UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

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FORM 10-Q	

(Mark One)

X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 19

For the quarterly period ended September 30, 2022

ΛR

O TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 19

For the transition period from _____ to ____

Commission File Number: 001-38205

ZAI LAB LIMITED (Exact Name of Registrant as Specified in its Charter)

Cayman Islands 98-1144595
(State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.)

4560 Jinke Road Bldg. 1, Fourth Floor, Pudong Shanghai China

China

314 Main Street
4th Floor, Suite 100
Cambridge, MA, USA
(Address of principal executive offices)

02142 (Zip Code)

201210

+86 216163 2588 (Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 10 Ordinary Shares, par value \$0.000006 per share	ZLAB	The Nasdaq Global Market
Ordinary Shares, par value \$0.000006 per share*	9688	The Stock Exchange of Hong Kong Limited

^{*} Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

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 x No o

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 x No o

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

Large accelerated filer

X

Non-accelerated filer

O

Smaller reporting company

If an emerging growth company, 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 provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Emerging growth company

As of November 3, 2022, 979,087,430 ordinary shares of the registrant, par value \$0.000006 per share, were outstanding, of which 743,576,320 ordinary shares were held in the form of American Depositary Shares.

Zai Lab Limited Quarterly Report on Form 10-Q

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SPECIAL NOTES REGARDING THE COMPANY

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements include, without limitation, statements containing words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potentially," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information, that are not statements of historical facts, nor are they guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions, and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks, and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. 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 the following:

- The effects of the COVID-19 pandemic, including any government actions and lockdown measures taken in response, particularly in mainland China where our operations and product markets are primarily located;
- Changes in United States and China trade policies and relations, as well as relations with other countries, and/or changes in regulations and/or sanctions that may adversely impact our business, operating results, ability to raise capital, and market price of our ordinary shares and/or our ADSs;
- Actions the Chinese government may take to intervene in or influence our operations, which could result in a material change in our operations and significantly and adversely impact the value of our ADSs and ordinary shares, including potentially making those ADSs or ordinary shares worthless;
- Economic, political, and social conditions in mainland China, as well as governmental policies, that could affect the business environment and financial markets in mainland China and our ability to operate our business, liquidity, and access to capital;
- Uncertainties in the Chinese legal system that could materially and adversely affect us; including the Data Security Law, the Cyber Security Law, the Cybersecurity Review Measures, the Personal Information Protection Law, the Regulation on the Administration of Human Genetic Resources, the Biosecurity Law, the Security Assessment Measures, and any other future laws and regulations, which may entail significant expenses for compliance or otherwise materially affect our business;
- Any approval, filing, or procedural requirements by the China Securities Regulatory Commission ("CSRC") or other Chinese regulatory authorities in
 connection with issuing securities to foreign investors under Chinese law, which could affect our ability to raise capital;
- Any violation or liability under the U.S. Foreign Corrupt Practices Act or Chinese anti-corruption laws, which could have a material adverse effect on our business or reputation;
- Restrictions on currency exchange that could limit our ability to receive and use financing in foreign currencies effectively;
- Any limitation on the ability of our Chinese subsidiaries to make payments to us that could have a material and adverse effect on our ability to conduct our business or fund our cash and financing requirements;
- Chinese requirements on the ability of residents in mainland China to establish offshore special purpose companies by residents in mainland China, which may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in mainland 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 otherwise adversely affect us;
- Chinese regulations regarding acquisitions of mainland China based companies by foreign investors which could make it more difficult for us to pursue growth through acquisitions in mainland China;
- Any issues that our Chinese manufacturing facilities have with operating in conformity with established GMPs and international best practices, and passing FDA, National Medical Products Administration ("NMPA"), and EMA inspections, which could result in a longer and costlier GMP inspection and approval process by the FDA, NMPA, or EMA for our Chinese manufacturing processes and third-party contract manufacturers;
- Expiration of, or changes to, financial incentives or discretionary policies granted by local governments that could have an adverse effect on our results of operations;

- Any difficulty for overseas regulators to conduct investigations or collect evidence within mainland China that could adversely affect our business, compliance with regulatory requirements, ability to raise capital, and share price of our ordinary shares and/or ADSs;
- Any unfavorable tax consequences to us and our non-Chinese shareholders or ADS holders if we were to be classified as a Chinese resident enterprise for Chinese income tax purposes;
- Any failure to comply with applicable Chinese, U.S., and Hong Kong regulations that could lead to government enforcement actions, subject us to fines and other legal or administrative sanctions, or otherwise adversely affect our business, financial condition, and results of operations;
- · Any review by the Committee on Foreign Investment in the United States in our investments, which may delay or block a transaction from closing;
- · Failure to renew our current leases or locate desirable alternatives for our leased properties which could adversely affect our business;
- Our ability to generate revenues from our four approved products;
- Any inability of third parties on whom we rely to conduct our pre-clinical and clinical trials to successfully carry out their contractual duties or meet expected deadlines that could adversely affect our ability to obtain regulatory approval for, or commercialize, our products or product candidates; and
- Any inability to obtain or maintain sufficient patent protection for our products and product candidates that could adversely affect our business by allowing third parties to compete directly against us.

These factors should not be construed as exhaustive and should be read with the other cautionary statements and information in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 2022 (the "2021 Annual Report"), our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC on May 10, 2022 (the "Q1 2022 Form 10-Q"), our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 9, 2022 (the "Q2 2022 Form 10-Q"), and this Quarterly Report on Form 10-Q. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date. We anticipate that subsequent events and developments will cause our expectations and assumptions to change, and we undertake no obligation to 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 our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Usage of Terms

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Greater China" refer to mainland China, Hong Kong Special Administrative Region ("Hong Kong"), Macau Special Administrative Region ("Macau"), and Taiwan, collectively; references to "Zai Lab," the "Company," "we," "us," and "our" refer to Zai Lab Limited, a holding company and its subsidiaries, on a consolidated basis; and references to "Zai Lab Limited" refer to Zai Lab Limited, a holding company. Zai Lab Limited is the entity in which investors are purchasing their interest.

Our operating subsidiaries consist of Zai Lab (Hong Kong) Limited, domiciled in Hong Kong; Zai Auto Immune (Hong Kong) Limited, domiciled in Hong Kong; Zai Anti Infectives (Hong Kong) Limited, domiciled in Hong Kong; Zai Lab (Shanghai) Co., Ltd., domiciled in mainland China; Zai Lab International Trading (Shanghai) Co., Ltd., domiciled in mainland China; Zai Biopharmaceutical (Suzhou) Co., Ltd., domiciled in mainland China; Zai Lab Trading (Suzhou) Co., Ltd., domiciled in mainland China; Zai Lab (Taiwan) Limited, domiciled in Taiwan; Zai Lab (AUST) Pty. Ltd., domiciled in Australia; and Zai Lab (US) LLC, domiciled in the United States. As of the date of this Quarterly Report on Form 10-Q, Zai Anti Infectives (Hong Kong) Limited has non-substantial business operations.

Disclosures Relating to Our Chinese Operations

Zai Lab Limited is not a Chinese operating company, but a holding company incorporated in the Cayman Islands.

Zai Lab Limited is not a Chinese operating company, but a holding company incorporated in the Cayman Islands. As a holding company, we conduct a substantial portion of our operations through wholly owned subsidiaries based in mainland China. Investors will not hold direct investments in our Chinese operating companies. In July 2021, the Chinese government provided new guidance on Chinese companies raising capital outside of mainland China, including through arrangements called variable interest entities ("VIEs"). Currently, our corporate structure contains no VIEs, and the life sciences industry in which we operate is not subject to foreign ownership limitations in mainland China. However, there are uncertainties with respect to the Chinese legal system, and there may be changes in laws, regulations, and policies, including how those laws, regulations, and policies will be interpreted or implemented. If, in the future, the Chinese

government determines that our corporate structure does not comply with Chinese regulations, or if Chinese regulations change or are interpreted differently, the value of our American Depositary Shares ("ADSs") and/or ordinary shares may decline or become worthless.

There are significant legal and operational risks associated with conducting a substantial portion of our operations in mainland China, including that changes in the legal, political, and economic policies of the Chinese government, the relations between mainland China and the United States, or Chinese or U.S. regulations may materially and adversely affect our business, financial condition, results of operations, and the market price of our ADSs and/or ordinary shares.

There are significant legal and operational risks associated with conducting a substantial portion of our operations in mainland China, including that changes in the legal, political, and economic policies of the Chinese government, the relations between mainland China and the United States, or Chinese or U.S. regulations may materially and adversely affect our business, financial condition, results of operations, and the market price of our ADSs and/or ordinary shares. Any such changes could significantly limit or completely hinder our ability to offer or continue to offer our ADSs and/or ordinary shares to investors and could cause the value of our ADSs or ordinary shares to significantly decline or become worthless. For example, geopolitical events, such as developments with respect to Taiwan, continue to cause heightened tensions between the United States and China, which could have potential adverse effects on our business, results of operations, ability to raise capital or raise capital on favorable terms, or the market price of our ordinary shares and/or ADSs. In addition, our obligations to comply with the Personal Information Protection Law, the Data Security Law, the Cyber Security Law, the Cybersecurity Review Measures (which became effective on February 15, 2022), the Measures on Security Assessment of Cross-Border Data Transfer (which became effective on September 1, 2022) (the "Security Assessment Measures"), regulations and guidelines relating to the multi-level protection scheme, and any other future laws and regulations may require us to incur significant expenses and could materially affect our ability to conduct our business, accept foreign investments, or continue to be listed on a U.S. or foreign stock exchange.

For more information on these risks and other risks relating to our ADSs and ordinary shares, see "Item 1A. Risk Factors" in our 2021 Annual Report and in this Quarterly Report on Form 10-Q.

We are required to obtain certain permissions from Chinese authorities to operate in mainland China, issue securities to foreign investors, and transfer certain scientific data.

We are required to obtain certain permissions from Chinese authorities to operate in mainland China, issue securities to foreign investors, and transfer certain scientific data. The Chinese government has exercised, and may continue to exercise, substantial influence or control over virtually every sector of the Chinese economy through regulation and state ownership. Our ability to operate in mainland China may be undermined if our Chinese subsidiaries are not able to obtain or maintain approvals to operate in mainland China. The central or local governments could impose new, stricter regulations or interpretations of existing regulations that could require additional expenditures and efforts on our part to comply with such regulations or interpretations.

As of the date of this Quarterly Report on Form 10-Q, we are not currently required to obtain approval or prior permission from the CSRC or any other Chinese regulatory authority under the Chinese laws and regulations currently in effect to issue securities to foreign investors. However, in January 2022, the CSRC released for public comment draft rules titled Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) and Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (together, the "Draft Rules"). If the Draft Rules are adopted in their current form, we would likely be required to submit filings to the CSRC in connection with the future issuance of our equity securities to foreign investors. As there are uncertainties with respect to the Chinese legal system and changes in laws, regulations, and policies, including how those laws, regulations, and policies will be interpreted or implemented, we could be subject to additional requirements, approvals, or permissions in the future. We are required to obtain certain approvals from Chinese authorities in order to operate our Chinese subsidiaries. We are also required to obtain certain approvals from Chinese authorities before transferring certain scientific data abroad or to foreign parties or entities established or actually controlled by them.

We will be required to obtain approval from the Cyberspace Administration of China ("CAC") when the transfers out of mainland China of certain data that is determined to be important data or personal data falls into any of the scenarios requiring a security assessment by the CAC specified in the Security Assessment Measures. The cross-border transfer out of mainland China of data requiring such a security assessment will not be allowed if the CAC does not approve the security assessment filing. In addition, the disclosure, sharing, or exporting to a foreign entity by a Chinese-owned entity of any data derived from human organs, tissues, or cells of Chinese individuals that contain human genetic materials requires a project-level approval by or a separate notification to the Human Genetic Resources Administration of China ("HGRAC"). The HGRAC also requires submission of a copy of the data to be exported. If our Chinese subsidiaries intend

to receive certain clinical or personal data from Chinese-owned entities or transfer certain clinical or personal data out of mainland China, they will need to first evaluate whether a security assessment by the CAC or a clearance from the HGRAC will be triggered by such data transfer, pass the security assessment, make the necessary notification filings, or obtain the necessary project-level approvals for such data transfer.

If our Chinese subsidiaries do not receive or maintain approvals or inadvertently conclude that approvals needed for their business are not required, or if there are changes in applicable laws (including regulations) or interpretations of laws and our Chinese subsidiaries are required but unable to obtain approvals in the future, then such changes or need for approvals (if not obtained) could adversely affect the operations of our Chinese subsidiaries, including limiting or prohibiting the ability of our Chinese subsidiaries to operate, and the value of our ADSs and/or ordinary shares could significantly decline or become worthless.

For more information on these required permissions, see "Item 1A. Risk Factors" in our 2021 Annual Report.

To operate our general business activities currently conducted in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the State Administration for Market Regulation ("SAMR").

To operate our general business activities currently conducted in mainland China, each of our Chinese subsidiaries is required to obtain a business license from the local counterpart of the SAMR. Each of our Chinese subsidiaries has obtained a valid business license from the local counterpart of the SAMR, and no application for any such license has been denied. Our Chinese subsidiaries are also required to obtain certain licenses and permits, including but not limited to the following material licenses and permits: Pharmaceutical Manufacturing Permits, Pharmaceutical Distribution Permits, and Medical Device Distribution Permits to manufacture and/or distribute drugs and/or applicable medical devices. No application for any such material license or permit has been denied.

Because our prior auditor, which filed an audit report with our last annual report, was located in mainland China, a jurisdiction where the U.S. Public Company Accounting Oversight Board ("PCAOB") is unable to inspect or investigate completely because of restrictions imposed by Chinese authorities, SEC staff conclusively identified us under the Holding Foreign Companies Accountable Act ("HFCAA") in March 2022. Because the Company subsequently engaged KPMG LLP ("KPMG"), a U.S. auditor that is subject to inspection and review by the PCAOB, to be our independent registered public accounting firm for the fiscal year ending December 31, 2022 and because the Company has a principal executive office, significant operations, and a majority of our Board members and executives in the United States, we believe we have mitigated our risk of delisting pursuant to the HFCAA. However, if we were to fail to meet the audit requirements of the HFCAA for three consecutive years (or two years, if bills passed by the U.S. Senate or House of Representatives are enacted), we may be prohibited from listing our securities on a national securities exchange or over-the-counter market in the United States and delisted from the Nasdaq Global Market ("Nasdaq"). The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively.

In recent years, the U.S. Congress and regulatory authorities have expressed concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in mainland China, and in December 2020, the United States enacted the HFCAA. The HFCAA requires the SEC to identify issuers that have filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the PCAOB has determined it is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction (a "Commission-Identified Issuer"). The PCAOB has issued a Determination Report, which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by Chinese authorities in those jurisdictions, and in March 2022, SEC staff conclusively identified the Company as a Commission-Identified Issuer because our prior auditor, which filed an audit report with our 2021 Annual Report, was located in mainland China.

Under the HFCAA, if the SEC conclusively identifies an issuer as a Commission-Identified Issuer for three consecutive years, the SEC is required to prohibit the trading of the issuer's securities on a national securities exchange or through any other method that is within the jurisdiction of the SEC to regulate, including over-the-counter markets in the United States. If either the Accelerating Holding Foreign Companies Accountable Act passed by the U.S. Senate in June 2021 or the America Creating Opportunities for Manufacturing Pre-Eminence in Technology and Economic Strength (COMPETES) Act of 2022 passed by the U.S. House of Representatives in February 2022 are enacted, the number of non-inspection years would be reduced from three years to two years. It is unclear if or when either of these bills will be signed into law.

In May 2022 the Company engaged KPMG, an auditor located in the United States that is inspected by the PCAOB, as our independent registered public accounting firm for the fiscal year ending December 31, 2022. In addition, we have a

principal executive office, significant operations, and a majority of our Board members and executive officers in the United States. As a result, we believe that we have mitigated our risk of delisting pursuant to the HFCAA. However, if we were to fail to meet the audit requirements of the HFCAA for three consecutive years (or two years if the number of non-inspection years is reduced by legislation), our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges, and this ultimately could result in our ADSs being delisted. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. The foregoing could adversely affect the market price of our ordinary shares and/or ADSs and our ability to raise capital effectively. The market price of our ordinary shares and/or ADSs also could be adversely affected as a result of anticipated negative impacts of such legislative or executive actions upon, as well as negative investor sentiment toward, companies with significant operations in mainland China and Hong Kong that are listed in the United States, regardless of whether such actions are implemented and regardless of our actual operating performance.

On August 26, 2022, the PCAOB signed a Statement of Protocol with the CSRC and the Ministry of Finance of the PRC governing inspections and investigations of audit firms based in mainland China and Hong Kong, which marks the first time it has received such detailed and specific commitments from China that China would allow PCAOB inspection and investigations meeting U.S. standards. However, it is uncertain whether the PCAOB will determine that it has sufficient access to inspect and review the work papers of Chinese auditors of U.S. listed companies and whether or how this recent development will affect the SEC's designation of issuers under the HFCAA.

PART I - FINANCIAL INFORMATION

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial information and the accompanying notes included in our 2021 Annual Report.

Item 1. Financial Statements.

Zai Lab Limited

Unaudited condensed consolidated balance sheets

(In thousands of U.S. dollars ("\$") except for number of shares and per share data)

	Notes	September 30, 2022	December 31, 2021
-		\$	\$
Assets			
Current assets:			
Cash and cash equivalents	3	1,119,476	964,100
Short-term investments		_	445,000
Accounts receivable (net of allowance for credit loss of \$8 and \$11 as of September 30, 2022 and December 31, 2021, respectively)		27,736	47,474
Notes receivable		10,251	7,335
Inventories, net	4	29,131	18,951
Value added tax recoverable - current		1,080	· <u> </u>
Prepayments and other current assets		22,157	18,021
Total current assets	_	1,209,831	1,500,881
Restricted cash, non-current		803	803
Long term investments (including the fair value measured investment of \$3,316 and \$15,383 as of September 30, 2022 and		005	003
December 31, 2021, respectively)		3,316	15,605
		4,068	989
Prepayments for equipment Property and equipment, net	5	50,528	43,102
	5	20,269	45,102 14,189
Operating lease right-of-use assets			
Land use rights, net		6,824	7,811
Intangible assets, net		1,540	1,848
Long-term deposits		1,329	870
Value added tax recoverable	_	6	23,858
Total assets	_	1,298,514	1,609,956
Liabilities and shareholders' equity	_		
Current liabilities:			
Accounts payable		90,112	126,163
Current operating lease liabilities		6,980	5,927
Other current liabilities	8	58,456	60,811
Total current liabilities	_	155,548	192,901
Deferred income	_	23,205	27,486
Non-current operating lease liabilities		13,892	9,613
Total liabilities	_	192,645	230,000
Commitments and contingencies (Note 14)	_		
Shareholders' equity			
Ordinary shares (par value of \$0.000006 per share; 5,000,000,000 shares authorized; 961,829,720 and 955,363,980 shares issued as of September 30, 2022 and December 31, 2021, respectively; 959,724,940 and 954,981,050 shares outstanding as of September 30, 2022 and December 31, 2021, respectively)		6	6
Additional paid-in capital		2,877,361	2,825,948
Accumulated deficit		(1,799,591)	(1,418,074
		(1,799,591)	* * * * *
Accumulated other comprehensive income (loss) Transpure Steel (st. cost. 2 104.700 and 203.020 charge as of September 20, 2022 and December 21, 2021, respectively)			(23,645
Treasury Stock (at cost, 2,104,780 and 382,930 shares as of September 30, 2022 and December 31, 2021, respectively)		(11,456)	(4,279)
Total shareholders' equity	_	1,105,869	1,379,956
Total liabilities and shareholders' equity		1,298,514	1,609,956

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

Zai Lab Limited

Unaudited condensed consolidated statements of operations

(In thousands of U.S. dollars ("\$") except for number of shares and per share data)

	Three Months Ended September 30,			Nine Months September	
	Notes	2022	2021	2022	2021
		\$	\$	\$	\$
Revenues:					
Product revenue, net	6	56,963	43,103	150,633	100,141
Collaboration revenue	6	577		1,806	_
Total revenues		57,540	43,103	152,439	100,141
Expenses:					
Cost of sales		(20,044)	(12,162)	(53,094)	(30,535)
Research and development		(99,524)	(55,144)	(219,462)	(401,220)
Selling, general, and administrative		(66,555)	(59,002)	(186,947)	(149,254)
Loss from operations		(128,583)	(83,205)	(307,064)	(480,868)
Interest income		3,872	713	5,235	1,171
Other income (expenses), net		(36,479)	(13,580)	(79,467)	(12,401)
Loss before income tax and share of loss from equity method investment		(161,190)	(96,072)	(381,296)	(492,098)
Income tax expense	7	_	_	_	_
Share of loss from equity method investment		_	(340)	(221)	(548)
Net loss		(161,190)	(96,412)	(381,517)	(492,646)
Net loss attributable to ordinary shareholders		(161,190)	(96,412)	(381,517)	(492,646)
Loss per share - basic and diluted	9	(0.17)	(0.10)	(0.40)	(0.53)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		959,085,960	950,354,320	957,439,910	921,748,380
Loss per American Depositary Shares ("ADS") - basic and diluted		(1.68)	(1.01)	(3.98)	(5.34)
Weighted-average ADSs used in calculating net loss per ADS - basic and diluted $$		95,908,596	95,035,432	95,743,991	92,174,838

Note: All the numbers of ordinary shares and per share data in these unaudited condensed consolidated financial statements have been retrospectively adjusted as a result of the Share Subdivision and the ADS Ratio Change that became effective on March 30, 2022. The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company. Refer to Note 2(a) for a detailed discussion.

