and Section 5.4(a)(iii) 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 effective date of the termination of the Employee's employment, 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.

(c) 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 Sections 5.5, 5.6 and 5.7.

(d) 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. With regard to any payment considered to be nonqualified deferred compensation under Section 409A (as defined below), to the extent applicable, that is payable upon a Change in Control, to avoid the imposition of an additional tax, interest or penalty under Section 409A (as defined below), no amount will be payable unless such change in control constitutes a "change in control event" within the meaning of Section 1.409A-3(i)(5) of the Treasury Regulations.

5.5. Conditions to Receipt of Severance. The obligation of the Company to make any payments and benefits (other than Final Compensation) to or on behalf of the Employee under Section 5.2, 5.3 or 5.4 above is conditioned on the Employee or, as applicable, his beneficiary or estate signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release of Claims**"), provided that such separation agreement and 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 or his beneficiary or estate will forfeit any rights to severance or benefits (other than Final Compensation) under this Agreement. In no event will severance payments or benefits (other than Final Compensation) be paid or provided under this Agreement until such Release of Claims becomes effective and irrevocable. The first installment of any severance payments to which the Employee or his beneficiary or estate becomes entitled will be paid on the Company's next regular payday that is at least sixty (60) days following the termination date, retroactive to the day following the termination date. If the sixty (60) day period following termination referred to herein extends through two (2) taxable years, to the extent required to comply with Section 409A, such amount will be paid in the second taxable year (but within the sixty (60) day period) following the Employee's termination.

5.6. Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time 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 (a) 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); (b) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (c) other amounts or benefits that are not subject to the requirements of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"). 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). 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. 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.

5.7. 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 Internal Revenue Code of 1986, as amended (the "**Code**"), and (ii) but for this Section 5.7, 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 5.7 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.

6. **Compliance Agreement**. For the avoidance of doubt, the Compliance Agreement executed and delivered by the Employee as of May 7, 2017 (the "**Compliance 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 the Final Compensation) to or on behalf of the Employee under Section 5.3 or 5.4 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.

7. **Standards of Conduct**. The Employee will conduct himself in an ethical and professional manner at all times and in accordance with any employee policies or guidelines which the Parent Company or the Company may issue from time to time.

8. **Indemnification**.

8.1. Indemnification. In the event that (a) the Employee was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Employee's Corporate Status (as defined below) or (b) the Employee was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Employee's Corporate Status, the Employee shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by the Employee in connection with such Proceeding to the maximum extent permitted by applicable law (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, (ii) "**Corporate Status**" means the status of the Employee as an employee and/or

director of the Company, as applicable, (iii) "**Expenses**" means all fees, costs and expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys' fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants, counsels and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) "**Liabilities**" means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

8.2. Advancement of Expenses. The Company agrees that the Company shall pay to the Employee all Indemnifiable Amounts incurred by the Employee in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Employee provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Employee is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

8.3. Limitation on Indemnification. The Employee shall not be entitled to any indemnification under this Section 8 if the Employee knowingly violated any duty, responsibility or obligation imposed under this Agreement, the Compliance Agreement or any Company policy.

8.4. Change in Law. To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Employee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

9. **Representations and Warranties of the Company**. The Company represents and warrants to the Employee that the execution of this Agreement by the Company has been duly authorized by resolution of the Board.

10. **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 of the Company for purposes other than for the furtherance of the business of the Company and 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..

11. **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 11.

12. **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.

13. **Miscellaneous**.

13.1. 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 or 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.

13.2. Time. Time is of the essence in performance of the rights and obligations under this Agreement.

13.3. 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.

13.4. Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, 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.

13.5. 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.

13.6. 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 or understanding among the parties with respect thereto, including without limitation the Existing Agreement. For the avoidance of doubt, the Employee acknowledges, agrees and confirms that Zai Lab Hong Kong is, effective as of the Effective Date, fully and irrevocably discharged and released from any and all obligations arising under or in connection with the Existing Agreement, with the understanding that the Company shall, as of the Effective Date, shall be the Employee's employer of record. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

13.7. 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.

13.8. Severability. Subject to the provisions of Section 11 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.

13.9. 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 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.

13.10. 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.

13.11. 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.

13.12. 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.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

COMPANY: ZAI LAB (US) LLC	EMPLOYEE: HARALD REINHART
By: /s/ Samantha Du	By: /s/ Harald Reinhart
Address: c/o Zai Lab Limited 4560 Jinke Road, Bldg. 1, 4F Pudong, Shanghai, 201210, China	Address: On File with the Company

Exhibit 10.26

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT ("**Agreement**") is made and entered into as of December 1, 2018 (the "**Effective Date**"), by and between Zai Lab Limited, a limited company incorporated under the laws of the Cayman Islands (the "**Company**"), and Tao Fu, an individual (the "**Employee**").

WHEREAS, the Company and the Employee previously entered in that certain Employment Agreement, entered into as of September 12 and effective as of September 24, 2018 (the "**Existing Agreement**"); and

WHEREAS, the Company and the Employee desire to amend and replace the Existing Agreement in its entirely with the terms and conditions set forth in this 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**. The Employee's employment under the terms of this Agreement will commence as of the Effective Date and will continue until terminated in accordance with Section 4 (the "**Employment Period**").

1.1. Duties and Responsibilities. The Company agrees to employ the Employee as the President and Chief Operating Officer of the Company, to render such services and to perform such duties and responsibilities as are normally associated with and inherent in the aforementioned role and the capacity 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. The Employee shall report directly to the Chief Executive Officer of the Company or such other senior executive officer of the Company as designated by the Chief Executive Officer or the Board of Directors (the "**Board**") of the Company.

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 substantially all of his 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 Company 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 and any of the subsidiaries, parents or other affiliates of the Company (collectively, "**Affiliates**") and in one or more executive offices of any of the Affiliates of the Company, provided that the Employee is indemnified for serving in any and all such capacities pursuant to the indemnification provisions set forth in the bylaws of such affiliates.

1.4. Conflicts of Interest. The Employee has reviewed with the Company the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Employee or his associate(s) in all such business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Employee agrees to review with the Company 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. The Employee or his 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 other company that may be directly competitive or directly in conflict with the 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 may require that the Employee travel in furtherance of the business of the Company 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 (as it may be adjusted from time to time, the "**Base Salary**") of US$450,000, with the understanding that, at the sole discretion of the Company, up to an aggregate of (a) fifty percent (50%) of the Base Salary may be paid by the Company or one or more subsidiaries of the Company domiciled in the Cayman Islands (each such subsidiary, a "**Cayman Subsidiary**"), and (b) fifty percent (50%) of the Base Salary may be paid by one or more subsidiaries of the Company domiciled in the United States (each, a "**U.S. Subsidiary**"), in each case, pursuant to a short-form labor contract between the Employee and such Cayman Subsidiary, or U.S. Subsidiary, as applicable, identified by the Company, to the extent required by or desirable under applicable laws. The Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service or similar 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 shall pay such Base Salary in arrears on the last working day (Monday to Friday) of each month in accordance with the standard payroll procedures of the Company (as they may be modified from time to time). The Base Salary will be subject to review by the Board or the Compensation Committee of the Board (the "**Compensation Committee**") and adjustments will be made by the Board or the Compensation Committee based upon its respective normal performance review practices.

3.2. Equity Incentives. For the avoidance of doubt, the Employee acknowledges, agrees and confirms (i) that, as of the date of this Agreement, the Employee has been granted, in accordance with the provisions of the Existing Agreement and the Zai Lab Limited 2017 Equity Incentive Plan (the "**Plan**"), (A) an option to purchase 500,000 American Depository Shares representing ordinary shares of the Company (the "**Existing Option**"), as evidenced by that certain Option Agreement dated as of September 24, 2018 and entered into by and between the Company and the Employee (the "**Option Agreement**") and (B) 200,000 American Depository

Shares representing ordinary shares of the Company (the "**Existing Restricted Stock Award**"), as evidenced by that certain Restricted Stock Agreement dated as of September 24, 2018 and entered into by and between the Parent and the Employee (the "**Restricted Stock Agreement**"); (ii) that this Agreement does not modify or otherwise supplement the terms and conditions pertaining to the Existing Option or the Existing Restricted Stock Award; and (iii) that the Employee has no further rights or claims to any additional options or equity incentive awards other than the Existing Option and the Existing Restricted Stock Award. The Plan, the Option Agreement and the Restricted Stock Agreement are incorporated herein by reference.

3.3. Bonuses.

(a) Annual Bonus. During the Employment Period, the Employee may be eligible to receive an annual bonus with a target equal to 45% of the Base Salary (the "**Target Bonus**"), the actual amount of which shall be determined by the Board or the Compensation Committee in its respective 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.