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

Unaudited condensed consolidated statements of comprehensive loss

(In thousands of U.S. dollars ("\$") except for number of shares and per share data)

	Three Months Ended	Three Months Ended September 30,		Ended · 30,
	2022	2021	2022	2021
	\$	\$	\$	\$
Net loss	(161,190)	(96,412)	(381,517)	(492,646)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	35,062	1,741	63,194	(600)
Comprehensive loss	(126,128)	(94,671)	(318,323)	(493,246)

 $The\ accompanying\ notes\ are\ an\ integral\ part\ of\ these\ unaudited\ condensed\ consolidated\ financial\ statements.$

Zai Lab Limited
Unaudited condensed consolidated statements of shareholders' equity
(In thousands of U.S. dollars ("\$") except for number of shares and per share data)

	Ordinary S	rdinary Shares				Accumulated		Treasury Stock			
	Number of Shares	Amount	Additional paid in capital	Accumulated deficit	other comprehensive (loss) income	Shares	Amount	Total			
		\$	\$	\$	\$		\$	\$			
Balance at December 31, 2021	955,363,980	6	2,825,948	(1,418,074)	(23,645)	(382,930)	(4,279)	1,379,956			
Issuance of ordinary shares upon vesting of restricted shares	514,800	0	0	_	_	_	_	_			
Exercise of shares options	1,156,660	0	297	_	_	_	_	297			
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	_	_	_	_	_	(15,150)	(68)	(68)			
Share-based compensation	_	_	12,410	_	_	_	_	12,410			
Net loss	_	_	_	(82,394)	_	_	_	(82,394)			
Foreign currency translation	_	_	_	_	(2,193)	_	_	(2,193)			
Balance at March 31, 2022	957,035,440	6	2,838,655	(1,500,468)	(25,838)	(398,080)	(4,347)	1,308,008			
Issuance of ordinary shares upon vesting of restricted shares	683,700	0	0			_		_			
Exercise of shares options	2,801,000	0	4,322	_	_	_	_	4,322			
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	_	_	_	_	_	(1,627,230)	(6,782)	(6,782)			
Share-based compensation	_	_	14,225	_	_	_	_	14,225			
Net loss	_	_	_	(137,933)	_	_	_	(137,933)			
Foreign currency translation	_	_	_	_	30,325	_	_	30,325			
Balance at June 30, 2022	960,520,140	6	2,857,202	(1,638,401)	4,487	(2,025,310)	(11,129)	1,212,165			
Issuance of ordinary shares upon vesting of restricted shares	230,250	0	0								
Exercise of shares options	1,079,330	0	1,052	_	_	_	_	1,052			
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	_	_	_	_	_	(79,470)	(327)	(327)			
Share-based compensation	_	_	19,107	_	_	_	_	19,107			
Net loss	_	_	_	(161,190)	_	_	_	(161,190)			
Foreign currency translation					35,062	_	_	35,062			
Balance at September 30, 2022	961,829,720	6	2,877,361	(1,799,591)	39,549	(2,104,780)	(11,456)	1,105,869			

	Ordinary Shares				Accumulated	Treasury	Stock		
_	Number of Shares	Amount	Additional paid in capital	Accumulated deficit	other comprehensive (loss) income	Shares	Amount	Total	
		\$	\$	\$	\$		\$	\$	
Balance at December 31, 2020	878,110,260	5	1,897,467	(713,603)	(14,524)	_	_	1,169,345	
Issuance of ordinary shares upon vesting of restricted shares	816,000	0	0	_	_	_	_	_	
Exercise of shares options	583,640	0	702	_	_	_	_	702	
Issuance of ordinary shares in connection with collaboration and license arrangement	5,681,820	0	62,250	_	_	_	_	62,250	
Issuance cost adjustment for secondary listing	_	_	65	_	_	_	_	65	
Share-based compensation	_	_	7,318	_	_	_	_	7,318	
Net loss	_	_	_	(232,910)	_	_	_	(232,910)	
Foreign currency translation	_	_	_	_	2,900	_	_	2,900	
Balance at March 31, 2021	885,191,720	5	1,967,802	(946,513)	(11,624)			1,009,670	
Issuance of ordinary shares upon vesting of restricted shares	321,000	0	0					_	
Exercise of shares option	4,905,170	0	3,289	_	_	_	_	3,289	
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of \$879	57,164,000	1	817,995	_	_	_	_	817,996	
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	_	_	_	_	_	(60,860)	(924)	(924)	
Share-based compensation	_	_	10,232	_	_	_	_	10,232	
Net loss	_	_	_	(163,324)	_	_	_	(163,324)	
Foreign currency translation	_	_	_	_	(5,241)	_	_	(5,241)	
Balance at June 30, 2021	947,581,890	6	2,799,318	(1,109,837)	(16,865)	(60,860)	(924)	1,671,698	
Issuance of ordinary shares upon vesting of restricted shares	540,500	0	0					_	
Exercise of shares option	4,613,500	0	2,916	_	_	_	_	2,916	
Issuance cost adjustment for follow-on public offering	_	_	40	_	_	_	_	40	
Receipt of employees' shares to satisfy tax withholding obligations related to share-based compensation	_	_	_	_	_	(216,360)	(2,609)	(2,609)	
Share-based compensation	_	_	10,556	_	_	_	_	10,556	
Net loss	_	_	_	(96,412)	_	_	_	(96,412)	
Foreign currency translation	_	_	_	_	1,741	_	_	1,741	
Balance at September 30, 2021	952,735,890	6	2,812,830	(1,206,249)	(15,124)	(277,220)	(3,533)	1,587,930	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements. "0" in above table means less than 1,000 dollars.

Unaudited condensed consolidated statements of cash flows

(In thousands of U.S. dollars ("\$") except for number of shares and per share data)

	Nine Months Ended September 30,		
	2022	2021	
On something and delice	\$	\$	
Operating activities Net loss	(301 E17)	(402,646)	
Adjustments to reconcile net loss to net cash used in operating activities:	(381,517)	(492,646)	
Allowance for credit (gain) loss	(3)	5	
Inventory write-down	480	402	
Depreciation and amortization expenses	6,100	4,612	
Amortization of deferred income	(2,041)	(234)	
Share-based compensation	45,742	28,106	
Noncash research and development expenses		62,250	
Share of loss from equity method investment	221	548	
Loss from fair value changes of equity investment with readily determinable fair value	12,067	9,930	
(Gain) loss on disposal of property and equipment	(11)	12	
Noncash lease expenses	5,820	4,595	
Foreign currency remeasurement loss	73,052	2,838	
Changes in operating assets and liabilities:		_,===	
Accounts receivable	16,483	(15,858)	
Notes receivable	(3,861)		
Inventories	(13,235)	248	
Prepayments and other current assets	(5,860)	(6,142)	
Long-term deposits	(459)	(39)	
Value added tax recoverable	21,432	(1,249)	
Accounts payable	(28,850)	(11,235)	
Other current liabilities	1,628	20,591	
Operating lease liabilities	(6,008)	(3,834)	
Deferred income	470	863	
Net cash used in operating activities	(258,350)	(396,237)	
Cash flows from investing activities:			
Purchases of short-term investments	(260,274)	(170,000)	
Proceeds from maturity of short-term investment	705,274	743,902	
Purchase of property and equipment	(20,172)	(11,917)	
Purchase of intangible assets	(439)	(539)	
Payment for investment in equity investee	-	(30,000)	
Net cash provided by investing activities	424,389	531,446	
Cash flows from financing activities:			
Proceeds from exercises of stock options	5,640	6,907	
Proceeds from issuance of ordinary shares upon public offerings	_	818,874	
Payment of public offering costs	-	(1,836)	
Employee taxes paid related to net share settlement of equity awards	(7,171)	(3,467)	
Net cash (used in) provided by financing activities	(1,531)	820,478	
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(9,132)	695	
Net increase in cash, cash equivalents and restricted cash	155,376	956,382	
Cash, cash equivalents and restricted cash - beginning of period	964,903	442,859	
Cash, cash equivalents and restricted cash - end of period	1,120,279	1,399,241	
Supplemental disclosure on non-cash investing and financing activities:			
Payables for purchase of property and equipment	3,234	1,797	
Payables for intangible assets	32	24	
Payables for treasury stock	32	_	
Receivables for stock option exercise under equity incentive plans	31	_	
Right-of-use asset acquired under operating leases	12,861	_	
Supplemental disclosure of cash flow information:			
Cash and cash equivalents	1,119,476	1,398,498	
Restricted cash, non-current	803	743	
Total cash and cash equivalents and restricted cash	1,120,279	1,399,241	

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

Notes to the unaudited condensed consolidated financial statements

1. Organization and principal activities

Zai Lab Limited 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 (as amended). Zai Lab Limited and its subsidiaries (collectively referred to as the "Company") are focused on developing and commercializing products and product candidates that address medical conditions with unmet needs, including in the areas of oncology, autoimmune disorders, infectious diseases, and neurological disorders.

The Company's principal operations and geographic markets are in Greater China. The Company has a substantial presence in Greater China and the United States.

2. Basis of presentation and consolidation and significant accounting policies

(a) Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), and applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"), regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. As such, the information included in this Quarterly Report on Form 10-Q should be read in conjunction with the consolidated financial statements and accompanying notes included in the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022 (the "2021 Annual Report"). The December 31, 2021 condensed consolidated balance sheet data included in this Quarterly Report on Form 10-Q were derived from the audited financial statements included in the 2021 Annual Report.

The accompanying condensed consolidated financial statements reflect all normal recurring adjustments that are necessary to present fairly the results for the interim periods presented. Interim results are not necessarily indicative of the results for the year ending December 31, 2022.

Effective as of March 30, 2022, the Company subdivided each of its issued and unissued ordinary shares into ten ordinary shares (the "Share Subdivision"). Following the Share Subdivision, the Company's authorized share capital became \$30,000 divided into 5,000,000,000 shares with a par value of \$0.000006 per share. The numbers of issued and unissued ordinary shares and per share data as disclosed elsewhere in these unaudited condensed consolidated financial statements and notes thereto are presented on a basis after taking into account the effects of the Share Subdivision and have been retrospectively adjusted, where applicable. In connection with the Share Subdivision, the conversion ratio of our ADSs to ordinary shares changed from one ADS to one ordinary share to a new ratio of one ADS to ten ordinary shares (the "ADS Ratio Change"). The Share Subdivision and ADS Ratio Change did not result in any change to the number of outstanding ADSs of the Company.

A reclassification has been made within the condensed consolidated statement of cash flow for the nine months ended September 30, 2021 to conform to the current period presentation. The Company reclassified \$2.8 million from other current liabilities into foreign currency remeasurement loss. The net cash used in operating activities did not change as a result of the reclassification.

(b) Principles of consolidation

The unaudited condensed consolidated financial statements include the financial statements of the Company and its subsidiaries. All intercompany transactions and balances among the Company and its subsidiaries are eliminated upon consolidation.

(c) Use of estimates

The preparation of the unaudited condensed 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

Notes to the unaudited condensed consolidated financial statements

disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, and assessing the impairment of long-lived assets, discount rate of operating lease liabilities, accrual of rebates, allocation of research and development expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets, and a lack of marketability discount of the ordinary shares issued in connection with license and collaboration arrangements (Note 12). Management bases its 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) Fair value measurements

As of September 30, 2022 and December 31, 2021, information about inputs into the fair value measurement of the Company's assets that are measured at a fair value on a recurring basis in periods subsequent to their initial recognition is as follows (in thousands):

Description	Fair Value as of September 30, 2022 \$	Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) US\$
Equity Investments with Readily Determinable Fair Value	3,316	3,316
Description	Fair Value as of December 31, 2021 \$	Fair Value Measurement at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1) US\$
Equity Investments with Readily Determinable Fair Value	15,383	15,383

The Company did not have assets or liabilities measured at fair value on a nonrecurring basis during the periods presented.

Financial instruments of the Company primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities. As of September 30, 2022 and December 31, 2021, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, notes receivable, prepayments and other current assets, accounts payable, and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximated its fair value based on the nature of the assessment of the ability to recover these amounts.

(e) Recent accounting pronouncements

Adopted accounting standards

In November 2021, the FASB issued ASU2021-10, Government Assistance (Topic 832) — Disclosures by Business Entities about Government Assistance. The amendments in this ASU require disclosures about transactions with a government that have been accounted for by analogizing to a grant or contribution accounting model to increase transparency about (1) the types of transactions, (2) the accounting for the transactions, and (3) the effect of the transactions on an entity's financial statements. The amendments in this ASU are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted this standard as of January 1, 2022. There was no material impact on the Company's financial position or results of operations upon the adoption.

Notes to the unaudited condensed consolidated financial statements

(f) Significant accounting policies

For a more complete discussion of the Company's significant accounting policies, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the 2021 Annual Report.

3. Cash and cash equivalents

The following table presents the Company's cash and cash equivalents as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
	\$	\$
Cash at bank and in hand	818,407	663,472
Cash equivalents (i)	301,069	300,628
	1,119,476	964,100
Denominated in:		
US\$	1,072,376	932,888
RMB (ii)	41,138	23,791
Hong Kong dollar ("HK\$")	5,035	6,674
Australian dollar ("A\$")	579	475
Taiwan dollar ("TW\$")	348	272
	1,119,476	964,100

- (i) Cash equivalents represent short-term and highly liquid investments in a money market fund.
- (ii) Certain cash and bank balances denominated in RMB were deposited with banks in mainland China. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the Chinese government.

4. Inventories, net

The Company's net inventory balance of \$29.1 million and \$19.0 million as of September 30, 2022 and December 31, 2021, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline ("GSK"), for distribution in Hong Kong, from NovoCure Limited ("NovoCure") for distribution in Hong Kong and mainland China, and from Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong, mainland China and Taiwan, as well as finished goods and certain raw materials for ZEJULA and NUZYRA commercialization in mainland China. The following table presents the Company's inventories, net, as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
	\$	\$
Finished goods	8,703	5,632
Raw materials	20,397	13,231
Work in Progress	31	88
Inventories, net	29,131	18,951

The Company writes down inventory for any excess or obsolete inventories or when the Company believes that the net realizable value of inventories is less than the carrying value. The Company recorded write-downs in cost of sales of \$0.3 million and \$0.5 million during the three and nine months ended September 30, 2022, respectively, and of \$0.1 million and \$0.4 million during the three and nine months ended September 30, 2021, respectively.

Notes to the unaudited condensed consolidated financial statements

5. Property and equipment, net

The following table presents the components of the Company's property and equipment, net as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
	\$	\$
Office equipment	818	836
Electronic equipment	6,744	5,036
Vehicle	198	220
Laboratory equipment	18,673	17,069
Manufacturing equipment	14,366	14,600
Leasehold improvements	10,160	10,432
Construction in progress	19,882	11,334
	70,841	59,527
Less: accumulated depreciation	(20,313)	(16,425)
Property and equipment, net	50,528	43,102

Depreciation expense was \$2.1 million and \$5.7 million for the three and nine months ended September 30, 2022, respectively, and \$1.5 million and \$4.3 million for the three and nine months ended September 30, 2021, respectively.

6. Revenue

Product revenue, net

The Company's product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. The table below presents the Company's net product sales for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ende	ed September 30,	Nine Months End	ed September 30,
	2022	2021	2022	2021
	\$	\$	\$	\$
Product revenue - gross	60,446	47,555	168,095	135,490
Less: Rebate and sales return	(3,483)	(4,452)	(17,462)	(35,349)
Product revenue - net	56,963	43,103	150,633	100,141

Sales rebates are offered to distributors in mainland China, and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories.

Notes to the unaudited condensed consolidated financial statements

The following table presents net revenue by product for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended	September 30,	Nine Months Ende	d September 30,
	2022	2021	2022	2021
	\$	\$	\$	\$
ZEJULA	39,214	28,162	102,863	64,134
Optune	10,662	10,653	35,051	27,318
QINLOCK	5,541	4,288	9,123	8,689
NUZYRA	1,546	_	3,596	_
Product revenue - net	56,963	43,103	150,633	100,141

Collaboration revenue

The Company's collaboration revenue was \$0.6 million and \$1.8 million for the three and nine months ended September 30, 2022, respectively, and nil for the three and nine months ended September 30, 2021. This collaboration revenue was from the Company's collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

7. Income tax

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

The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of September 30, 2022 and December 31, 2021. No unrecognized tax benefits and related interest and penalties were recorded in the periods presented.

8. Other current liabilities

The following table presents the Company's other current liabilities as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
	\$	\$
Payroll	25,208	25,685
Accrued rebate to distributors	8,843	15,001
Tax payables	10,405	8,817
Accrued professional service fee	5,927	4,319
Other (i)	4,839	4,421
Payables for purchase of property and equipment	3,234	2,568
Total	58,456	60,811

i) Other primarily consists of tax withholding related to share-based compensation and accrued travel and business entertainment expenses.

9. Loss per share

The following table presents the computation of the basic and diluted net loss per share for the three and nine months ended September 30, 2022 and 2021 (in thousands, except share and per share data):

Notes to the unaudited condensed consolidated financial statements

	Three Months End	led September 30,	Nine Months End	ed September 30,
	2022	2021	2022	2021
-	\$	\$	\$	\$
Numerator:				
Net loss attributable to ordinary shareholders	(161,190)	(96,412)	(381,517)	(492,646)
Denominator:				
Weighted average number of ordinary shares - basic and diluted	959,085,960	950,354,320	957,439,910	921,748,380
Net loss per share - basic and diluted	(0.17)	(0.10)	(0.40)	(0.53)

As a result of the Company's net loss for the three and nine months ended September 30, 2022 and 2021, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	September 30, 2022	September 30, 2021
Share options	90,511,530	81,801,570
Non-vested restricted shares	34.103.830	6.366.190

10. Related party transactions

The Company incurred research and development expenses for product research and development services provided by MEDx (Suzhou) Translational Medicine Co., Ltd ("MEDx"), over which an immediate family member of our Chief Executive Officer and Chairperson of the Board held significant influence. The Company incurred development expenses with MEDx of an insignificant amount and \$0.3 million during the three and nine months ended September 30, 2022, respectively, and \$0.1 million and \$0.3 million, during the three and nine months ended September 30, 2021, respectively.

11. Share-based compensation

In March 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan"), pursuant to which the Board of Directors could grant options to purchase ordinary shares to management including officers, directors, employees, and individual advisors who rendered services to the Company. In August 2017, in connection with the completion of the initial public offering (the "IPO") of the Company, the Board of Directors approved the 2017 Equity Incentive Plan (the "2017 Plan"). All equity-based awards subsequent to the IPO would be granted under the 2017 Plan. The 2017 Plan provided for an automatic annual increase to the number of ordinary shares reserved under the 2017 Plan on each January 1st between January 1, 2018 and January 1, 2027 equal to the lesser of 4% of the number of ordinary shares outstanding as of the close of business on the immediately prior December 31st or such number as approved by the Board on or prior to such date each year. The aggregate number of shares reserved and available for issuance under the 2017 Plan as of April 1, 2022 was 75.562,170.

On June 22, 2022, at the 2022 Annual General Meeting of Shareholders of the Company (the "Annual General Meeting"), the Company's shareholders approved the 2022 Equity Incentive Plan (the "2022 Plan"), which was previously approved by the Company's Board of Directors on April 20, 2022, conditioned on and subject to (i) the dual primary listing of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the "Hong Kong Stock Exchange") and (ii) the granting of a waiver on Note 1 to Rule 17.03(9) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited. The Company's voluntary conversion of its secondary listing status to primary listing status on the Hong Kong Stock Exchange became effective on June 27, 2022, and the waiver was granted to the Company in connection with the primary conversion. As such, the 2022 Plan became effective on June 27, 2022, and the aggregate number of shares that may be delivered in satisfaction of awards under the 2022 Plan is 97,908,743 ordinary shares as of June 22, 2022. No new grants will be made under the 2015 Plan or the 2017 Plan as of the effective date of the 2022 Plan.

Notes to the unaudited condensed consolidated financial statements

For the nine months ended September 30, 2022, the Company granted 19,357,640 share options and 28,320,790 non-vested restricted shares to certain management and employees of the Company under the 2017 Plan. The share options were granted at an exercise price ranging from \$2.95 to \$6.29 per share. The share options granted were valued using the Black-Scholes model, and the weighted-average grant-date fair value was \$2.84 per share.

The options granted have a contractual term of ten years and generally vest ratably over a five-year period, with 20% of the awards vesting on each anniversary of the grant date. The non-vested restricted shares granted vest ratably over a five- or four-year period, with 20% or 25% of the awards vesting on each anniversary of the grant date. The restricted shares will be released from the restrictions once they vest. Upon termination of the award holders' service with the Company for any reason, any shares that are outstanding and not yet vested will be immediately forfeited unless otherwise set forth in an agreement between the Company and the award holder.

Upon each settlement date of the share awards, shares were withheld to cover the required withholding tax, which was based on the value of a share on the settlement date as determined by the closing price of the ADSs on the trading day of the applicable settlement date. The remaining shares after the withholding were delivered to the recipient. The amount remitted to the tax authorities for employee tax obligations was reflected as a financing activity on the condensed consolidated statements of cash flows. These shares withheld by the Company as a result of the net settlement were accounted for as treasury stock and not considered issued and outstanding.

Stock-based compensation expense has been reported in the Company's condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

	Three Months End	led September 30,	Nine Months End	led September 30,
	2022	2021	2022	2021
	\$	\$	\$	\$
Selling, general and administrative	11,298	6,147	27,221	16,579
Research and development	7,809	4,409	18,521	11,527
Total	19,107	10,556	45,742	28,106

As of September 30, 2022, there was unrecognized share-based compensation expense of \$111.9 million related to unvested share options which the Company expects to recognize over a weighted-average period of 3.47 years.

As of September 30, 2022, there was unrecognized share-based compensation expense of \$143.0 million related to unvested restricted shares which the Company expects to recognize over a weighted-average period of 3.70 years.

12. License and collaboration arrangements

The following is a description of the license and collaboration agreements for which the Company recorded expenses or made payments related to upfront or milestone fees during the three and nine months ended September 30, 2022.

License and collaboration agreement with GSK

In September 2016, the Company entered into a collaboration, development, and license agreement with Tesaro, Inc., a company later acquired by GSK, pursuant to which the Company obtained an exclusive sublicense under certain patents and know-how of GSK to develop, manufacture, and commercialize GSK's proprietary PARP inhibitor, niraparib, in mainland China, Hong Kong, and Macau for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer).

Under the terms of the agreement, in the third quarter of 2022, the Company made a development milestone payment of \$3.5 million which was accrued in the fourth quarter of 2019 and a sales-based milestone payment of \$8.0 million which was accrued in the fourth quarter of 2021, and accrued another development milestone of \$4.0 million.

Notes to the unaudited condensed consolidated financial statements

The Company may be required to pay an additional aggregate amount of up to \$28.0 million in development, regulatory, and sales-based milestones as well as certain royalties at tiered percentages rates ranging from mid- to high-teens on annual net sales of the licensed products in the licensed territory.

License and collaboration agreement with Paratek Bermuda Ltd. ("Paratek")

In April 2017, the Company entered into a license and collaboration agreement with Paratek, pursuant to which the Company 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, and commercialize products containing omadacycline (ZL-2401) as an active ingredient in Greater China in the field of all human therapeutic and preventative uses other than biodefense.

Under the terms of the agreement, in the first quarter of 2022, the Company made a milestone payment of \$6.0 million which was accrued in the fourth quarter of 2021 related to the regulatory approval of omadacycline for the treatment of adults with Acute Bacterial Skin and Skin Structure Infections and Community-Acquired Bacterial Pneumonia in mainland China in December 2021.

The Company may be required to pay an additional aggregate amount of up to \$40.5 million in development and sales-based milestones as well as certain royalties at tiered percentages rates ranging from low- to mid-teens on annual net sales of licensed products in the licensed territory.

Collaboration and license agreement with argenx BV ("argenx")

In January 2021, the Company entered into a collaboration and license agreement with argenx pursuant to which the Company received an exclusive license to develop and commercialize products containing argenx's proprietary antibody fragment, known as efgartigimod, in Greater China.

Pursuant to the collaboration and license agreement, a share issuance agreement was entered into between the Company and argenx. As the upfront payment to argenx, the Company issued 5,681,820 ordinary shares of the Company with a par value of \$0.000006 per share to argenx on the closing date of January 13, 2021. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares were subject to certain restrictions. The fair value of the shares on the closing date was determined to be \$62.3 million in the aggregate. In addition, the Company made a non-creditable, non-refundable development cost-sharing payment of \$75.0 million to argenx during the first quarter of 2021.

Under the terms of the agreement, the Company made a milestone payment of \$25.0 million in the first quarter of 2022 which was accrued in the fourth quarter of 2021 related to the first regulatory approval for the licensed product by the U.S. Food and Drug Administration ("FDA") in December 2021.

The Company may be required to pay certain royalties at tiered percentages rates ranging from mid-teen to low-twenties on annual net sales of licensed products in the licensed territory.

Collaboration and license agreement with Mirati Therapeutics, Inc. ("Mirati")

In May 2021, the Company entered into a collaboration and license agreement with Mirati pursuant to which the Company obtained the right to research, develop, manufacture, and exclusively commercialize adagrasib in Greater China.

Under the terms of the agreement, the Company made an upfront payment of \$65.0 million to Mirati in the second quarter of 2021. In the third quarter of 2022, the Company made a development milestone payment of \$5.0 million which was accrued in the second quarter of 2022 and accrued a development milestone payment of \$5.0 million.

The Company may be required to pay an additional aggregate amount of up to \$263.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from high-teens to low-twenties on annual net sales of adagrasib in Greater China.

Notes to the unaudited condensed consolidated financial statements

License agreement with Karuna Therapeutics, Inc. ("Karuna")

In November 2021, the Company entered into a license agreement with Karuna for the development, manufacturing, and commercialization of KarXT (xanomeline-trospium) in Greater China.

Under the terms of the agreement, the Company made an upfront payment of \$35.0 million to Karuna in the fourth quarter of 2021. The Company also made a development milestone payment of \$5.0 million in the third quarter of 2022 which was accrued in the second quarter of 2022.

The Company may be required to pay an additional aggregate amount of up to \$147.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from low- to high-teens on annual net sales of licensed products in Greater China.

Collaboration and license agreement with Seagen Inc. ("Seagen")

In September 2022, the Company entered into a collaboration and license agreement with Seagen, pursuant to which the Company and Seagen agreed to collaboratively develop and commercialize TIVDAK® (tisotumab vedotin). Under the agreement, the Company obtained an exclusive license to develop and commercialize TIVDAK in Greater China.

Under the terms of the agreement, the Company accrued an upfront payment of \$30.0 million in the third quarter of 2022. The Company may be required to pay an additional aggregate amount of up to \$263.0 million in development, regulatory, and sales-based milestone payments as well as certain royalties at tiered percentage rates ranging from mid-teens to low-twenties on annual net sales of licensed products in Greater China, subject to reduction under specified circumstances.

The agreement will remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last licensed product. The agreement contains customary provisions for termination by either party, including in the event of a material breach by the other party that remains uncured, by the Company for convenience, for certain bankruptcy events, and by Seagen upon a challenge of the licensed patent rights.

Full details of the licenses and collaborative arrangements, other than the agreement with Seagen which we entered into during the third quarter of 2022, are included in the notes to the financial statements in our 2021 Annual Report. As noted above, the Company has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements, the Company is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management's evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Company up to an aggregate of approximately \$5,830.7 million in future contingent development and sales-based milestone payments as well as certain royalties at tiered percentage rates on annual net sales. The development milestones, such as regulatory approval for the product candidates, may occur before the Company has commercialized the product or received any revenue from sales of such product candidate. These milestone payments are subject to uncertainties and contingencies and may not occur.

13. Restricted net assets

The Company's ability to pay dividends may depend on the Company receiving distributions of funds from its Chinese subsidiaries. Relevant Chinese laws and regulations permit payments of dividends by the Company's Chinese subsidiaries only out of its retained earnings, if any, as determined in accordance with Chinese accounting standards and regulations. The results of operations reflected in the unaudited condensed consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Company's Chinese subsidiaries.

In accordance with the Company Law of the People's Republic of China, 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 Chinese statutory accounts. A domestic enterprise may provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's

Notes to the unaudited condensed consolidated financial statements

Chinese statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's Chinese subsidiaries were established as domestic enterprises and therefore are subject to the above-mentioned restrictions on distributable profits.

During the three and nine months ended September 30, 2022 and 2021, no appropriation to statutory reserves was made because the Chinese subsidiaries had substantial losses during such periods.

As a result of these Chinese laws and regulations, subject to the limits discussed above that require annual appropriations of 10% of after-tax profit to be set aside, prior to payment of dividends, as general reserve fund, the Company's Chinese subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulation in mainland China may further restrict the Company's Chinese subsidiaries from transferring funds to the Company in the form of dividends, loans, and advances. As of September 30, 2022 and December 31, 2021, amounts restricted are the paid-in capital of the Company's Chinese subsidiaries, which both amounted to \$406.0 million.

14. Commitments and Contingencies

(a) Purchase commitments

As of September 30, 2022, the Company's commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statements were \$13.8 million and were expected to be incurred within one year.

(b) Contingencies

The Company 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 12).

15. Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date financial statements were issued. The Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our 2021 Annual Report and our unaudited condensed consolidated financial statements and the accompanying notes included in "Item 1. Financial Statements" in this Quarterly Report on Form 10-Q.

Overview

We are a patient-focused, innovative, commercial-stage, global biopharmaceutical company with a substantial presence in both Greater China and the United States. We are discovering, developing, and commercializing innovative products that target medical conditions with unmet needs affecting patients in Greater China and worldwide, in the areas of oncology, autoimmune disorders, infectious diseases, and neurological disorders. As of November 3, 2022, we have four commercialized products that have received marketing approval in one or more territories in Greater China and thirteen programs in late-stage product development.

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. Developing high quality product candidates requires a significant investment related to our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and positive cash flow from operations over the next several years depends upon our ability to successfully market our four commercial products – ZEJULA, Optune, QINLOCK, and NUZYRA – and to successfully develop and commercialize our other product candidates. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory, and commercial milestones as well as tiered royalties based on annual net sales of the licensed products. During the nine months ended September 30, 2022, we recorded \$50.2 million of research and development expense related to upfront license fees and development milestones payments. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

Furthermore, as we pursue our strategy of growth and development, we anticipate that our financial results will fluctuate from quarter to quarter based upon the balance between the successful marketing of our commercial products and our significant research and development expenses. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

Recent Developments

Recent Product Developments

Commercial Products

ZEJULA (Niraparib). Throughout this year, the FDA has been reviewing data on PARP inhibitors, and other companies have issued Dear HCP Letters in the U.S. as a result of ongoing discussions with the FDA. In September 2022, GSK disclosed that it was in discussions with the FDA to discuss overall survival ("OS") data from GSK's ENGOT-OV16/NOVA phase III clinical trial for adult patients with recurrent ovarian cancer irrespective of the gBRCA mutation. We do not expect the FDA's discussions with GSK to impact our approval from the NMPA for ZEJULA in China. The NMPA's full approval of ZEJULA in the recurrent ovarian cancer setting is based on a separate study, the NORA study, which is a Phase 3 randomized, double-blind, placebo-controlled study of ZEJULA that the Company independently conducted in China. While the NORA study is not fully mature, to date, favorable trends have been observed in OS irrespective of gBRCA mutation status. We expect to present this data at a future scientific congress. As a result, we do not anticipate that our second-line all-comer label in China will be affected by the FDA's discussions with GSK. We also do not expect a change in our first-line label for ZEJULA; the FDA's discussions with GSK do not apply to this indication.

Optune (Tumor Treating Fields or TTFields). As of September 30, 2022, Optune has been listed in 72 regional customized commercial health insurance plans guided by provincial or municipal governments (or "supplemental insurance plans") since its commercial launch in China in the third quarter of 2020, compared to 25 supplemental insurance plans as of September 30, 2021.

QINLOCK. In August 2022, the recommendation level of QINLOCK for second-line treatments for advanced gastrointestinal stromal tumor ("GIST") patients was advanced from Level III to Level II (1A evidence) in the Chinese

Society of Clinical Oncology ("CSCO") Guidelines for Diagnosis and Treatment of GIST 2022. As of September 30, 2022, QINLOCK has been listed in 96 supplemental insurance plans since its commercial launch in mainland China in May 2021, compared to 28 supplemental insurance plans as of September 30, 2021. We are seeking inclusion of QINLOCK in the NRDL for a fourth-line gastrointestinal stromal tumor indication.

<u>NUZYRA</u>. We are seeking inclusion of NUZYRA in the NRDL for community-acquired bacterial pneumonia ("CABP") and acute bacterial skin and skin structure infections ("ABSSSI") indications.

<u>Product Candidates – Oncology</u>

Adagrasib. In September 2022, our partner Mirati presented results from KRYSTAL-1, a multicohort Phase 1/2 study evaluating adagrasib with or without cetuximab in patients with advanced colorectal cancer ("CRC") harboring a KRAS^{G12C} mutation at the European Society for Medical Oncology Congress 2022. Of the evaluable patients in the adagrasib monotherapy cohort (n=43), the investigator assessed confirmed objective response rate ("ORR") was 19% (8/43), and the disease control rate ("DCR") was 86% (37/43). The median duration of response ("DOR") was 4.3 months (95% CI, 2.3–8.3), and median PFS was 5.6 months (95% CI, 4.1–8.3). Of the evaluable patients in the adagrasib plus cetuximab combination cohort (n=28), the investigator assessed confirmed ORR was 46% (13/28), and the DCR was 100% (28/28). The median DOR was 7.6 months (95% CI 5.7–NE), and median PFS was 6.9 months (95% CI, 5.4–8.1). The prognosis for patients with CRC has historically been poor in later lines of therapy with response rates of approximately 1-2% and median PFS of approximately 2 months in patients with late-line CRC; patients with KRAS^{G12C}-mutated CRC tend to have even worse outcomes than the broader CRC patient population. In the overall subset of patients with KRAS^{G12C}-mutated CRC evaluated in this study, adagrasib was found to be well-tolerated as a monotherapy and in combination with cetuximab. The majority of observed treatment-related adverse events ("TRAEs") were grade 1-2 (59%); no grade 5 TRAEs were observed.

In addition, in August 2022, we treated the first patient in Greater China for the global Phase 2 KRYSTAL-7 study of adagrasib in combination with pembrolizumab in first-line KRAS^{G12C}-mutated non-small cell lung cancer ("NSCLC") patients.

Bemarituzumab. Our partner Amgen continues to enroll patients in several studies of bemarituzumab, including: FORTITUDE-101, a Phase 3 study of bemarituzumab plus chemotherapy, versus placebo plus chemotherapy in first-line gastric cancer with FGFR2b overexpression, and FORTITUDE-102, the Phase 3 portion of the 1b/3 study of bemarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab in first-line gastric cancer with FGFR2b overexpression.

Repotrectinib. In October 2022, our partner Turning Point Therapeutics (a wholly owned subsidiary of Bristol Myers Squibb Company) provided a clinical data update from the global, registrational Phase 1/2 TRIDENT-1 study of repotrectinib at the 34th EORTC-NCI-AACR ("ENA") Symposium 2022. Repotrectinib continued to demonstrate meaningful clinical activity in patients with ROS1+ advanced NSCLC, who were tyrosine kinase inhibitor ("TKI")-naïve or TKI-pretreated, including with ROS1 G2032R resistance mutation. Durable responses and intracranial efficacy were observed in both TKI-naïve and TKI-pretreated patients. Repotrectinib also continued to show clinical activity in patients with NTRK+ advanced solid tumors who were TKI-naïve or TKI-pretreated, and responses were seen across diverse tumor types. Safety is well characterized, manageable with known protocols, and signals potential compatibility with long-term use. Also in October 2022, we completed enrollment in China in all cohorts of the registrational Phase 1/2 TRIDENT-1 study.

<u>BLU-945</u>. In November 2022, our partner Blueprint Medicines Corporation presented an update on the Phase 1/2 SYMPHONY trial data supporting plans to develop BLU-945 in combination with osimertinib in first-line epidermal growth factor receptor ("EGFR") L858R mutation-positive NSCLC.

<u>Global R&D Oncology Programs</u>. In November 2022, we presented data from our internal oncology pipeline at the Society for Immunotherapy of Cancer ("SITC") Annual Meeting in Boston, Mass. These presentations focus on two key global discovery programs: ZL-1211, an anti-CLDN18.2 antibody, and ZL-1218, an anti-CCR8 antibody.

Product Candidates - Autoimmune Disorders

<u>VYVGART (Efgartigimod)</u>. In September 2022, our partner argenx announced the submission of a Biologics License Application to the FDA for subcutaneous efgartigimod for the treatment of generalized myasthenia gravis ("gMG") in adult patients and that the European Commission has granted marketing authorization for VYVGART as an add-on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive. As of November 1, 2022, VYGART has been listed in 10 supplemental insurance plans in China.

<u>ZL-1102</u>. In September 2022, we presented results of the Phase 1 proof-of-concept study for ZL-1102 at the 2022 European Academy of Dermatology and Venereology Congress in Milan, Italy.

Product Candidates - Neuroscience

<u>KarXT</u>. In September 2022, we obtained agreement from the NMPA on the development plan of a bridging study in schizophrenia in China. In October 2022, we started patient enrollment for a pharmacokinetic ("PK") study of KarXT in China.

In the third quarter of 2022, our partner Karuna initiated the Phase 3 ADEPT-1 study evaluating KarXT as a treatment for psychosis in Alzheimer's disease, and in the fourth quarter of 2022, Karuna completed enrollment in the Phase 3 EMERGENT-3 trial in schizophrenia. In addition, in October 2022, Karuna announced that data from the Phase 3 EMERGENT-2 trial of KarXT in schizophrenia was shared at the 35th European College of Neuropsychopharmacology Congress in Vienna, Austria. A poster presentation and symposium included previously reported efficacy and safety data, as well as new additional safety data from the trial.

Recent Business Developments

In September 2022, we entered into a collaboration and license agreement with Seagen for the development and commercialization of TIVDAK (tisotumab vedotin) in Greater China. TIVDAK is the first and only anti-body drug conjugate ("ADC") approved in the United States for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy and is an important addition to our oncology portfolio.

In the second half of 2022, we have continued to enhance our global leadership team. For example, Dr. Peter Huang joined the Company from Zentalis Pharmaceuticals in November as Chief Scientific Officer. Dr. Huang brings to the Company an extensive scientific background and strong leadership and research and development experience, including over 16 years working within the biopharmaceutical industry. Dr. Huang will be a key member of the Company's executive management team and is responsible for leading and overseeing the Company's discovery efforts and translational medicine. In addition, Alette Verbeek joined the Company from Novartis in October as SVP, Head of Global Strategic Partnering. She is our first employee based in Europe and is responsible, among other things, for leading our European business development efforts.