(b) Sign-on Bonus. The Employee will be eligible to receive a cash payment of US$300,000 (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 according to the regularly scheduled payroll for such month of payment. In the event that the Employee's employment is terminated by the Company for Cause (as defined below) within the three (3) year period following the commencement of his employment with the Company, 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 for any reason or the Employee is terminated by the Company without Cause prior to the third anniversary of the commencement of his employment with the Company, he/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, in its respective sole and exclusive 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 him for or on behalf of the Company in the performance of his duties hereunder upon presentation by the Employee of appropriate documentation. 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 or a subsidiary of the Company shall deduct from any compensation payable to the Employee the sums which the Company or such subsidiary 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 or such subsidiary 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 him mentally or physically incapable of performing the services required to be performed by him 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 him 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 3.1, notwithstanding any such physical or mental disability. Termination pursuant to this Section 4.1 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 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 occurs first.

4.3. Disability Income Payments. While receiving disability income payments under the Company's disability income insurance, if any (the "**Disability Payments**"), 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, 3.4 and 3.5 until the date of the Employee's termination of employment.

4.4. Verification of Disability. If any question arises 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 arises and the Employee fails to submit to such medical examination, the Company's determination of the issue shall be binding on the Employee.

4.5. Termination by the Company for Cause. The Company may terminate the employment of the Employee hereunder at any time during the Employment Period for Cause (as defined below) (such termination being referred to in this Agreement 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 Agreement, "**Cause**" means any one of the following grounds, as determined by the Board in its reasonably judgment:

(a) 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;

(b) the Employee's commission of a felony, or any crime involving fraud, moral turpitude or misrepresentation or violation of applicable securities laws;

(c) 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;

(d) the Employee's material 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; or

(e) 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.

4.6. Termination by the Company without Cause. The Company may terminate the employment of the Employee hereunder at any time during the Employment Period without "Cause" (such termination referred to in this Agreement as a "**Termination without Cause**").

4.7. Termination by the Employee for Good Reason. The Employee may terminate his employment hereunder at any time for Good Reason (as defined below) by giving the Company written notice of such termination, provided that such notice specifies: (a) the basis for termination and (b) the effective date of termination (such termination being referred to in this

Agreement as a "**Termination for Good Reason**"). For purposes of this Agreement, the term "**Good Reason**" shall mean (i) 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; (ii) any material breach of this Agreement by the Company which is not cured within ten (10) business day days after written notice thereof is given to the Company; or (iii) a relocation of the Employee (other than any relocation requested by the Employee) from the place of assignment of the Employee by the Company as of the Effective Date 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.

4.8. Termination by the Employee without Good Reason. The Employee may terminate his employment hereunder without Good Reason (such termination being referred to in this Agreement as a "**Termination without Good Reason**") at any time upon reasonable notice by the Employee to the Board of no fewer than thirty (30) calendar days; provided that the Company may elect to waive all or any portion of such notice period).

5. **Effect of Termination**.

5.1. Termination for Cause or without Good Reason.

(a) Upon the termination of the Employee's employment hereunder pursuant to a Termination for Cause or a Termination without Good Reason, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries 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) reimbursement for any expenses for which the Employee has not been reimbursed as provided in Section 3.5, provided that 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 but unused vacation time as of the effective date of such termination.

(b) Final Compensation (other than any 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).

5.2. Involuntary Termination. Upon the termination of the Employee's employment hereunder pursuant to an Involuntary Termination, neither the Employee nor his 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 5.1; and

(ii) an aggregate amount equal to one (1) months' Base Salary plus an amount equal to one month of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Employee, payable in accordance with the Company's normal payroll practices, subject to Sections 5.5, 13.3 and 13.4; and

(iii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 3.5.

5.3. Termination without Cause or for Good Reason.

(a) 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to twelve (12) months' Base Salary; and

(iii) an aggregate payment equal to twelve (12) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Employee; and

(iv) a payment equal to a pro-rated Target Bonus (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.

(b) Subject to Sections 5.5, 13.3 and 13.4, 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 effective date of the termination of the Employee's employment,

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.

5.4. Change in Control Termination.

(a) 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 his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Enhanced Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to twelve (12) months' Base Salary;

(iii) an aggregate payment equal to twelve (12) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Employee; and

(iv) a payment equal to the Pro-rated Bonus.