In November 2022, The Stock Exchange of Hong Kong Limited (the "Hong Kong Stock Exchange") approved the Company's transition from a listing under Chapter 18A of the Listing Rules of the Hong Kong Stock Exchange (Biotech Companies) to a general listing under Rule 8.05(3) of the Listing Rules (Qualifications for Listing), as the Company has satisfied applicable revenue and market capitalization requirements for listing outside of Chapter 18A. As a result of this approval, the "B" marker will be removed from the Company's stock short name on the Hong Kong Stock Exchange, effective November 11, 2022.

Recent Legal and Regulatory Developments

Measures on Security Assessment of Cross-Border Data Transfer

On July 7, 2022, the CAC issued the "Security Assessment Measures", which sets out a security assessment framework for cross-border data transfers out of mainland China as well as ground rules for a security assessment filing for cross-border data transfers which was stipulated in the Cybersecurity Law and the Personal Information Protection Law.

A security assessment will be triggered if a cross-border data transfer out of mainland China falls into any of the following scenarios: (i) transfer of important data by data processors; (ii) transfer of personal information ("PI") by critical information infrastructure operators ("CIIOs") and data processors that process PI of more than one million individuals; (iii) transfer of PI by data processors that have transferred either PI of over 100,000 individuals or sensitive PI of over 10,000 individuals abroad since January 1 of the preceding year; and (iv) other situations as determined by the CAC. According to statements by the CAC, a cross-border data transfer includes (i) an outbound transfer and overseas storage of data collected and generated during a data processor's operation in mainland China; and (ii) a remote access or use of data collected and generated by a data processor stored within mainland China by overseas institutions, organizations, and individuals.

Prior to applying for a security assessment with the CAC, data processors are required to carry out a self-risk assessment, which needs to be presented to the CAC along with an application filing and other required materials for a security assessment. During a security assessment, the CAC will primarily focus on risks to national security, public interests, and the legitimate rights and interests of individuals or organizations that such cross-border data transfer may

cause. A cross-border data transfer of relevant data will not be allowed if the CAC does not approve the security assessment filing. Once the CAC approves the security assessment filing, such approval will remain valid for two years and may be renewed. An application for security assessment needs to be re-submitted if there is a change in the cross-border data transfer that may affect the security of the exported data, such as changes in the purpose, method, scope, and type of the exported data and changes in the purpose and method of the processing of the exported data by overseas recipients.

The Security Assessment Measures have retroactive effect for cross-border data transfers out of mainland China of relevant data conducted prior to their effective date on September 1, 2022. If a Data Processor fails to complete its security assessment for any of its cross-border data transfers of relevant data out of mainland China prior to the effective date of the Security Assessment Measures, it needs to rectify the failure within six months after the effective date of the Security Assessment Measures.

Proposed Amendments to the Cybersecurity Law of the People's Republic of China

On September 14, 2022, the CAC published a draft amendment to China's Cybersecurity Law for public comment. According to the CAC, the draft revisions were formulated to align the Cybersecurity Law with several new laws that were released after the Cybersecurity Law came into effect in June 2017. These new laws include the Administrative Punishment Law of the People's Republic of China, the Data Security Law of the People's Republic of China, and the Personal Information Protection Law of the People's Republic of China, all of which were adopted or amended in 2021.

The draft amendment mainly proposes revisions to Chapter VI of the Cybersecurity Law on legal responsibility which adjust the types and ranges of administrative penalties for violating the Cybersecurity Law that endanger network security and strengthens the network security responsibilities of CIIOs. Generally, the fines and penalties available to be imposed by Chinese regulators have been significantly increased and expanded. The proposed revisions also defer to the legal liability provisions under relevant laws or administrative regulations with respect to violations of the Cybersecurity Law provisions relating to the illegal use of networks, overseas transfers of data by critical information infrastructure operations, and personal information protection.

Guide to Applications for Security Assessment of Outbound Data Transfers (First Edition)

On August 31, 2022, the CAC promulgated the first edition of the Guide to Applications for Security Assessment of Outbound Data Transfers (the "Guide"). The Guide provides practical guidance to the implementation of the Security Assessment Measures, which sets out a security assessment framework for cross-border data transfers out of mainland China.

The Guide reiterates the timeline and procedures for applications for security assessment of outbound data transfers under the Security Assessment Measures. The Guide specifies the dossier requirements for applications for security assessment and provides templates for some required documents. Prior to submitting an application for security assessment, the applicant must first conclude an outbound data transfer contract with the overseas recipient of the data transfer and conduct a self-assessment of the risks of the outbound data transfer. Additionally, the Guide clarifies that the application of security assessment shall be submitted to provincial branches of the CAC, who will forward it to the CAC for further review and assessment.

The Guide also clarifies that a cross-border data transfer out of mainland China includes where a data processor stores data collected or generated in its operations in mainland China to an overseas recipient, and where a data processor allows an overseas entity, organization, or individual to access, retrieve, download, or export data the data processor collects or generates and stores in mainland China.

Measures for the Supervision and Administration of Online Drug Sales

On September 1, 2022, the SAMR announced the Measures for the Supervision and Administration of Online Drug Sales (the "Measures"), which will take effect as of 1 December 2022. The Measures set out a comprehensive regulatory framework for the online sale of drugs, including the online sale of prescription drugs and the regulation of trading platforms that engage in the online sale of drugs.

The Measures include six chapters and 42 articles. The main sections include: (i) the obligations, qualifications, and responsibilities of online drug sellers; (ii) the responsibilities of trading platforms for online drug sales; (iii) the supervision and management of online sales of prescription drugs; (iv) the division of responsibilities of drug regulators at all levels in the supervision of online drug sales; and (v) the legal liability for illegal online drug sales. Notably, both drug marketing authorization holders and drug distributors can qualify as online drug sellers. Online sale of prescription drugs is permitted,

but drug retailers and providers of trading platforms for the online sale of prescription drugs must abide by the regulatory requirements specified in the Measures.

PRC Anti-Monopoly Law

On June 24, 2022, the Standing Committee of the National People's Congress published amendments to the PRC Anti-Monopoly Law (the "AML"), which came into effect on August 1, 2022. The amended AML formally implements China's latest anti-monopoly policies by, among other things, improving regulatory rules for anti-competitive agreements, expressly addressing monopoly issues in the platform economy, and substantially increasing the penalties for violating the law.

The improvements of the regulatory rules for anti-competitive agreements made by the amended AML mainly includes: (i) expressly stipulating that an agreement which fixes or limits resale prices, that is, a vertical anti-competitive agreement, is not prohibited if relevant business operators can prove that such agreement does not have the effect of eliminating or restricting competition; (ii) formally provides the "safe harbor" regime which stipulates that a vertical anti-competitive agreement is not prohibited, if the parties' market share in the relevant market is lower than the market share percentage set by the anti-monopoly enforcement agency and other conditions established by the anti-monopoly enforcement agency are met; (iii) codifies that business operators shall not organize other business operators to reach a monopoly agreement.

The amended AML formally extends the anti-monopoly regulatory regime to the platform economy by outlining the general principal that business operators shall not engage in monopolistic activities, such as by taking advantage of data and algorithms, technology, capital advantage, and platform rules. The amended AML also specifically prohibits business operators from abusing market dominance, such as by using data and algorithms, technology, and platform rules.

Penalties for violation of the AML have been substantially increased by the amended AML. For example, according to the amended AML, if a company completes a concentration of business in violation of the AML that will have or is likely to have the effect of eliminating or restricting competition, in addition to other remedial measures, a fine of up to 10% of the last year's sales revenue may be imposed. If the concentration of business in violation of the AML completed by the company does not have the effect of eliminating or restricting competition, a fine of up to RMB 5 million may be imposed. In the case that the aforementioned violation has particularly serious circumstances, bad impact, or consequences, the fine imposed may be further increased to between two and five times the aforementioned fine amount.

Factors Affecting Our Results of Operations

Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product 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 product candidates has been advancing and expanding, with thirteen late-stage clinical product candidates being investigated as of September 30, 2022.

We have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, multiple follow-on offerings, and a secondary listing on the Hong Kong Stock Exchange in September 2020. Through September 30, 2022, we have raised approximately \$164.6 million from private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offering, follow-on offerings, and secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$258.4 million and \$396.2 million for the nine months ended September 30, 2022 and 2021, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our thirteen late-stage clinical product candidates, research and develop our clinical- and pre-clinical-stage product candidates, and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. We review such expenditures for prioritization and efficiency purposes. These expenditures include:

- expenses incurred for contract research organizations ("CROs"), contract manufacture organizations ("CMOs"), investigators, and clinical trial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits, and equity compensation expenses;
- expenses for licensors:
- the cost of acquiring, developing, and manufacturing clinical study materials;

- facilities 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.

The Company is in the process of evaluating its development programs and is developing a series of recommendations for prioritizing these programs to concentrate our resources on programs that have the greatest potential to beneficially impact patients, strengthen our global competitiveness, and provide long-term sustainability.

Selling, General, and Administrative Expenses

Our selling, general, and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for commercial and administrative personnel. Other selling, general, and administrative expenses include product distribution and promotion costs, professional service fees for legal, intellectual property, consulting, auditing, and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies used in selling, general, and administrative activities. We anticipate that our selling, general, and administrative expenses will increase in future periods to support increases in our commercial and research and development activities and as we continue to commercialize, develop, and manufacture our products and assets. These increases will likely include increased headcount, increased share-based compensation charges, increased product distribution and promotion costs, expanded infrastructure, and increased costs for insurance. We also anticipate incurring additional legal, compliance, accounting, and investor and public relations expenses associated with being a public company.

Our Ability to Commercialize Our Product Candidates

As of November 3, 2022, thirteen of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in Greater China and the United States. Our ability to generate revenue from our product candidates is dependent on our receipt of regulatory approvals for and successful commercialization of such products, which may not occur. Certain of our product candidates may require additional pre-clinical and/or clinical development, regulatory approvals 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 products under these agreements as well as tiered royalties based on annual net sales of the licensed products. We recorded research and development expense related to upfront license fees and development milestone payments of \$39.8 million and \$50.2 million for the three and nine months ended September 30, 2022, respectively, and \$5.1 million and \$274.3 million for the three and nine months ended September 30, 2021, respectively.

The COVID-19 Pandemic

Our results of operations have been, and we expect them to continue to be, adversely affected by the effects of the COVID-19 pandemic, including government actions and quarantine measures taken in response, particularly in mainland China where our operations and product markets are primarily located. For example, the COVID-19 pandemic has adversely affected patient access to our products, such as through reduced hospital patient load, fewer newly diagnosed oncology patients, and delayed or interrupted treatments. The COVID-19 pandemic has also adversely affected our manufacturing and supply chain and our research and development, sales, marketing, and clinical trial activities. The operations of our suppliers, CROs, CMOs, and other contractors and third parties on which we rely also have been, and may continue to be, adversely affected. Although our net product revenues increased in the three and nine months ended September 30, 2022, as compared to the same periods in the prior year, these revenue increases were negatively affected by the effects of the pandemic, and we expect some additional residual revenue impacts in the fourth quarter of 2022 and perhaps beyond.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2022 and 2021 (in thousands, except percentages):

	Three Mont Septemb		Chang	e	Nine Mont Septeml		Chai	ıge
	2022	2021	\$	%	2022	2021	\$	%
Revenues:								
Product revenue, net	56,963	43,103	13,860	32 %	150,633	100,141	50,492	50 %
Collaboration revenue	577	_	577	100 %	1,806	_	1,806	100 %
Total revenues	57,540	43,103	14,437	33 %	152,439	100,141	52,298	52 %
Expenses:								
Cost of sales	(20,044)	(12,162)	(7,882)	65 %	(53,094)	(30,535)	(22,559)	74 %
Research and development	(99,524)	(55,144)	(44,380)	80 %	(219,462)	(401,220)	181,758	(45)%
Selling, general, and administrative	(66,555)	(59,002)	(7,553)	13 %	(186,947)	(149,254)	(37,693)	25 %
Loss from operations	(128,583)	(83,205)	(45,378)	55 %	(307,064)	(480,868)	173,804	(36)%
Interest income	3,872	713	3,159	443 %	5,235	1,171	4,064	347 %
Other income (expenses), net	(36,479)	(13,580)	(22,899)	169 %	(79,467)	(12,401)	(67,066)	541 %
Loss before income tax and share of loss from equity method investment	(161,190)	(96,072)	(65,118)	68 %	(381,296)	(492,098)	110,802	(23)%
Income tax expense	_	_	_	— %	_	_	_	— %
Share of loss from equity method investment	_	(340)	340	(100)%	(221)	(548)	327	(60)%
Net loss	(161,190)	(96,412)	(64,778)	67 %	(381,517)	(492,646)	111,129	(23)%
Net loss attributable to ordinary shareholders	(161,190)	(96,412)	(64,778)	67 %	(381,517)	(492,646)	111,129	(23)%

Revenues

Product Revenue, Net

The table below presents the components of the Company's product revenue, net for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,				Ch	nange		Nine Mon Septen	 	Change		
	 2022		2021		\$		%	2022	2021		5	%
Product revenue - gross	\$ 60,446	\$	47,555	\$	12,891		27 %	\$ 168,095	\$ 135,490		32,605	24 %
Less: Rebate and sales return	(3,483)		(4,452)		969		(22)%	(17,462)	(35,349)		17,887	(51)%
Product revenue - net	56,963		43,103		13,860		32 %	150,633	100,141		50,492	50 %

Our product revenue is primarily derived from the sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong. Our net product revenue increased by \$13.9 million and \$50.5 million in the three and nine months ended September 30, 2022, as compared to the three and nine months ended September 30, 2021, respectively. These net revenue increases were driven by increased sales volumes, although these increased volumes were negatively affected by the effects of the COVID-19 pandemic, including government restrictions or lockdown measures in mainland China, which negatively affected patient access to our products. These net revenue increases were also driven by a decrease in sales rebates related to product price reductions.

Sales rebates are offered to distributors in mainland China and the amounts are recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories. The Company lowered the selling price of ZEJULA in December 2020 when it was included in the NRDL and again in December 2021 as a result of an extension in ZEJULA's indications. Accordingly, the Company accrued nil and \$2.8 million for sales rebates as compensation to distributors in mainland China for those products previously sold at the price prior to the NRDL implementation during the three and nine months ended September 30, 2022, respectively, and nil and \$22.0 million during the three and nine months ended September 30, 2021, respectively.

The Company is scheduled to enter into negotiations with the National Healthcare Security Administration regarding potential inclusion of QINLOCK and NUZYRA in the NRDL, and in June 2022, the Company lowered the selling price for these products. Accordingly, the Company accrued nil and \$2.4 million for sales rebates as compensation to distributors previously sold at the price prior to the reduction for QINLOCK during the three and nine months ended September 30, 2022, respectively, and nil and \$0.2 million for NUZYRA during the three and nine months ended September 30, 2022, respectively.

The following table presents net revenue by product for the three and nine months ended September 30, 2022 and 2021 (in thousands, except percentages):

	Three Months Ended September 30,				Ch	ange	Nine Mor Septen		Change		
	2022		2021		\$	%	2022	2021	\$	%	
ZEJULA	\$ 39,214	\$	28,162	\$	11,052	39 %	\$ 102,863	\$ 64,134	38,729	60 %	
Optune	10,662		10,653		9	— %	35,051	27,318	7,733	28 %	
QINLOCK	5,541		4,288		1,253	29 %	9,123	8,689	434	5 %	
NUZYRA	1,546		_		1,546	— %	3,596	_	3,596	— %	
Total product revenue, net	\$ 56,963	\$	43,103	\$	13,860	32 %	\$ 150,633	\$ 100,141	\$ 50,492	50 %	

Collaboration Revenue

Collaboration revenue increased by \$0.6 million to \$0.6 million for the three months ended September 30, 2022 from nil for the three months ended September 30, 2021. Collaboration revenue increased by \$1.8 million for the nine months ended September 30, 2022 from nil for the nine months ended September 30, 2021. These increases were due to our collaborative arrangement with Huizheng (Shanghai) Pharmaceutical Technology Co., Ltd.

Cost of Sales

Cost of sales increased by \$7.9 million to \$20.0 million for the three months ended September 30, 2022 from \$12.2 million for the three months ended September 30, 2021, and increased by \$22.6 million to \$53.1 million for the nine months ended September 30, 2022 from \$30.5 million for the nine months ended September 30, 2021. These increases were primarily due to increasing sales volume, higher product costs, and higher royalties.

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the three and nine months ended September 30, 2022 and 2021 (in thousands, except percentages):

	Three Mor Septen	 	Nine Months Ended Change September 30,							Cha	inge	
	2022	2021		\$	%		2022		2021		\$	%
Research and development expenses:												
Personnel compensation and related costs	\$ 28,478	\$ 20,564	\$	7,914	38 %	\$	80,325	\$	50,543	\$	29,782	59 %
Licensing fees	39,769	5,051		34,718	687 %		50,205		274,299		(224,094)	(82)%
CROs/CMOs/Investigators expenses	23,407	17,102		6,305	37 %		70,325		52,246		18,079	35 %
Other costs	7,870	12,427		(4,557)	(37)%		18,607		24,132		(5,525)	(23)%
Total	\$ 99,524	\$ 55,144	\$	44,380	80 %	\$	219,462	\$	401,220	\$	(181,758)	(45)%

Research and development expenses increased by \$44.4 million to \$99.5 million for the three months ended September 30, 2022 from \$55.1 million for the three months ended September 30, 2021 primarily due to:

- an increase of \$34.7 million in licensing fees in connection with the increased upfront and milestone payments for our license and collaboration agreements;
- an increase of \$7.9 million in personnel compensation and related costs primarily due to headcount growth and the grants of new share options and restricted shares and the continued vesting of those awards;

• an increase of \$6.3 million in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials.

Research and development expenses decreased by \$181.8 million to \$219.5 million for the nine months ended September 30, 2022 from \$401.2 million for the nine months ended September 30, 2021 primarily due to:

- a decrease of \$224.1 million in licensing fees in connection with decreased upfront payments for new license and collaboration agreements as well
 as decreased milestone payments; partially offset by
- an increase of \$29.8 million in personnel compensation and related costs primarily due to headcount growth and the grants of new share options
 and restricted shares and the continued vesting of those awards;
- an increase of \$18.1 million in CROs/CMOs/Investigators expenses related to ongoing and newly initiated clinical trials.

The following table summarizes our research and development expenses by program for the three and nine months ended September 30, 2022 and 2021 (in thousands, except percentages):

		Three Mor Septen		Change Nine Months Ended September 30, Change						inge			
		2022	2021		\$	%	2022		2021		\$		%
Research and development expenses:	-												
Clinical programs	\$	63,324	\$ 20,248	\$	43,076	213 %	\$	119,468	\$	299,937	\$	(180,469)	(60)%
Pre-clinical programs		2,965	9,988		(7,023)	(70)%		7,487		41,033		(33,546)	(82)%
Unallocated research and development expenses		33,235	24,908		8,327	33 %		92,507		60,250		32,257	54 %
Total	\$	99,524	\$ 55,144	\$	44,380	80 %	\$	219,462	\$	401,220	\$	(181,758)	(45)%

Research and development expenses attributable to clinical programs increased by \$43.1 million to \$63.3 million for the three months ended September 30, 2022 from \$20.2 million during the three months ended September 30, 2021 related to ongoing and newly initiated clinical trials. Research and development expenses attributable to pre-clinical programs decreased by \$7.0 million for the three months ended September 30, 2022 and by \$33.5 million for the nine months ended September 30, 2022, compared to the same periods in 2021, primarily driven by decreased license fees.

Research and development expenses attributable to clinical programs decreased by \$180.5 million to \$119.5 million for the nine months ended September 30, 2022 from \$299.9 million during the nine months ended September 30, 2021. Research and development expenses attributable to pre-clinical programs decreased by \$33.5 million to \$7.5 million for the nine months ended September 30, 2022 from \$41.0 million during the nine months ended September 30, 2021. Those decreases were driven by decreased license fees.

Although 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 given time.

Selling, General, and Administrative Expenses

The following table summarizes our selling, general and administrative expenses by program for the three and nine months ended September 30, 2022 and 2021 (in thousands, except percentages):

		Three Months Ended September 30,				Change				Nine Months Ended September 30,				Change		
		2022		2021		\$		%	%		2021		\$		%	
Selling, General and Administrative Expenses:																
Personnel c	ompensation and related costs	\$	41,859	\$	34,088	\$	7,771	23 %	\$	121,382	\$	87,560	\$	33,822		39 %
Professional service fees			9,381		6,194		3,187	51 %)	24,886		14,583		10,303		71~%
Other costs			15,315		18,720		(3,405)	(18)%	ò	40,679		47,111		(6,432)	((14)%
Total		\$	66,555	\$	59,002	\$	7,553	13 %	\$	186,947	\$	149,254	\$	37,693		25 %

Selling, general, and administrative expenses increased by \$7.6 million to \$66.6 million for the three months ended September 30, 2022 from \$59.0 million for the three months ended September 30, 2021 primarily due to:

- an increase of \$7.8 million in personnel compensation and related costs which was primarily due to headcount growth, particularly in commercial and administrative personnel, and grants of new share options and restricted shares and the continued vesting of those awards;
- an increase of \$3.2 million in professional service fees mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong after our commercial launch of these four commercialized products; those increases were partially offset by
- a decrease of \$3.4 million in other costs mainly related to selling, rental, and administrative expenses for commercial operations in mainland China, Hong Kong, and Taiwan.

Selling, general, and administrative expenses increased by \$37.7 million to \$186.9 million for the nine months ended September 30, 2022 from \$149.3 million for the nine months ended September 30, 2021 primarily due to:

- an increase of \$33.8 million in personnel compensation and related costs which was primarily due to headcount growth, particularly in commercial and administrative personnel, and grants of new share options and restricted shares and the continued vesting of those awards;
- an increase of \$10.3 million in professional service fees mainly attributable to our increased legal, compliance, accounting, and investor and public relations expenses associated with being a public company and in connection with sales of ZEJULA, Optune, QINLOCK, and NUZYRA in mainland China and Hong Kong after our commercial launch of these four commercialized products; those increases were partially offset by
- a decrease of \$6.4 million in other costs mainly related to selling, rental, and administrative expenses primarily for the commercial operation in mainland China, Hong Kong, and Taiwan.

Interest Income

Interest income increased by \$3.2 million to \$3.9 million from \$0.7 million for the three months ended September 30, 2022 and 2021, and increased by \$4.1 million to \$5.2 million from \$1.2 million for the nine months ended September 30, 2022 and 2021, due to increased interest rates during the third quarter of 2022.

Other Income (Expenses), Net

Other expenses, net increased by \$22.9 million to \$36.5 million for the three months ended September 30, 2022 from \$13.6 million for the three months ended September 30, 2021 primarily as a result of an increase in foreign exchange loss of \$36.7 million partially offset by an increase in equity investment gain in MacroGenics, Inc. ("MacroGenics") of \$10.4 million and an increase in subsidy income of \$3.4 million.

Other expenses, net increased by \$67.1 million to \$79.5 million for the nine months ended September 30, 2022 from \$12.4 million for the nine months ended September 30, 2021 primarily as a result of an increase in foreign exchange loss of

\$70.2 and an increase in equity investment loss in MacroGenics of \$2.1 million, partially offset by an increase in subsidy income of \$4.9 million.

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 periodically evaluate these judgments, estimates, and assumptions based on the most recently available information, our own historical experiences, and various other assumptions that we believe to be reasonable under the circumstances. Since the use of estimates is an integral component of the financial reporting process, actual results could differ from our expectations as a result of changes in our estimates. Some of our accounting policies require a higher degree of judgment than others in their application and require us to make significant accounting estimates.

The selection of critical accounting policies, the judgments, and other uncertainties affecting application of those policies and the sensitivity of reported results to changes in conditions and assumptions are factors that should be considered when reviewing our financial statements. We believe the following accounting policies involve the most significant judgments and estimates used in the preparation of our financial statements.

Revenue recognition

Description

In mainland China, we sell our products to distributors, who ultimately sell the products to healthcare providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the product's delivery to distributors.

Judgments and Uncertainties

Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates, if any, is recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes, and level of distributor inventories. We regularly review the information related to these estimates and adjust the amount accordingly.

Sensitivity of Estimate to Change

Actual amounts of rebates ultimately paid or billed may differ from our estimates. We will reassess estimates for rebates periodically. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Research and Development Expenses

Description

Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

Pre-clinical and clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various pre-clinical and clinical trial activities on our behalf in the ongoing development of our product candidates. Expenses related to pre-clinical and clinical trials are accrued based on our estimates of the actual services performed by the third parties for the respective period.

Judgments and Uncertainties

The process of estimating our research and development expenses involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule, or when contractual milestones are met; however, some require advanced payments. We make estimates of our expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

Sensitivity of Estimate to Change

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of research and development expenses.

Share-Based Compensation

Description

Share-based awards for our employees 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.

To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expenses relating to those awards are reversed.

Judgments and Uncertainties

We determine the fair value of the stock options granted to employees using the Black-Scholes option valuation model. Using this model, fair value is calculated based on assumptions with respect to (i) the expected volatility of our ADS price, (ii) the periods of time over which grantees are expected to hold their options prior to exercise (expected lives), (iii) the expected dividend yield on our ADSs, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the expected lives of the options. Expected volatility has been estimated based on actual movements in the stock prices of certain comparable companies over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previous option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

Sensitivity of Estimate to Change

The assumptions used in this method to determine the fair value of our ordinary shares consider historical trends, macroeconomic conditions, and projections consistent with the Company's operating strategy. Changes in these estimates can have a significant impact on the determination of fair value of the stock options. If factors change or different assumptions are used, our share-based compensation expenses could be materially different for any period.

Income Taxes

Description

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.

Judgments and Uncertainties

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.

Sensitivity of Estimate to Change

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 September 30, 2022 and 2021, we did not have any significant unrecognized uncertain tax positions.

B. Liquidity and Capital Resources

We have financed our activities primarily through private placements, our September 2017 initial public offering on Nasdaq, various follow-on offerings, and our September 2020 secondary listing on the Hong Kong Stock Exchange of our ordinary shares and/or ADSs. Through September 30, 2022, we have raised approximately \$164.6 million from private equity financing and approximately \$2,462.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us from our initial public offering, secondary listing and subsequent follow-on offerings.

Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$258.4 million and \$396.2 million for the nine months ended September 30, 2022 and 2021, respectively. We have commitments for capital expenditure of \$13.8 million as of September 30, 2022, mainly for the purpose of plant construction and installation. We currently are not aware of any events that are reasonably likely to cause a material change in the relationship between our costs and revenues.

As of September 30, 2022, we had cash, cash equivalents, restricted cash and short-term investment of \$1,120.3 million. Our expenditures are principally focused on research and development and are largely discretionary. Based on our current operating plan, we expect that our cash, cash equivalents, restricted cash and short-term investments will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months. However, in order to bring to fruition our research and development objectives, we will ultimately need additional funding sources, and there can be no assurances that they will be made available to us on acceptable terms or at all.

The following table provides information regarding our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30, Change				
		2022		2021	\$
Net cash used in operating activities	\$	(258,350)	\$	(396,237)	\$ 137,887
Net cash provided by investing activities		424,389		531,446	(107,057)
Net cash (used in) provided by financing activities		(1,531)		820,478	(822,009)
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash		(9,132)		695	(9,827)
Net increase in cash, cash equivalents and restricted cash	\$	155,376	\$	956,382	\$ (801,006)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2022, our operating activities used \$258.4 million of cash, which resulted from our net loss of \$381.5 million and cash used in our operating assets and liabilities of \$18.3 million, partially offset by non-cash charges of \$141.4 million.

During the nine months ended September 30, 2021, our operating activities used \$396.2 million of cash, which resulted from our net loss of \$492.6 million and cash used in our operating assets and liabilities of \$16.7 million, partially offset by non-cash charges of \$113.1 million.

Net Cash Provided by Investing Activities

Net cash provided by investing activities decreased by \$107.1 million to \$424.4 million for the nine months ended September 30, 2022 from \$531.4 million for the nine months ended September 30, 2021. The decrease was primarily due to an increase of \$90.3 million in purchases of short-term investments, a decrease of \$38.6 million in proceeds from

maturity of short-term investment, and an increase of \$8.3 million in purchase of property and equipment, offset by a decrease of \$30.0 million in payment for investment in equity investee.

Net Cash (Used In) Provided by Financing Activities

Net cash used in financing activities was \$1.5 million for the nine months ended September 30, 2022 compared to net cash provided by financing activities of \$820.5 million for the nine months ended September 30, 2021. The shift from cash provided by to cash used in financing activities was primarily because we had proceeds of \$818.9 million from our issuance of ordinary shares upon public offerings during the nine months ended September 30, 2021 while there were no such transactions during the nine months ended September 30, 2022.

C. Research and Development Activities and Expenditures, Including Patents and Licenses

Full details of our research and development activities and expenditures are provided in the "Research and Development Expenses" and "Results of Operations" sections above.

D. Trend Information

Other than as described elsewhere in this Quarterly Report on Form 10-Q, 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.

Recently Issued Accounting Standards

For more information regarding recently issued accounting standards, please see "Item 8. Financial Statements and Supplementary Data-Recent accounting pronouncements" in our 2021 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk including foreign exchange risk, credit risk, cash flow interest rate risk, and liquidity risk.

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China ("PBOC"), 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 Company included aggregated amounts of RMB292.1 million and RMB151.7 million, which were denominated in RMB, representing 4% and 2% of the cash and cash equivalents as of September 30, 2022 and December 31, 2021, respectively.

Our business mainly operates in mainland China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have significant direct foreign exchange risk and have not used 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 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 Greater 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 Chinese 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 Chinese 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, in August 2015, the PBOC significantly devalued the RMB.

The value of our ADSs and our ordinary shares will be affected by the foreign exchange rates between U.S. dollars, HK dollars and the RMB. For example, to the extent that we need to convert U.S. dollars or HK dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars or HK dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar or the HK 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 or HK 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 or the HK dollar against the RMB would have a negative effect on the conversion amounts available to us.

Since 1983, the Hong Kong Monetary Authority ("HKMA") has pegged the HK dollar to the U.S. dollar at the rate of approximately HK\$7.80 to US\$1.00. However, there is no assurance that the HK dollar will continue to be pegged to the U.S. dollar or that the HK dollar conversion rate will remain at HK\$7.80 to US\$1.00. If the HK dollar conversion rate against the U.S. dollar changes and the value of the HK dollar depreciates against the U.S. dollar, our assets denominated in HK dollars will be adversely affected. Additionally, if the HKMA were to repeg the HK dollar to, for example, the RMB rather than the U.S. dollar, or otherwise restrict the conversion of HK dollars into other currencies, then our assets denominated in HK dollars will be adversely affected.

Credit Risk

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, short-term investments, accounts receivable, and notes receivable.

The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of \$1,119.5 million and \$964.1 million and short-term investments of nil and \$445.0 million as of September 30, 2022 and December 31, 2021, respectively. As of September 30, 2022 and December 31, 2021, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in mainland China and international financial institutions outside of mainland China which we believe are of high credit quality and for which we monitor continued credit worthiness.

Accounts receivable are typically unsecured and are derived from product sales and collaborative arrangement. We manage credit risk of accounts receivable through ongoing monitoring of the outstanding balances and limit the amount of credit extended based upon payment history and the debtor's current credit worthiness. Historically, we have collected these receivables from customers within the credit terms with no significant credit losses incurred. As of September 30, 2022, our two largest debtors accounted for approximately 38% of our total accounts receivable collectively.

Certain accounts receivable balances are settled in the form of notes receivable. As of September 30, 2022, such notes receivable included bank acceptance promissory notes that are non-interest bearing and due within six months. These notes receivable were used to collect the receivables based on an administrative convenience, given these notes are readily convertible to known amounts of cash. In accordance with the sales agreements, whether to use cash or bank acceptance promissory notes to settle the receivables is at our discretion, and this selection does not impact the agreed contractual purchase prices.

Inflation

In recent years, mainland China has not experienced significant inflation. Although the global economy, including the U.S. economy, has experienced rising inflation in recent quarters, which can increase the costs of our products and product candidates purchased from third parties and, as a result, adversely affect our results of operations, inflation has not had a material impact on our results of operations. 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 mainland China or in other countries in which our third-party partners operate.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2)

accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2022, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2022, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the three months ended September 30, 2022, there have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We may be, 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 actual or threatened material legal or administrative proceedings.

Item 1A. Risk Factors.

This Quarterly Report on Form 10-Q should be read in conjunction with our 2021 Annual Report, Q1 2022 Form 10-Q, and Q2 2022 Form 10-Q, which describe various material risks and uncertainties to which we are or may become subject. These risks and uncertainties could, directly or indirectly, adversely affect our business, results of operations, financial condition, liquidity, or cash flows and could cause our actual results to differ materially from our past results or the results contemplated by any forward-looking statements we make. We believe the risks described in this section of our Quarterly Report on Form 10-Q and our 2021 Annual Report, Q1 2022 Form 10-Q, and Q2 2022 Form 10-Q are the most significant we face; however, these are not the only risks we face. We face additional risks and uncertainties not currently known to us or that we currently believe are not material.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
10.1*^	Collaboration and License Agreement by and between Seagen Inc. and Zai Lab (Hong Kong) Limited dated as of September 23, 2022
10.2**	Form of Restricted Share Unit Award Agreement
10.3*#	Form of Restricted Stock Award Agreement
10.4**	Form of Non-Statutory Stock Option Award Agreement
31.1*	Certification of Chief Executive Officer Required by Exchange Act Rule 13a-14(a)
31.2*	Certification of Chief Financial Officer Required by Exchange Act Rule 13a-14(a)
32.1**	Certification of Chief Executive Officer Required by 18 U.S.C. Section 1350
32.2**	Certification of Chief Financial Officer Required by 18 U.S.C. Section 1350
101.INS*	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File because its XBRL tags are embedd within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

^{*} Filed herewith

^{**} Furnished herewith

** Management contract or compensatory plan

^ Certain confidential information contained in this exhibit has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ZAI LAB LIMITED

Dated: November 9, 2022 By: /s/ Billy Cho

Name: Billy Cho

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

COLLABORATION AND LICENSE AGREEMENT

by and between

SEAGEN INC.

and

ZAI LAB (HONG KONG) LIMITED

dated as of September 20, 2022

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Exhibit A Schedule of Seagen Paten

- Exhibit B Description of Chemical Structure of tisotumab vedotin
- Exhibit C Initial Development Plan
- Exhibit D Participating Global Trial Cost Sharing Illustration for Global Trials Other Than TV-301 Global Trial

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is entered into as of September 20, 2022 (the "**Effective Date**"), by and between **Seagen Inc.**, a Delaware corporation, having a place of business at 21823 30th Drive S.E., Bothell, WA 98021, United States ("**Seagen**"), and **Zai Lab (Hong Kong) Limited**, a company organized and existing under the laws of Hong Kong, having a place of business at Room 2301, 23/F., Island Place Tower, 510 King's Road, North Point, Hong Kong ("**Licensee**").

Recitals

Whereas, Seagen is a biopharmaceutical company that, in collaboration with Genmab pursuant to the Genmab Agreements, is developing and commercializing the antibody-drug conjugate tisotumab vedotin (TIVDAK®) for the treatment of cancer and Controls certain patents and know-how relating to tisotumab vedotin;

Whereas, Licensee is engaged in the research, development and commercialization of pharmaceutical products in the Licensee Territory; and

Whereas, Licensee desires to obtain from Seagen, and Seagen desires to grant to Licensee, an exclusive license under the Seagen Technology to Develop and Commercialize the Licensed Products in the Field in the Licensee Territory (each as defined below), subject to the terms and conditions of this Agreement.

Now, Therefore, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Seagen and Licensee hereby agree as follows:

ARTICLE 1 DEFINITIONS

- **1.1** "ADC" shall mean [***]. For clarity, "ADC" as defined in this Agreement shall not include [***].
- **1.2** "Additional Active(s)" shall mean any active pharmaceutical or biologic ingredient(s) that is not the Licensed Compound.
- **1.3** "**Affiliate**" shall mean any company or entity controlled by, controlling, or under common control with a Party or another entity. For the purpose of this definition, an entity shall be deemed to "**control**" another entity, if it owns directly or indirectly, more than fifty percent (50%) of the outstanding voting securities, capital stock, or other comparable equity or ownership interest of such entity, or exercises equivalent influence over such entity.
- **1.4** "Aggregate Global Trial Costs" means, in respect of a Global Trial, the sum of each Party's [***], including, for example, in respect of [***] as well as [***]. For clarity, the examples set forth above are for illustration purposes only and are not comprehensive as regards activities that are global in nature or jurisdiction specific.

- **1.5** "Aggregate Net Sales" shall mean aggregate Net Sales of all Licensed Products by Licensee, its Affiliates and Sublicensees in the Licensee Territory. For the avoidance of doubt, any and all forms, presentations, dosage forms and formulations for Licensed Products incorporating the Licensed Compound shall be aggregated for purposes of Section 9.3 and Section 9.4.
 - **1.6** "Alliance Manager" shall have the meaning provided in Section 3.1.
- **1.7** "**Antibody to TF**" shall mean the monoclonal antibody included in the Licensed Compound or a derivative of such antibody, in each case that [***] to Tissue Factor (TF).
- 1.8 "Applicable Laws" shall mean collectively the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, and any license, franchise, permit or similar right granted under any of the foregoing (including Regulatory Approvals) and any policies and other requirements of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item or subject person, including the FCPA, Export Control Laws and other comparable laws.
 - **1.9** "**Approved Subcontractor**" shall mean each of the subcontractors in the list to be appended pursuant to Section 2.2(c).
 - **1.10** "Bankruptcy Laws" shall have the meaning provided in Section 14.5.
- 1.11 "Biosimilar Product" shall mean with respect to a given Licensed Product in a given Region, any biological product on the market in such Region for which a Third Party received Regulatory Approval (a) by the applicable Regulatory Authority in such Region as a generic, follow-on, hybrid, biosimilar, or interchangeable product of such Licensed Product, including without limitation any product that received Regulatory Approval in Mainland China under and in application of the Technical Guideline for the Research, Development and Evaluation of Biosimilars dated 28 February 2015 by the Center of Drug Evaluation, or under any similar or equivalent Applicable Laws, on a Region-by-Region basis where such Licensed Product is marketed, provided that such Applicable Laws exist, and (b) in reliance in whole or in part, on a prior Regulatory Approval (or on any safety or efficacy data submitted in support of such prior Regulatory Approval) of such Licensed Product. For countries or jurisdictions where no explicit biosimilar regulations exist, "Biosimilar Product" includes products which have been deemed to be a biosimilar or otherwise deemed interchangeable by a Regulatory Authority in the United States or Mainland China. Any product or component thereof (including any Licensed Product or component thereof) licensed, marketed, sold, manufactured, or produced by or on behalf of a Party, its Affiliates or Sublicensees will not constitute a Biosimilar Product for purposes of the royalty reduction pursuant to Section 9.6(a).
- **1.12** "**Bridging Study**" shall mean a clinical study performed in Mainland China in accordance with the then-current Development Plan to provide pharmacodynamic or clinical data on efficacy, safety, dosage and dose regimen in Mainland China that will allow extrapolation of clinical data collected from outside the Territory to Mainland China.