(b) Subject to Sections 5.5, 13.3 and 13.4, Enhanced Severance Payments (other than Final Compensation) will be paid as follows: the amounts under Section 5.4(a)(ii)-(iv) 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 effective date of the termination of the Employee's employment, 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.

(c) 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 Company, subject to Sections 5.5, 13.3 and 13.4.

(d) 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 Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company, except

that any change in the ownership of the stock of the Company as a result of a private financing of the 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 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 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 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 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 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 Company's securities immediately before such transaction. With regard to any payment considered to be nonqualified deferred compensation under Section 409A (as defined below), to the extent applicable, that is payable upon a Change in Control, to avoid the imposition of an additional tax, interest or penalty under Section 409A (as defined below), no amount will be payable unless such change in control constitutes a "change in control event" within the meaning of Section 1.409A-3(i)(5) of the Treasury Regulations.

5.5. Conditions to Receipt of Severance. The obligation of the Company to make any payments and benefits to or on behalf of the Employee under Sections 5.2-5.4 above (other than Final Compensation) is conditioned on the Employee or, as applicable, his beneficiary or estate signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release of Claims**"), provided that such separation agreement and 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 or his beneficiary or estate will forfeit any rights to severance or benefits (other than Final Compensation) under this Agreement. In no event will severance payments or benefits (other than Final Compensation) be paid or provided under this Agreement until such Release of Claims becomes effective and irrevocable. The first installment of any severance payments to which the Employee or his beneficiary or estate becomes entitled will be paid on the Company's next regular payday that is at least sixty (60) days following

the termination date, retroactive to the day following the termination date. If the sixty (60) day period following termination referred to herein extends through two (2) taxable years, to the extent required to comply with Section 409A, such amount will be paid in the second taxable year (but within the sixty (60) day period) following the Employee's termination.

6. **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 the Final Compensation) to or on behalf of the Employee under Section 5.3 or 5.4 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.

7. **Standards of Conduct**. The Employee will conduct himself 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.

8. **Indemnification**.

8.1. Indemnification. In the event that (a) the Employee was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Employee's Corporate Status (as defined below) or (b) the Employee was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Employee's Corporate Status, the Employee shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by the Employee in connection with such Proceeding to the maximum extent permitted by applicable law (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, (ii) "**Corporate Status**" means the status of the Employee as an employee and/or director of the Company, as applicable, (iii) "**Expenses**" means all fees, costs and expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys' fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants, counsels and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) "**Liabilities**" means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

8.2. Advancement of Expenses. The Company agrees that the Company shall pay to the Employee all Indemnifiable Amounts incurred by the Employee in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Employee provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Employee is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

8.3. Limitation on Indemnification. The Employee shall not be entitled to any indemnification under this Section 8 if the Employee knowingly violated any duty, responsibility or obligation imposed under this Agreement, the Compliance Agreement or any Company policy.

8.4. Change in Law. To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Employee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

9. **Representations and Warranties of the Company**. The Company represents and warrants to the Employee that the execution of this Agreement by the Company has been duly authorized by resolution of the Board.

10. **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 of the Company for purposes other than for the furtherance of the business of the Company and 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..

11. **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 11.

12. **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.

13. **Miscellaneous**.

13.1. 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 or 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.

13.2. Time. Time is of the essence in performance of the rights and obligations under this Agreement.

13.3. Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time 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 (a) 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); (b) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (c) 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**"). 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). 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. 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.

13.4. 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 5.7, 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 5.7 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.

13.5. 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.

13.6. Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the State 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.

13.7. 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.

13.8. 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 or understanding among the parties with respect thereto, including without limitation the Existing Agreement. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

13.9. 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.

13.10. Severability. Subject to the provisions of Section 11 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.

13.11. 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 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.

13.12. 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.

13.13. 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.

13.14. 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.

ZAI LAB LIMITED	EMPLOYEE:
By: /s/Samantha Du	By: /s/Tao Fu
Address:	Address:
4560 Jinke Road, Bldg. 1, 4F Pudong, Shanghai, 201210, China	On File with the Company

SIGNATURE PAGE OF EMPLOYMENT AGREEMENT

Exhibit 10.27

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT ("**Agreement**") is made and entered into as of March 22, 2019 (the "**Effective Date**"), by and between Zai Lab (US) LLC (the "**Company**"), and **Yongjiang Hei** (the "**Employee**").