- **1.13** "Business Day" shall mean any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by law to close in Seattle, Washington, U.S., or Hong Kong Special Administrative Region.
- **1.14** "Calendar Quarter" shall mean each period of three (3) consecutive months commencing on January 1, April 1, July 1 or October 1 (or any portion thereof at the beginning or end of the Term or other relevant period).
- **1.15** "Calendar Year" shall mean each period of twelve (12) consecutive months commencing on January 1 and ending on December 31 (or any portion thereof at the beginning or end of the Term or other relevant period).
- 1.16 "Change of Control" shall mean, with respect to a Party, that: (a) any Third Party acquires directly or indirectly, through one or more related transactions, the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least fifty percent (50%) of the total voting power of all of the then-outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party, through one or more related transactions, is consummated which would result in shareholders or equity holders of such Party immediately prior thereto, no longer owning at least fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such merger, consolidation, recapitalization, or reorganization; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.
 - 1.17 "China PK Study" shall mean [***].
 - **1.18** "CMO Manufacturing Agreement" shall have the meaning provided in Section 7.3(b).
- **1.19** "Combination Product" shall mean a Licensed Product comprising the Licensed Compound and one or more Additional Active(s), where the Licensed Compound and the Additional Active(s) are (i) sold as a fixed dose/unit or otherwise coformulated, or (ii) sold as separate doses/units in a single package or otherwise co-packaged for a single invoiced price.
- **1.20** "Commercialization" shall mean, with respect to a product, all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale, and distribution of such product, including strategic marketing, sales force detailing, advertising, market product support, all customer support, product distribution, and invoicing and sales activities, but excluding Development, Manufacturing and Medical Affairs Activities. "Commercialize" and "Commercializing" shall have the correlative meanings.
 - **1.21** "**Commercialization Plan**" shall have the meaning provided in Section 8.2.
 - **1.22** "Commercialization Report" shall have the meaning provided in Section 8.2.

- 1.23 "Commercially Reasonable Efforts" shall mean, (a) where applied to carrying out specific tasks and obligations of a Party under this Agreement, expending (on its own and/or acting through any of its Affiliates, sublicensees or agents) reasonable, diligent, good faith efforts and resources to accomplish such task or obligation as [***] would normally use to accomplish a similar task or obligation under similar circumstances in accordance with Applicable Laws; and (b) where applied to the Development and/or Commercialization of the Licensed Products under this Agreement, the use of reasonable, diligent, good faith efforts and resources, in an active and ongoing program, as normally used by [***], in accordance with Applicable Laws. It is understood that in fulfilling any obligation to use Commercially Reasonable Efforts in this Agreement, a Party shall not take into account [***].
- **1.24** "Competing Product" shall mean, other than the Licensed Compound or a Licensed Product, any product for the treatment, prevention or diagnosis of conditions or diseases in humans [***].
- 1.25 "Confidential Information" shall mean all Know-How and other proprietary scientific, marketing, financial or commercial information or data Controlled by a Party or its Affiliates, which one Party or any of its Affiliates has furnished or made available to the other Party or its Affiliates, whether in oral, written or electronic form. All clinical data and results of any Global Trial shall be deemed Confidential Information of Seagen notwithstanding the fact that certain of such clinical data and results may be generated from trials conducted under Licensee's name and disclosed to Seagen by Licensee; and all Inventions shall be deemed the Confidential Information of the owning Party as set forth in Section 13.1. The existence and terms of this Agreement shall be deemed Confidential Information of each Party.
 - **1.26** "Contribution Percentage" shall mean, in respect of a Global Trial, the [***].
- 1.27 "Control" (including any variations such as "Controlled" and "Controlling") shall mean, with respect to any product, material (including Regulatory Materials), Know-How, Patents or other intellectual property rights, possession by a Party or Third Party of the right, power and authority (whether by ownership, license or otherwise, other than by virtue of any rights granted under this Agreement) to grant access to, to grant use of, or to grant a license or a sublicense to such material, Know-How, Patents or intellectual property rights without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any product, material, Know-How, Patents, or other intellectual property rights that are in-licensed or acquired by such Party or its Affiliates from a Third Party after the Effective Date, unless the other Party agrees to (a) comply with the terms and conditions of the agreement under which such product, material, Know-How, Patents, or other intellectual property rights were in-licensed or acquired by such Party; and (b) pay all amounts that such Party would be obligated to pay in connection with the grant, maintenance and exercise of a (sub)license as reasonably allocable to such other Party for use in its territory under such product, material, Know-How, Patents, or other intellectual property rights.
- **1.28** "Core Data Sheet" shall mean, with respect to a Licensed Product, a document prepared and maintained by Seagen setting forth material information relating to safety, efficacy, indications, dosing, pharmacology, and other information concerning such Licensed Product, that serves as a global reference document and the basis for local labeling for use in Regulatory

Materials and discussions with Regulatory Authorities both inside and outside the Licensee Territory with respect to such Licensed Product.

- **1.29** "Cover" shall mean, with respect to a Patent, that a Valid Claim of such Patent would (absent a license or ownership thereof) be infringed (or, in the case of a claim of a Patent that has not yet issued, would be infringed if it were issued) by the Manufacturing, use, offering for sale, sale or importation of the Licensed Compound or Licensed Products. "Covered" and "Covering" shall have the correlative meanings.
- **1.30** "**Data**" shall mean all data, including non-clinical data, preclinical data and clinical data, generated by or on behalf of a Party or its Affiliates or their respective (sub)licensees pursuant to activities conducted under this Agreement.
- **1.31** "**Development**" shall mean, with respective to a product, all non-clinical and clinical drug development activities and processes, including toxicology, pharmacology, project management and other non-clinical efforts, statistical analysis, delivery system development, the performance of clinical trials (excluding the Manufacturing of such product for use in clinical trials) and other activities, in each case, which are reasonably necessary to prepare submissions for, and obtain or maintain, Regulatory Approval of such product, including lifecycle management studies and other activities. "**Develop**" and "**Developing**" shall have the correlative meanings.
 - **1.32** "**Development Cost Amount**" shall have the meaning provided in Section 4.4(i).
 - **1.33** "**Development Cost Payment**" shall have the meaning provided in Section 4.4(i).
 - **1.34** "**Development Cost Report**" shall have the meaning provided in Section 4.4(i).
 - **1.35** "**Development Plan**" shall mean [***].
 - **1.36** "**Disclosing Party**" shall have the meaning provided in Section 11.1.
 - **1.37** "**Dispute**" shall have the meaning provided in Section 16.1.
 - **1.38** "**Divestiture**" shall have the meaning provided in Section 2.7.
 - **1.39** "Effective Date" shall have the meaning provided in the introductory paragraph of this Agreement.
 - **1.40** "Executive Officers" shall have the meaning provided in Section 3.6.
- **1.41** "Export Control Laws" shall mean all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986.

- **1.42** "FCPA" shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et seq.).
- **1.43** "FDA" shall mean the U.S. Food and Drug Administration and any successor entity thereto.
- **1.44** "Field" shall mean all preventative and therapeutic uses in humans.
- **1.45** "Final Contribution Percentage" shall have the meaning provided in Section 4.4(i).
- **1.46** "**First Commercial Sale**" shall mean, with respect to a Licensed Product, the first sale by or on behalf of Licensee, its Affiliate or Sublicensee of the Licensed Product in a Region in the Licensee Territory.
 - **1.47** "Force Majeure Event" shall have the meaning provided in Section 17.10.
 - **1.48** "**Fourth Tumor Type**" shall mean a tumor type other than [***].
- **1.49** "FTE" shall mean a full-time equivalent's work time for a twelve (12) month period, where "full-time" is determined by [***] per year. [***].
 - **1.50** "FTE Rate" shall mean [***]. [***].
- **1.51** "Fully Burdened Manufacturing Cost" shall mean, with respect to any Licensed Product supplied by or on behalf of Seagen: (a) if such Licensed Product is Manufactured by one (1) or more Seagen CMOs, the amount paid by Seagen to such Seagen CMOs for the supply of such Licensed Product; and (b) to the extent such Licensed Product is Manufactured by Seagen or its Affiliates, the fully-burdened cost of such Manufacturing, including the cost of [***].
- **1.52** "GCP" shall mean the then-current standards, practices and procedures for good clinical practices promulgated or endorsed by any applicable Regulatory Authority, as may be updated from time to time, including applicable guidelines promulgated under the ICH guidelines.
 - **1.53** "**Genmab**" shall mean Genmab A/S or any Affiliate or successor thereto under the Genmab Agreements.
- **1.54** "Genmab Agreements" shall mean (i) the License and Collaboration Agreement dated as of October 7, 2011, and (ii) the Joint Commercialization Agreement dated as of October 19, 2020, each entered into by and between Seagen and Genmab, pursuant to which Seagen and Genmab agreed to certain co-development and co-commercialization matters in relation to the Licensed Compound and Licensed Products, in each case (clauses (i) and (ii)), as amended.
 - **1.55** "Global Study Plan" shall have the meaning provided in Section 4.4(a).
- **1.56 "Global Trial"** shall mean a multi-regional clinical trial that is designed to support Regulatory Approvals for a Licensed Product in multiple regions and/or countries both

inside and outside the Licensee Territory through the conduct of a clinical trial for a Licensed Product in multiple countries, regions, territories and/or medical institutions both inside and outside the Licensee Territory, in all circumstances conducted as part of one (1) unified clinical trial or separately but concurrently in accordance with a common clinical trial protocol.

- **1.57** "GLP" shall mean the then-current standards, practices and procedures for good laboratory practices promulgated or endorsed by any applicable Regulatory Authority, as may be updated from time to time, including applicable guidelines promulgated under the ICH guidelines.
- **1.58** "**GMP**" shall mean the then-current standards, practices and procedures for good manufacturing practices promulgated or endorsed by any applicable Regulatory Authority, as may be updated from time to time, including applicable guidelines promulgated under the ICH guidelines.
- **1.59** "Governmental Authority" shall mean any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal.
- 1.60 "HGR Approval" shall mean (i) the applicable Regulatory Approval for Sampling, Collecting, Trading and Exporting Human Genetic Resources (中国人类遗传资源的采集、收集、买卖、出口、出境审批书) and (ii) the Export Certificate for Human Genetic Resources (人类遗传资源出口、出境证明), in each case, to be issued by the Ministry of Science and Technology (中华人民共和国科学技术部), in connection with disclosure or sharing of clinical data from clinical trials in Mainland China or other information as contemplated under this Agreement.
 - **1.61** "HK Tax Withholdings" shall have the meaning provided in Section 10.4(b)(i).
 - **1.62** "HK Tax Withholdings Rate" shall have the meaning provided in Section 10.4(b)(i).
 - **1.63** "**Human Materials**" shall have the meaning provided in Section 12.4(d).
 - **1.64** "**ICC**" shall have the meaning provided in Section 16.1.
- **1.65** "**ICH**" shall mean the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.
 - **1.66** "**Indemnitee**" shall have the meaning provided in Section 15.3.
 - **1.67** "**Indemnitor**" shall have the meaning provided in Section 15.3.
- **1.68** "**Initiation**" of a clinical study shall mean the administration of the first dose of the Licensed Product to the first human subject or patient in a particular clinical study.
- **1.69** "**Invention**" shall mean any inventions and/or discoveries, including processes, manufacture, composition of matter, Know-How, methods, assays, designs, protocols, and

formulas, and improvements or modifications thereof, patentable or otherwise, that are generated, developed, conceived or reduced to practice (constructively or actually) by or on behalf of one Party or its Affiliates or their respective (sub)licensees or the Parties jointly during the Term under this Agreement, including all rights, title and interest in and to the intellectual property rights therein and thereto.

- **1.70** "**Jointly Owned Other Inventions**" shall have the meaning provided in Section 13.1(b).
- **1.71** "Jointly Owned Other Invention Patents" shall have the meaning provided in Section 13.1(b).
- **1.72** "JSC" shall mean the Joint Steering Committee to be established by the Parties pursuant to Section 3.2.
- **1.73** "**Know-How**" shall mean all technical, scientific, regulatory and other information, results, knowledge, techniques and data, in whatever form and whether or not confidential, proprietary, patented or patentable, invention disclosures, plans, processes, practices, methods, knowledge, know how, skill, experience, ideas, concepts, test data (including pharmacological, toxicological and clinical test data), analytical and quality control data, formulae, specifications, marketing, pricing, distribution, cost, sales, and manufacturing data or descriptions. For clarity, Know-How does not include issued Patents or the inventions claimed thereby.
 - **1.74** "License" shall mean, collectively, the licenses granted by Seagen to Licensee pursuant to Section 2.1.
 - **1.75** "**License Payments**" shall have the meaning provided in Section 10.4(b).
- **1.76** "**Licensed Compound**" shall mean the ADC tisotumab vedotin, a monoclonal antibody against human Tissue Factor covalently coupled, via a protease-cleavable peptide linker, to monomethyl auristatin E (MMAE), the structure of which is described in **Exhibit B** hereto.
- **1.77** "**Licensed Product**" shall mean any product containing the Licensed Compound, in any and all forms, presentations, dosage forms, and formulations. For clarity, different forms, presentations, dosage forms, and formulations would be distinct Licensed Products
 - **1.78** "Licensee Indemnitees" shall have the meaning provided in Section 15.2.
- **1.79** "**Licensee Know-How**" shall mean any and all Know-How that is (a) Controlled by Licensee or any of its Affiliates as of the Effective Date or during the Term, and (b) necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Products. Notwithstanding the foregoing, Licensee Know-How shall not include [***].
 - **1.80** "Licensee Manufacturing Agreement" shall have the meaning provided in Section 7.3(a).

- **1.81** "Licensee Patents" shall mean any and all Patents that are (a) Controlled by Licensee or any of its Affiliates as of the Effective Date or during the Term, and (b) necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Products. Notwithstanding the foregoing, Licensee Patents shall not include [***].
 - **1.82** "Licensee Publication" shall have the meaning provided in Section 11.5(c).
 - **1.83** "Licensee Technology" shall mean the Licensee Know-How and Licensee Patents.
- **1.84** "**Licensee Territory**" shall mean the Mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan (each jurisdiction as listed, a "**Region**").
 - **1.85** "Licensee Territory Specific Study" shall have the meaning provided in Section 4.3.
 - **1.86** "Licensee Territory Specific Study Development Plan" shall have the meaning provided in Section 4.3.
 - **1.87** "Losses" shall have the meaning provided in Section 15.1.
- **1.88** "**MAA**" shall mean an application for the authorization for marketing of a product, including New Drug Application and Biologics License Application, and shall include all amendments and supplements thereto, filed with the applicable Regulatory Authority to gain approval to market such product in the applicable jurisdiction.
- **1.89** "Manufacture" shall mean, with respect to a product, activities related to the manufacture and supply of the product, including manufacturing supplies for Development or Commercialization, packaging, labeling, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of product, ongoing stability tests, storage, and shipment and regulatory activities directly related to any of the foregoing, but not including any Development or Commercialization activities. "Manufacturing" shall have the correlative meanings.
 - **1.90** "Manufacture Technology Transfer" shall have the meaning provided in Section 7.3.
 - **1.91** "**Manufacturing Agreements**" shall have the meaning provided in Section 7.3(b).
- **1.92** "Medical Affairs Activities" shall mean the following activities of medical affairs personnel (including, in certain cases, medical science liaisons; provided, for clarity, that not all of the following activities are performed by medical science liaisons related to a product): (a) providing input and assistance with consultancy meetings, recommending investigators for clinical trials and providing input in the design of trials, and delivering non-promotional scientific exchanges and conducting non-promotional activities such as presenting new clinical

trial and other scientific information; (b) providing grants to support continuing medical education or symposia for educational needs related to such product, including with respect to its therapeutic use; (c) development, publication, presentation and dissemination of publications relating to such product; (d) responding to medical inquiries and providing medical information services in response to inquiries communicated via sales representatives or received by letter, phone call or email, in each case, from healthcare professionals; (e) conducting so-called "named patient," "compassionate use," or similar patient assistance or access programs; (f) providing appropriate support for investigator-initiated trials and investigator-sponsored research; and (g) meetings with or presentations to (in-person or otherwise) physicians, administrators, or other professionals that are conducted in a hospital setting or healthcare organizations with respect to clinical value and outcomes, and clinical value and outcomes activities conducted with any hospital, health system, healthcare organization, or any other Third Party.

- **1.93** "Medical Affairs Plan" shall have the meaning provided in Section 6.2.
- **1.94** "**Net Sales**" shall mean, with respect to a Licensed Product, the gross amounts invoiced in arm's-length transactions by or on behalf of Licensee or any of its Affiliates or Sublicensees (each, a "**Selling Party**") from or on account of the sale of the Licensed Product by such Selling Party to Third Parties ([***]), less the sum of the following:
 - (a) [***];
 - **(b)** [***];
 - (c) [***]:
 - (d) [***]:
 - **(e)** [***]; and
 - (f) [***].

All of the foregoing deductions from the gross amount invoiced for such sales of the Licensed Product shall be determined in accordance with the Accounting Standards. A Licensed Product transferred to Third Parties in connection with clinical and non-clinical research and trials, samples distributed to health care professionals, "named patient sales," "compassionate use sales," or any similar program or bona fide arrangement in which a Selling Party agrees to [***].

Licensed Products shall be considered "sold" in accordance with the Accounting Standards. Net Sales shall be determined from the books and records of the Selling Party.

It is understood that any accruals for individual items reflected in Net Sales are periodically trued up and adjusted by each Selling Party consistent with its customary practices and in accordance with the Accounting Standards.

Sale or transfer of any Licensed Product between any of the Selling Parties shall not result in any Net Sales, and Net Sales shall be calculated based on any subsequent sales or dispositions to a Third Party. To the extent that any Selling Party receives consideration other

than or in addition to cash in consideration for the sale of the Licensed Product to a Third Party, Net Sales shall include the fair market value of such non-cash consideration for such sale of Licensed Product. For clarity, sales by a Selling to a Third Party wholesaler or similar distributor, group purchasing organization, pharmacy benefit manager, or retail chain customer shall be considered sales to a Third Party and Net Sales hereunder.

Net Sales of any Combination Product for the purpose of calculating royalties due under this Agreement shall be determined on a Region-by-Region basis for a given accounting period as follows: [***]. All net selling prices of the elements of such end-user product or service shall be calculated as the average net selling price of said elements during the applicable accounting period for which the Net Sales are being calculated. In the event that, in any Region, no separate sale of either the Licensed Product or Additional Active(s) included in such Combination Product are made during the accounting period in which the sale was made or if the net selling price for an active ingredient cannot be determined for an accounting period, Net Sales allocable to the Licensed Product in each such Region shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account, on a Region-by-Region basis, all relevant factors (including variations in potency, the relative contribution and value to the end user of the Licensed Product and the Additional Active(s) in the combination).

- **1.95** In the case where a drug delivery device is sold with or for use with the Licensed Product and included in the gross sales amount, any appropriate adjustment to Net Sales shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining same that takes into account all relevant factors. "**NMPA**" shall mean the National Medical Products Administration and any successor entity thereto or its provincial or local counterpart.
 - **1.96** "Non-Participating Global Trial" shall have the meaning provided in Section 4.4(b).
 - **1.97** "**OFAC**" shall have the meaning provided in Section 12.3(c).
 - **1.98** "Participating Global Trial" shall have the meaning provided in Section 4.4(b).
 - 1.99 "Party" shall mean Licensee or Seagen individually, and "Parties" shall mean Licensee and Seagen collectively.
- **1.100** "Patents" shall mean (a) patent applications filed in the applicable jurisdiction; (b) all patents, including supplemental protection certificates, that have issued or in the future issue from any of the foregoing, including utility models, design patents and certificates of invention; and (c) all divisionals, continuations, continuations-in-part, reissues, re-examination certificates, renewals, extensions or additions to any such patents and patent applications (as applicable).
 - **1.101** "**Permitted Domestic CMO**" shall have the meaning provided in Section 7.3(b).
 - **1.102** "**Pharmacovigilance Agreement**" shall have the meaning provided in Section 5.6.

- **1.103** "**Platform Inventions**" shall have the meaning provided in Section 13.1(a).
- **1.104** "Platform Invention Patents" shall have the meaning provided in Section 13.1(a).
- **1.105** "PRC" shall mean The People's Republic of China.
- **1.106** "**Product Infringement**" shall have the meaning provided in Section 13.3(a).
- **1.107** "**Product Inventions**" shall have the meaning provided in Section 13.1(a).
- **1.108** "**Product Invention Patents**" shall have the meaning provided in Section 13.1(a).
- **1.109** "**Product Marks**" shall have the meaning provided in Section 8.6.
- **1.110** "**Publication**" shall have the meaning provided in Section 11.5.
- **1.111** "**Receiving Party**" shall have the meaning provided in Section 11.1.
- **1.112** "Reconciliation Amount" shall have the meaning provided in Section 4.4(j).
- **1.113** "**Reconciliation Payment**" shall have the meaning provided in Section 4.4(j).
- **1.114** "**Reconciliation Report**" shall have the meaning provided in Section 4.4(j).
- **1.115** "Registrational Study" shall mean, with respect to a product, a human clinical trial (regardless of whether such clinical trial is referred to as a "phase 2 clinical trial", "phase 2b clinical trial", "phase 2/3 clinical trial", "phase 2b/3 clinical trial" or "phase 3 clinical trial") for such product, the results of which, together with prior information concerning such product, are determined by the sponsor to be intended to be sufficient to establish that such product is safe and effective for its intended indication to support the filing of an MAA. If a clinical trial of a product is not initially designed as a Registrational Study but is later redesigned, converted or expanded into such a trial, then it shall be deemed to be a Registrational Study hereunder as of the date it satisfies the criteria for a Registrational Study (including any required written acknowledgement by a Regulatory Authority). For clarity, TV-301 Global Trial shall be deemed to be a Registrational Study.
- **1.116** "**Regulatory Approval**" shall mean any and all approvals, licenses, permits, registrations or authorizations of or from any Regulatory Authority that are necessary to market and sell a pharmaceutical product in any country, region or other jurisdiction. For clarity, unless necessary to initiate marketing and selling of a product in a particular country, Regulatory Approval shall not include pricing or reimbursement approval.
- **1.117** "Regulatory Authority" shall mean any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country, region or jurisdiction, including for example the FDA in the United States or the NMPA in the PRC.

- **1.118** "Regulatory Exclusivity" shall mean marketing or data exclusivity conferred by the applicable Regulatory Authority in a country, region or jurisdiction on the holder of a marketing approval for a pharmaceutical product in such country, region or jurisdiction, including, by way of example and not of limitation, regulatory data exclusivity, orphan drug exclusivity, new chemical entity exclusivity and pediatric exclusivity.
- **1.119 "Regulatory Materials"** shall mean, with respect to a product, regulatory applications (including MAA), submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, market, sell or otherwise Commercialize such product in a particular country, region or jurisdiction.
 - **1.120** "**Remedial Action**" shall have the meaning provided in Section 5.8.
 - **1.121** "**Review Period**" shall have the meaning provided in Section 11.5(c).
 - **1.122** "**ROFN**" shall have the meaning provided in Section 2.7(c).
 - **1.123** "**ROFN Exercise Notice**" shall have the meaning provided in Section 2.7(c).
 - **1.124** "ROFN Exercise Period" shall have the meaning provided in Section 2.7(c).
 - **1.125** "**ROFN Negotiation Period**" shall have the meaning provided in Section 2.7(c).
 - **1.126** "**ROFN Offer Notice**" shall have the meaning provided in Section 2.7(c).
 - **1.127** "**Royalty Term**" shall have the meaning provided in Section 9.5.
 - **1.128** "**Rules**" shall have the meaning provided in Section 16.1.
 - **1.129** "Seagen Centralized Global Trial Costs" shall mean, [***].
 - **1.130** "Seagen CMO" shall mean any Third Party contract manufacturing organization engaged by Seagen.
 - **1.131** "Seagen Global Medical Affairs Plan" shall have the meaning provided in Section 6.2.
 - **1.132** "Seagen Indemnitees" shall have the meaning provided in Section 15.1.
- **1.133** "Seagen Know-How" shall mean any and all Know-How that (i) is Controlled by Seagen or any of its Affiliates as of the Effective Date and during the Term, and (ii) is necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or Licensed Products in the Field in the Licensee Territory. Notwithstanding the foregoing, Seagen Know-How shall not include [***]. [***].
- **1.134** "Seagen Manufacturing Know-How" shall mean any and all Know-How that (i) is Controlled by Seagen or any of its Affiliates as of the Effective Date and during the Term, and (ii) is necessary or reasonably useful for the Manufacture of the Licensed Compound or Licensed

Products in the Field in the Licensee Territory. Notwithstanding the foregoing, Seagen Manufacturing Know-How shall not include [***].

- **1.135** "Seagen Manufacturing Patents" shall mean any and all Patents that (i) are Controlled by Seagen or any of its Affiliates as of the Effective Date and during the Term and (ii) are necessary or reasonably useful for the Manufacturing of the Licensed Compound or Licensed Products in the Field in the Licensee Territory. Notwithstanding the foregoing, Seagen Manufacturing Patents shall not include [***].
 - **1.136** "Seagen Non-compete Period" shall have the meaning provided in Section 2.7(b).
- **1.137** "Seagen Patents" shall mean any and all Patents that (i) are Controlled by Seagen or any of its Affiliates as of the Effective Date and during the Term and (ii) are necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or Licensed Products in the Field in the Licensee Territory. A list of Seagen Patents as of the Effective Date is attached hereto on **Exhibit A**. Notwithstanding the foregoing, Seagen Patents shall not include [***]. For clarity, Seagen Patents shall not include Seagen Manufacturing Patents.
- **1.138** "Seagen Platform" shall mean Seagen's proprietary antibody-drug conjugate platform (i) generally relating to [***] and (ii) not solely and specifically related to the Licensed Compound.
 - **1.139** "Seagen Platform Patents" shall mean any and all Patents that Covers any aspect of the Seagen Platform.
 - **1.140** "Seagen Publication" shall have the meaning provided in Section 11.5(b).
- **1.141** "Seagen Technology" shall mean the Seagen Know-How, Seagen Patents, Seagen Manufacturing Know-How and Seagen Manufacturing Patents.
 - **1.142** "SEC" shall have the meaning provided in Section 11.4(a)(i).
- **1.143** "Segregate" shall mean, with respect to a Competing Product, to use diligent efforts to segregate the Development, Manufacturing and Commercialization activities relating to such Competing Product, from the Development, Manufacturing and Commercialization activities with respect to Licensed Products, including using diligent efforts to ensure that: [***], in each case (a) and (b) to the extent that such activities are subject to exclusivity obligations for a Party as set forth herein.
 - **1.144** "Solely Owned Other Inventions" shall have the meaning provided in Section 13.1(b).
 - **1.145** "Solely Owned Other Invention Patents" shall have the meaning provided in Section 13.1(b).
- **1.146** "Sublicense" shall mean a license, sublicense, covenant not to sue or other rights granted by Licensee to a Third Party under the rights it receives from Seagen in accordance with

<u>Section 2.2</u> (Sublicense Rights), to Develop or Commercialize a Licensed Compound or a Licensed Product, but excluding any grant of rights to or agreement with (a) any Third Party acting as a service provider or subcontractor for such Party or its Affiliates, or (b) any Third Party wholesaler, distributor, or the like.

- **1.147** "Sublicensee" means a Third Party that is receiving rights under a Sublicense.
- **1.148** "Sublicensee/Subcontractor Background Technology" shall have the meaning provided in Section 13.1(d).
- **1.149** "Tax Withholdings" shall have the meaning provided in Section 10.4(c).
- **1.150** "**Term**" shall have the meaning provided in Section 14.1.
- **1.151** "Third Party" shall mean any entity other than Licensee and its Affiliates and Seagen and its Affiliates.
- **1.152** "**Tissue Factor**" or "**TF**" shall mean: [***], in each case including any isoforms, polymorphisms, variants, and truncated forms, and in each case to the extent such variant, isoform, polymorphism, variant and truncated form are produced from an allele of the same gene.
 - **1.153** "**Third Party Claims**" shall have the meaning provided in Section 15.1.
- **1.154 "TV-301 Global Trial"** shall mean the clinical trial known as Phase 3 Randomized Study of Tisotumab Vedotin vs Chemotherapy in Recurrent or Metastatic Cervical Cancer.
- **1.155** "**United States**" or "**U.S.**" shall mean the United States of America, including its territories and possessions as recognized by the United Nations from time to time, but in all cases including, for clarity, Puerto Rico
 - 1.156 "US\$" or "U.S. Dollars" shall mean U.S. dollars, the lawful currency of the U.S.
 - **1.157** "**Upfront Payment**" shall have the meaning provided in Section 9.1.
- **1.158** "Valid Claim" shall mean a claim contained in (a) an issued and unexpired Patent, which claim has not been found to be unpatentable, invalid, revocable or unenforceable by a decision of a court or other authority of competent jurisdiction in the subject country or jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal, and has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise, or (b) a Patent application that has not been irretrievably cancelled, withdrawn, abandoned or rejected; provided, however, that Valid Claim will exclude any such claim in a Patent application that has not been granted within [***] following the earliest priority filing date for such application (except that any claim issued from such an excluded pending patent application shall become a Valid Claim at and after its date of issuance).
 - **1.159** "Withholding Tax Action" shall have the meaning provided in Section 10.4(d).

ARTICLE 2 LICENSE

2.1 License Grant. Subject to the terms and conditions of this Agreement (including Seagen's retained rights in Section 2.4), Seagen hereby grants to Licensee, during the Term, an exclusive (even as to Seagen and its Affiliates), royalty-bearing license, under the Seagen Technology solely to Develop, use, sell, offer for sale, import and otherwise Commercialize the Licensed Products in the Field in the Licensee Territory.

2.2 Sublicense Rights; Subcontractors.

- **(a) Right to Sublicense.** Subject to the terms and conditions of this Agreement, Licensee shall have the right to grant Sublicenses under the License, to (i) an Affiliate, or (ii) to a Third Party with Seagen's prior written consent in its reasonable discretion for the sole purpose of performing Licensee's obligations with respect to the Development and Commercialization of Licensed Products in the Field in the Licensee Territory.
- **(b) Sublicense Terms**. Any Sublicense granted by Licensee under this Agreement shall be (i) in writing and (ii) subject and subordinate to, and consistent with, the terms and conditions of this Agreement. It shall be a condition of any Sublicense that the Affiliate or Sublicensee, as applicable, agrees to be bound by the terms of this Agreement applicable to Licensee. Without limiting the foregoing, each Sublicense agreement shall include the following additional terms and conditions: [***].
- (c) Subcontractors. Subject to the terms and conditions of this Agreement, Licensee shall have the right to engage subcontractors with Seagen's written consent (not to be unreasonably withheld, delayed or conditioned) to any contract research organization and other Third Party subcontractor solely to the extent required and for the sole purpose of performing Licensee's obligations with respect to the Development and Commercialization of Licensed Products in the Field in the Licensee Territory, provided that Licensee shall (a) provide written notice to Seagen no less than [***] prior to engaging any such subcontractors that are not Approved Subcontractors, and (b) ensure such subcontractors are bound by written obligations of confidentiality and non-use consistent with this Agreement and have agreed in writing to assign to Licensee all Data, Know-How, Inventions or other intellectual property generated by such subcontractor in the course of performing such subcontracted work (subject to Section 13.1(d)). Without prejudice to Licensee's obligations under Section 2.7(a), Section 2.7(a) will not apply to any of Licensee's subcontractors except to the extent such subcontractor is researching, Developing, Manufacturing or Commercializing any Competing Product on behalf of Licensee, its Affiliates or Sublicensees. Within [***] after the Effective Date and subject to Seagen's reasonable due diligence of any such proposed subcontractors, the Parties will prepare and append hereto a mutually agreed list of Approved Subcontractors and may supplement such list by mutual agreement from time-to-time.
- **(d) Licensee's Responsibility**. Licensee will be responsible for ensuring that the performance by any of its Affiliates, Sublicensees and subcontractors hereunder is in accordance with the applicable terms of this Agreement. Licensee shall be responsible for any actions of its Affiliates, Sublicensees and subcontractors to the same extent as if such actions had been taken

by Licensee itself, and Seagen shall have the right to proceed directly against Licensee without any obligation to first proceed against such Affiliate, Sublicensee, or subcontractor. Licensee shall provide Seagen with a copy of any Sublicensee agreement entered into with a Sublicensee, and any amendment thereto, at least [***] prior to its execution, *provided* that (i) Licensee may redact confidential or commercially sensitive information that is not relevant to the rights licensed to Licensee under this Agreement, and (ii) the terms of such agreement will be Licensee's Confidential Information. Licensee shall be liable for the failure of its Affiliates, Sublicensees or subcontractors to comply with the relevant obligations under this Agreement and shall, at its own cost, enforce compliance by its Affiliates, Sublicensees, and subcontractors with the terms of the applicable sublicense agreement.

- **2.3 Negative Covenants**. Licensee hereby covenants not to practice, and not to permit or cause any Affiliate, Sublicensee or other Third Party to practice, any Seagen Technology for any purpose except as expressly authorized in this Agreement.
- **2.4 No Implied Licenses; Retained Rights.** No right or license under any Patents or Know-How of either Party is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Seagen hereby expressly reserves all rights not expressly licensed to Licensee in Section 2.1, including (i) all rights under the Seagen Technology with respect to the Licensed Compound and Licensed Products outside the Field in the Licensee Territory, (ii) all rights under the Seagen Technology with respect to the Licensed Compound and Licensed Products both in and outside the Field outside the Licensee Territory, (iii) all rights under the Seagen Technology to exercise its rights or perform its obligations under this Agreement, (iv) all rights under the Seagen Technology to conduct Development activities in the Licensee Territory for the purpose of Developing the Licensed Compound or Licensed Products outside the Licensed Products, whether in or outside the Licensee Territory for the purpose of Developing or Commercializing the Licensed Compound or Licensed Products outside the Licensee Territory, in each case whether directly or through its Affiliates, licensees or contractors.
- **2.5 License to Seagen**. Licensee hereby grants to Seagen an exclusive (even as to Licensee and its Affiliates), fully paid, royalty-free license, with the right to sublicense through multiple tiers to any Affiliate of Seagen, Genmab, or any other Third Party, under the Licensee Technology, to (i) fulfill, either itself, through its Affiliates, Genmab or its Affiliates, or through subcontractors, its obligations under this Agreement, including its Manufacturing and supply obligations under Sections 7.1 and 7.2, and (ii) Develop for the purpose of Developing the Licensed Compound or Licensed Products outside the Licensee Territory or Commercialize for the purpose of Commercializing the Licensed Compound or Licensed Products outside the Licensee Territory.
- **2.6 Know-How Transfer**. After Seagen's receipt of the Upfront Payment, Seagen will provide or make available to Licensee (to the extent not previously provided or made available to Licensee) access in electronic format to Seagen Know-How as mutually agreed with respect to scope and timing that is necessary or reasonably useful for Licensee to perform its obligations under this Agreement, including the activities assigned to Licensee under the Global Development Plan or Licensee Territory Specific Study Development Plan.

2.7 Exclusivity.

- **(a)** During the Term, neither Licensee nor any of its Affiliates shall, without prior written consent of Seagen, (i) directly or indirectly, whether by itself or with or through any of its Affiliates, or (ii) with, through or in collaboration with any Third Party, whether through license, assignment, joint venture or otherwise (including via any arrangement or series of arrangements with a Third Party), research, Develop, Manufacture or Commercialize any Competing Product in the Licensee Territory.
- **(b)** During the period commencing on the Effective Date and ending on the [***] (the "Seagen Non-compete Period"), neither Seagen nor any of its Affiliates shall, without prior written consent of Licensee, (i) directly or indirectly, whether by itself or with or through any of its Affiliates, or (ii) with, through or in collaboration with any Third Party, whether through license, assignment, joint venture or otherwise (including via any arrangement or series of arrangements with a Third Party), Commercialize any Competing Product in the Field in the Licensee Territory.
- (c) Following the expiration of the Seagen Non-compete Period and continuing until the [***] thereof, Seagen hereby grants Licensee a right of first negotiation (the "ROFN") such that if Seagen or any of its Affiliates decides to [***], Seagen will provide Licensee with written notice of such a decision, together with the [***] Controlled by Seagen and as [***] reasonably determines would be reasonably needed for Licensee to determine its interest in pursuing such opportunity with respect to such Competing Product in the Field in the Licensee Territory ("ROFN Offer Notice"). Within [***] following the date of such ROFN Offer Notice (the "ROFN Exercise Period"), Licensee may exercise its ROFN by providing Seagen with written notice of its exercise thereof (a "ROFN Exercise Notice"). Upon timely provision of a ROFN Exercise Notice by Licensee, Seagen will, and will cause any applicable Affiliates to, negotiate in good faith with Licensee for a period of at least [***] from the date of the ROFN Exercise Notice (the "ROFN Negotiation Period") the terms of a definitive agreement with respect to the Commercialization of such Competing Product in the Field in the Licensee Territory. Neither Seagen nor Licensee shall have any obligation to enter into a definitive agreement with respect to such opportunity. If (i) Licensee does not provide Seagen with a ROFN Exercise Notice with respect to pursuing such opportunity for such Competing Product within the ROFN Exercise Period, or if (ii) Licensee timely provides Seagen with a ROFN Exercise Notice, but Seagen and Licensee (or Licensee and any applicable Affiliate of Seagen) fail to reach a definitive agreement with respect to such Opportunity for such Competing Product during the ROFN Negotiation Period, then the ROFN with respect to such Competing Product will expire, upon which Seagen and its Affiliates are free to negotiate or enter into any agreement with any Third Party with respect to such Competing Product in the Licensee Territory.
 - **(d)** Notwithstanding subsection (a) and subsection (b), if:
- (i) Licensee or any of its Affiliates acquires any Competing Product or the rights to Develop, Manufacture or Commercialize any Competing Product anywhere in the Licensee Territory in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction) then such acquisition, and the Development, Manufacture, or Commercialization of such Competing Product thereafter, shall not constitute a breach of subsection (a) if Licensee or such Affiliate, as applicable, [***];

- (ii) Licensee is acquired by a Third Party in connection with a Change of Control of Licensee that is at the time of such acquisition or thereafter Developing, Manufacturing, or Commercializing a Competing Product anywhere in the Licensee Territory, then such acquisition, and the Development, Manufacture, or Commercialization of such Competing Product by such acquiror or its Affiliates, shall not constitute a breach of subsection (a) [***];
- (iii) Seagen or any of its Affiliates acquires any Competing Product or the rights to Commercialize any Competing Product anywhere in the Licensee Territory in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction), then such acquisition, and the Commercialization of such Competing Product thereafter, shall not constitute a breach of subsection (b) if Seagen or such Affiliate, as applicable, [***]; and
- **(iv)** Seagen is acquired by a Third Party in connection with a Change of Control of Seagen that is at the time of such acquisition or thereafter Commercializing a Competing Product anywhere in the Licensee Territory, then such acquisition, and the Commercialization of such Competing Product by such acquiror or its Affiliates, shall not constitute a breach of subsection (b) [***].

For purposes of subsection (d), "**Divestiture**" means (a) the divestiture of the applicable Competing Product through (i) an outright sale or assignment of all material rights in such Competing Product to a Third Party or (ii) an exclusive out-license of all Development, Manufacturing, and Commercialization rights with respect to such Competing Product in the case of Licensee and an exclusive out-license of all Commercialization rights with respect to such Competing Product in the case of Seagen, or (b) the [***] Development, Manufacturing, and Commercialization activities with respect to such Competing Product in the case of Licensee and of all Commercialization activities with respect to such Competing Product in the case of Seagen. [***]. "**Divest**" has a corresponding meaning.