RECITALS

WHEREAS, 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**");

WHEREAS, the Company and the Employee previously entered into that certain Employment Agreement, dated as of August 6, 2018 (the "**Existing Agreement**"); and

WHEREAS, the Company and the Employee desire to amend and replace the Existing Agreement in its entirety with the terms and conditions set forth in 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 Medical Officer, Oncology** of the Company. In addition, the Employee shall serve as the Chief Medical Officer, Oncology 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 Shanghai, China. 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$500,000, with the understanding that, at the sole discretion of the Company or the Parent Company, up to an aggregate of (a) sixty percent (60%) of the Base Salary may be paid by the Company, (b) forty percent (40%) of the Base Salary may be paid by one of more Affiliates of the Company domiciled in China, in this case, pursuant to a short-form labor contract between you and such Affiliates, as applicable, identified by the Company, to the extent required by or desirable under applicable laws. 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. For the avoidance of doubt, the Employee acknowledges, agrees and confirms that (i) as of the date of this Agreement, the Employee has been granted, in accordance with the provisions of the Existing Agreement and the Parent Company's 2017 Equity incentive Plan (the "**Plan**"), (A) an option to purchase 375,000 American Depositary Shares ("**ADSs**") representing ordinary shares of the Parent Company (the "**Existing Option**"), as evidenced by that certain Option Agreement dated of [ ], 2018 and entered into by and between the Employee and the Parent Company (the "**Option Agreement**") and (B) 125,000 ADSs representing ordinary shares of the Parent Company (the "**Existing Restricted Stock Grant**"), as evidenced by that certain Restricted Stock Agreement dated as of [ ], 2018 and entered into by and between the Employee and the Parent Company (the "**Restricted Stock Agreement**"); (ii) this Agreement does not modify or otherwise supplement the terms and conditions pertaining to the Existing Option or the Existing Restricted Stock Grant; and (iii) the Employee has no further rights or claims to any additional options or equity incentive awards other than the Existing Option and the Existing Restricted Stock Grant. The Plan, the Option Agreement and the Restricted Stock Agreement are incorporated herein by reference.

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 50% 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 eligible to receive a cash payment of US$150,000 (the "**Sign-On Bonus**") on the seven-month anniversary of his continuous employment with the Company (calculated as of a start date of August 6, 2018), 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 August 6, 2018, 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 August 6, 2018, he 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 him for or on behalf of the Company in the performance of his 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 him mentally or physically incapable of performing the services required to be performed by him 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 him 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

(vi) 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 his 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 his 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 his 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 his 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 his 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 (3rd) anniversary of August 6, 2018, or (ii) for twelve (12) months if such termination occurs on or following the third (3rd) anniversary of August 6, 2018, (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 (3rd) anniversary of August 6, 2018, or (ii) for twelve (12) months if such **termination** occurs on or following the third (3rd) anniversary of August 6, 2018, (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 his 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 himself 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:		**EMPLOYEE:**	
By:	/s/ Samantha Du	/s/ Yongjiang Hei	
Print Name:	Samantha Du	Yongjiang Hei	
Title:	Chairperson and CEO		
		Address:	XXX
Address:			
Facsimile:			
E-mail:	XXX	E-Mail:	XXX

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 with respect to the period covered by this report;

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, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, 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 and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 29, 2019

By: /s/ Samantha Du
Samantha Du
Chief Executive Office

Exhibit 12.2

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, William 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 with respect to the period covered by this report;

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, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, 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 and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 29, 2019

By: /s/ William Cho
William Cho
Chief Financial Officer

Exhibit 15.1

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, 2018 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: March 29, 2019

By: /s/ Samantha Du
Samantha Du
Chief Executive Office

Exhibit 15.2

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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William 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: March 29, 2019

By: /s/ William Cho
William Cho
Chief Financial Officer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement No. 333-221616 on Form S-8 of our report dated March 29, 2019, relating to the consolidated financial statements and financial statement schedule of Zai Lab Limited and its subsidiaries (the "Group"), appearing in this Annual Report on Form 20-F of Zai Lab Limited for the year ended December 31, 2018.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China
March 29, 2019

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

March 29, 2019

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, 2018 (the "**Annual Report**"), which will be filed with the Securities and Exchange Commission (the "**SEC**") in the month of March 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