ARTICLE 3 GOVERNANCE

3.1 Alliance Managers. Each Party shall appoint an individual, who is fluent in English and an employee of such Party, to act as its alliance manager under this Agreement within [***] after the Effective Date (the "**Alliance Manager**"). 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 and subcommittee meetings (in each case, as a non-voting participant); provided that the Alliance Managers shall not count toward the number of representatives that each Party may have on each such committee. An Alliance Manager may also bring any matter to the attention of the JSC, 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**. Within [***] following the Effective Date, the Parties shall establish a JSC to approve, plan, coordinate, integrate monitor and oversee the Parties' activities in the Licensee Territory and facilitate information exchange between the Parties under this Agreement. The JSC shall in particular:
- **(a)** review, discuss and coordinate the overall strategy for the Development and Commercialization of the Licensed Products in the Licensee Territory;
- **(b)** review, discuss and approve any proposed amendments or revisions to the Development Plan(s), Medical Affairs Plan(s), and Commercialization Plan(s);
 - (c) review, discuss and approve any study protocols relating to the Development Plan(s) (and any amendments thereto);
- **(d)** review, discuss, and approve the portion of the Global Study Plan to be performed in the Licensee Territory (and any amendment thereto);
- **(e)** review, discuss, and approve the Licensee Territory Specific Study Development Plan, including clinical trial sites, investigators, and contract research organizations that Licensee proposes to engage to perform activities in connection with any Licensee Territory Specific Study;
- **(f)** review, discuss and serve as a forum for the sharing of information between the Parties regarding the operation of any Development activities by Licensee;
- **(g)** oversee and coordinate the on-going disclosure, sharing and/or transfer of new Inventions generated in or related to the Development of the Licensed Products in the Licensee Territory;
 - (h) review and discuss any Regulatory Materials to be submitted to any Regulatory Authority in the Licensee Territory;
- (i) discuss, review and determine whether to approve any deviation to the Core Data Sheet in connection with a Regulatory Approval for a Licensed Product in the Licensee Territory;
- **(j)** oversee and coordinate the Commercialization of the Licensed Products in the Field and branding strategies in the Licensee Territory to ensure consistent global marketing of the Licensed Products;
- **(k)** review and discuss the Commercialization Plan, [***], in compliance with Applicable Laws (including antitrust and competition laws);
 - (I) oversee and coordinate the Medical Affairs Activities of the Licensed Products in the Field;
 - (m) coordinate supply of Licensed Product in accordance with Article 7; and

- **(n)** perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.
- **3.3 Subcommittees**. From time to time during the Term, the JSC may establish and disband one or more subcommittee(s) to oversee particular activities of the Parties, and the JSC may assign to such subcommittee(s) duties or tasks independent of the duties of the JSC, or delegate part of such duties of the JSC to such subcommittee(s) as it deems necessary and appropriate.
- 3.4 Composition; Meetings. The JSC shall be composed of [***] representatives from each Party (or such other equal number of representatives of each of Licensee and Seagen as the JSC may determine), and each Party shall notify the other Party of its initial JSC representatives within [***] after the Effective Date. [***] shall designate a representative to be the chairperson of the JSC (and subcommittees, if any), who shall schedule meetings, prepare meeting agenda and meeting minutes and follow up on action items. Each Party may change its representatives to the JSC from time to time in its sole discretion, effective upon notice to the other Party of such change. Each Party's JSC representatives shall be employees of such Party with appropriate experience and seniority within such Party's organization, and shall have the authority to make decisions on behalf of the Party they represent. In addition, at least one (1) of Licensee's JSC representatives must be someone whose job responsibilities within Licensee include active involvement in the development and implementation of Licensee's Development strategy with respect to the Licensed Products in the Field in the Licensee include active involvement in the development and implementation of Licensee's marketing and sales strategy with respect to the Licensed Products in the Field in the Licensee Territory.
- **3.5 Non-Member Attendance**. Each Party may from time to time invite [***] to attend a meeting of the JSC or its subcommittee(s) (in a non-voting capacity) in the event that the planned agenda for such JSC or subcommittee meeting would require such participants' expertise; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend (except in the case of Genmab or its Affiliates for which no approval shall be required), and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.
- **3.6 Decision-Making**. All decisions of the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. Except where consent or approval on any matter by a Party is expressly required herein, if after reasonable discussion and good faith consideration of each Party's view on any matter within the decision-making authority of the JSC, the representatives of the Parties on the JSC cannot reach an agreement as to such matter within [***] after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to [***] and [***] (collectively, the "**Executive Officers**") for resolution. If the Executive Officers cannot resolve such matter within [***] after such matter has been referred to them, then:
- **(a)** Seagen shall be entitled to make final decisions on all matters (A) [***] relating to the Development or Commercialization of the Licensed Compound and Licensed Products

outside the Licensee Territory, (B) relating to any Global Trial, [***], provided that Seagen shall not exercise such final decision-making authority to [***] to Licensee or [***] the Development of Licensed Products in the Licensee Territory, (C) relating to Manufacturing, [***], provided that Seagen shall not exercise such final decision-making authority to [***] Licensed Products in the Licensee Territory, (D) relating to any Development of the Licensed Compound or a Licensed Product in combination with one or more Additional Active(s), including any clinical trial combination study, (E) relating to any Development of a new form, presentation, dosage form or formulation of a Licensed Product, (F) relating to any Development or Commercialization of the Licensed Compound or Licensed Products in the Licensee Territory which, in Seagen's reasonable belief, could materially adversely affect the Development or Commercialization of the Licensed Compound and Licensed Products outside the Licensee Territory, or (G) that are subject to the final or joint decision-making authority of Genmab under the Genmab Agreements; and

- **(b)** Subject and subordinate to the foregoing subsection (a), Licensee shall be entitled to make final decisions with respect to matters [***] to the Development or Commercialization of the Licensed Products in the Field in the Licensee Territory, [***].
- **3.7 Limitations on Authority**. The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, the JSC shall not have the power to amend this Agreement, and no decision of the JSC may be in contravention of any terms and conditions of this Agreement. For clarity, the JSC shall have no decision-making authority regarding any Development, Manufacturing, Commercialization or other activity outside the Licensee Territory.
- **3.8 Meetings**. The JSC will hold a meeting every [***] or as otherwise determined by the JSC. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person meetings will be determined by the Parties. At least [***] prior to each JSC meeting, each Party shall provide written notice to the other Party of agenda items proposed by such Party for discussion at such meeting, together with appropriate information related thereto. Reasonably detailed written minutes will be kept for all JSC meetings. Meeting minutes will be prepared on an alternating basis and sent to each member of the JSC for review and approval within [***] after the meeting. Minutes will be deemed approved unless a member of the JSC objects to the accuracy of such minutes within [***] of receipt.
- **3.9 Discontinuation of JSC**. The JSC shall continue to exist until the Parties mutually agree to disband the JSC. Once the JSC is disbanded, the JSC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement, and the Parties shall reach decision directly on matters that are subject to the decision of the JSC as set forth in Section 3.2.

ARTICLE 4 DEVELOPMENT

4.1 Overview; Diligence.

- (a) Except as expressly provided herein, Licensee (itself and through its Affiliates and their respective Sublicensees) shall be responsible, [***], for the Development of the Licensed Products in the Field in the Licensee Territory under the oversight of JSC. Without limiting the generality of the foregoing, Licensee shall use Commercially Reasonable Efforts to (i) Develop the Licensed Products in Field in the Licensee Territory in accordance with the Development Plan(s) ([***]); (ii) perform the Development activities set forth in the Development Plan(s) or assigned to it under the Global Study Plan and in compliance with Applicable Laws (including GCP); and (iii) obtain or assist Seagen to obtain Regulatory Approvals for the Licensed Products in each Region in the Licensee Territory.
 - **(b)** Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to [***].
- **(c)** Notwithstanding subsections (a) and (b), for the avoidance of doubt, the activities assigned to Licensee pursuant to the Development Plan may vary from Global Trial to Global Trial and may vary from Region to Region with respect to any particular Global Trial.
- **4.2 Development Plan**. As of the Effective Date, the Parties have agreed to an initial plan for the clinical Development of the Licensed Products for cervical cancer in the Licensee Territory. The Development Plan shall set forth with reasonable details, *inter alia*, the scope, timeline, responsibilities of each Party, and budget (the budget component may be added to the initial Development Plan after the Effective Date) of the Development activities to be conducted by or on behalf of Licensee in order to obtain Regulatory Approvals for the Licensed Products in the Licensee Territory. From time to time during the Term, either Party may propose written amendments and updates to the then-current Development Plan, and shall submit such amendments and updates to the JSC for review and approval.
- **4.3 Licensee Territory Specific Studies.** Subject to the terms and conditions of this Agreement, including JSC oversight and Seagen's final decision-making rights in Section 3.6(a), Licensee will be solely responsible for conducting or engaging third party contractors [***] to conduct all non-clinical and clinical studies that are specifically required to obtain Regulatory Approval for Licensed Products solely in the Licensee Territory (i.e., such studies are not required to obtain Regulatory Approval of the Licensee Products outside the Licensee Territory) (each, a "Licensee Territory Specific Study") in accordance with the Development Plan(s) [***] (each, a "**Licensee Territory Specific Study Development Plan**"). The Parties will cooperate in all material aspects in such efforts with respect to obtaining Regulatory Approval of any Licensed Product in the Licensee Territory. Licensee shall not initiate any clinical Licensee Territory Specific Study unless the proposed indication, the study protocol and the Licensee Territory Specific Study Development Plan for such Licensee Territory Specific Study have been [***]. Licensee shall be responsible for all Development [***] incurred in conducting the Licensee Territory Specific Studies.

4.4 Global Trials.

- **(a) TV-301 Global Trial**. Seagen will include sites from the Licensee Territory in the ongoing TV-301 Global Trial of the Licensed Product for cervical cancer. The TV-301 Global Trial shall be deemed to be a Participating Global Trial (as defined below). After the Effective Date, the Parties shall discuss in good faith [***].
- (b) Opt-In to Participate in Global Trial(s) other than the TV-301 Global Trial. Seagen may consider from time to time the feasibility of conducting one or more Global Trial(s) in addition to the TV-301 Global Trial. Seagen shall include sites from the Licensee Territory in such additional Global Trial(s) unless such inclusion is [***]. If Seagen determines to conduct an additional Global Trial and sites in Mainland China will be included in such Global Trial, Seagen shall [***] (such trial, if such notice is timely delivered and affirms that Licensee will participate, a "Participating Global Trial"). During such [***] period (and, for clarity, without extending such period), Seagen shall [***] in respect of relevant information regarding such protocol or Global Trial design and budget. In the event Licensee notifies Seagen that it will not participate in such Global Trial, or during such [***] period does not notify Seagen that it will participate in such Global Trial, then Seagen shall have the right to conduct such trial on its own, [***] (and such Global Trial shall be deemed a "Non-Participating Global Trial").
- (c) Sponsorship and Design of Participating Global Trials; Cooperation. For each Participating Global Trial, except as may be otherwise agreed to by the Parties (i) Seagen or its designee will lead and be the sponsor of such Global Trial and will be fully responsible for preparing and adopting a plan for conducting such Global Trial (each a "Global Study Plan"), and (ii) Licensee shall act as the local agent of Seagen in the Licensee Territory in respect of each such Global Trial. Seagen shall, [***], design proposed Global Trials to support regulatory submissions in the Licensee Territory and Licensee shall reasonably cooperate and cause its permitted subcontractors and vendors to cooperate with Seagen and its subcontractors and vendors who may be engaged on work related to the applicable Global Study Plan.
- **(d) Conduct of Participating Global Trials**. Each Global Study Plan for a Participating Global Trial will set out the Development activities [***] that are to be conducted in the Licensee Territory, including the recruitment, if applicable, of study subjects in the Licensee Territory. Licensee shall use Commercially Reasonable Efforts to complete the activities [***] in accordance with the [***]. All such activities shall be conducted in accordance with Applicable Laws and this Agreement. Without limiting the foregoing, (X) for the TV-301 Global Trial, upon Seagen's request and in accordance with Seagen's directions, Licensee shall [***] and (Y) for each Participating Global Trial other than the TV-301 Global Trial, Licensee shall carry out such Participating Global Trial [***]. For each such Participating Global Trial with respect to (Y) above, Licensee shall, in accordance with the corresponding Global Study Plan, either by itself or through its Affiliates and permitted subcontractors in accordance with Section 2.2(c), be responsible for implementing, and shall use Commercially Reasonable Efforts to conduct, such Participating Global Trial [***].
 - (e) Patient Recruitment in the Licensee Territory. [***].
- **(f)** Cost Sharing for the TV-301 Global Trial. With respect to the TV-301 Global Trial, and subject to reconciliation as set forth in Section 4.4(j), Licensee shall be responsible for the amount equal to [***]. Notwithstanding the definition thereof in Article 1 referring to the Licensee Territory, the [***] for the TV-301 Global Trial is intended to reflect [***]. Such

Contribution Percentage shall, subject to reconciliation as set forth in Section 4.4(j), be deemed to be [***] for purposes of the TV-301 Global Trial.

- **(g) Cost Sharing for Participating Global Trials other than the TV-301 Global Trial.** With respect to each Participating Global Trial other than the TV-301 Global Trial, and subject to reconciliation as set forth in Section 4.4(j), Licensee shall be responsible for the amount equal to the sum of [***] for each Participating Global Trial other than the TV-301 Global Trial shall be included in the then-current Development Plan (as updated to incorporate each such Participating Global Trial therein). **Exhibit D** sets forth an illustration of such cost sharing.
- **(h)** Other Costs and Expenses regarding Participating Global Trials. Other than Licensee's responsibility for [***] Participating Global Trials as set out in subsections (f) and (g) above, as between Seagen and Licensee, Seagen shall be solely responsible for [***] incurred by it in connection with the Participating Global Trials, and Licensee shall be solely responsible for [***] incurred by it in connection with the Participating Global Trials.
- (i) Development Cost Reports and Payments. Each Party shall report to the JSC, within [***] after the end of each [***] during the Term, its costs and expenses with respect to each Participating Global Trial, along with an appropriate level of detail, as agreed upon by the JSC, of its calculation of costs and expenses for each Participating Global Trial. Within [***] after the end of each [***] during the Term, Seagen will calculate the allocation of each Participating Global Trial's costs and expenses based on the allocation set out subsections (f) and (g) above and generate and deliver to the JSC a report, in a format established by the JSC, [***] in accordance with the allocation set out in subsections (f) and (g) above (each such report, a "Development Cost Report", and such amount, the "Development Cost Amount"). The JSC will provide the Development Cost Report to both Parties, and the Parties will discuss and address questions related to the Development Cost Report raised by either Party within [***] after the JSC provides the same to the Parties. [***] (such payment, a "Development Cost Payment"). The Parties shall attempt to address any dispute in relation to any Contribution Percentage, Development Cost Report, Development Cost Amount or the related Development Cost Payment through the JSC, and if not successful such dispute will be resolved pursuant to escalation in accordance with Article 16.
- (j) Reconciliation. Within [***] as determined by the JSC, Seagen will calculate the allocation of such Participating Global Trial's costs and expenses based on the actual Contribution Percentage for such Participating Global Trial (each such percentage, a "Final Contribution Percentage" and generate and deliver to the JSC a report, in a format established by the JSC, provided that, except as may be otherwise agreed by Licensee, the Final Contribution Percentage [***] for such Participating Global Trial as established pursuant to subsections (f) and (g) above unless due to [***] established by the Parties in the Development Plan. Each such report shall include (i) the outstanding amount each Party should have been responsible for paying for such Participating Global Trial if such Final Contribution Percentage had been applied to all allocation of cost calculations made pursuant to subsections (f) and (g) above and (ii) the amount that one Party is responsible to pay to the other Party to reconcile amounts paid pursuant to the Development Cost Reports versus the amounts that should have been paid (each such report, a "Reconciliation Report", and such amount, the "Reconciliation Amount"). The JSC will provide the Reconciliation Report to both Parties, and the Parties will discuss and address questions related to the Reconciliation Report raised by either Party within [***] after the JSC

provides the same to the Parties. Upon the conclusion of such [***] period, the Party to whom the Reconciliation Amount is owed shall invoice the other Party, which Party shall remit the Reconciliation Amount within [***] after receipt of such invoice (each such payment, a "**Reconciliation Payment**"). The Parties shall attempt to address any dispute in relation to any Final Contribution Percentage, Reconciliation Report, Reconciliation Amount or the related Reconciliation Payment through the JSC, and if not successful such dispute will be resolved pursuant to escalation in accordance with Article 16.

4.5 Ownership of Data.

- **(a)** As between the Parties, Seagen shall own any and all Data generated in all Development studies conducted in Seagen's (or its designee's) name under this Agreement. For clarity, all clinical Data generated from any Global Trial in which Seagen or its designee acts as the sponsor and Licensee acts as the agent of Seagen shall be solely owned by Seagen and be considered the Confidential Information of Seagen.
- **(b)** Prior to the transfer of Regulatory Approvals in the Licensee Territory by Seagen to Licensee, Seagen will grant Licensee a right to access its Data if and to the extent required for Licensee to act as Seagen's agent to obtain Regulatory Approvals in the Licensee Territory at no cost to Licensee. If and after Seagen transfers the Regulatory Approvals to Licensee pursuant to Section 5.3, Seagen shall grant to Licensee during the Term a right of reference to such Data for Developing and Commercializing the Licensed Products in the Licensee Territory. Notwithstanding the foregoing or anything to the contrary in this Agreement, all Data generated by or on behalf of Seagen in a Non-Participating Global Trial shall be deemed not included within the license granted to Licensee pursuant to Section 2.1. Licensee shall have no right to reference or use such Data for any purpose (except for (x) as necessary pursuant to a written request by a Regulatory Authority in the Licensee Territory in support of a Regulatory Approval submission for the applicable Licensed Product in a different indication (and for clarity a different line of therapy) than that studied in such Non-Participating Global Trial) and (y) safety and other mandatory reporting purposes) regardless of subsequent publication unless and until Licensee both notifies Seagen in writing of its intention to use such Data (beyond (x) and (y) above) [***]. Such notice may be given by Licensee only after completion of the applicable Non-Participating Global Trial and [***], Seagen shall disclose the Data for such Non-Participating Global Trial to Licensee, and such Data shall thereafter be deemed to be included in the license granted to Licensee pursuant to Section 2.1 (i.e. Licensee shall have the right to reference and use such Data for the purpose of Developing, Manufacturing, and Commercializing Licensed Products in the Field in the Licensee Territory).
- (c) As between the Parties, Licensee will own any and all Data generated in all Licensee Territory Specific Studies if such studies are conducted in its name, and shall during the Term and after termination or expiration of this Agreement (as the case may be) grant to Seagen [***] and their respective Affiliates and other licensees a right to access and utilize its Data for the purpose of regulatory filings for the Licensed Compound or Licensed Products outside the Licensee Territory [***].
- **4.6 Development Records.** Licensee shall maintain or cause to be maintained complete, current and accurate records of all activities conducted by or on behalf of it pursuant to the Development Plan(s), and all Know-How and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the

performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall, and shall ensure that its Affiliates and their Sublicensees will, document all non-clinical studies and clinical trials in formal written study records in accordance with all Applicable Laws, including applicable national and international guidelines such as ICH, GCP and GLP. Each Party shall have the right to review and copy such records of the other Party at reasonable times and to obtain access to review the original to the extent necessary or useful for regulatory, patent or other reasonable purposes for the purpose of fulfilling its obligations under this Agreement upon reasonable notice to such other Party and at a time and location mutually acceptable to the Parties. For clarity, such review and copy rights shall not extend to records of activities conducted by or on behalf of Seagen for countries outside of the Licensee Territory, unless a Regulatory Authority in the Licensee Territory requests in writing the submission of such records, in which case such review and copy rights under this Section 4.6 shall extend to Licensee with respect to such records that are specifically requested by the Regulatory Authority.

4.7 Development Reports. Licensee shall keep Seagen reasonably and timely informed of the progress and results of its and its Affiliates' and Sublicensees' work under the Development Plan(s) [***]. Without limiting the generality of the foregoing, Licensee shall provide Seagen with a written report no later than [***] after the end of each [***] setting forth in details the Development activities performed during such [***] and the results thereof, and comparing such activities with the Development Plan(s) for such time period. Such reports shall be provided at a level of detail [***]. At each JSC meeting, the Parties shall discuss the status, progress and results of the Development activities conducted by the Parties pursuant to this Agreement. Each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development activities.

4.8 Disclosures by Licensee. Throughout the Term, Licensee shall:

- **(a)** keep Seagen fully informed of Licensee's and its Affiliates' and Sublicensees' Development, clinical trial progress, Medical Affairs Activities, and Commercialization efforts with respect to the Licensed Products in the Field in the Licensee Territory. Without limiting the generality of the foregoing, Licensee shall provide Seagen with prompt written notice of the following:
 - (i) Initiation of any clinical trial of the Licensed Products in the Field in the Licensee Territory;
 - (ii) termination of Development of any Licensed Product in the Field in the Licensee Territory;
 - (iii) filing of any MAA for the Licensed Products in the Field in the Licensee Territory;
 - (iv) receipt of any Regulatory Approval for the Licensed Products in the Field in the Licensee Territory;
 - **(v)** any other significant Development, Medical Affairs Activities, or Commercialization plans, activities or results with respect to the Licensed Products in the Field in the Licensee Territory; and

(vi) provide Seagen with written reports in accordance with Sections 4.7 and 8.5.

ARTICLE 5 REGULATORY

5.1 Conduct of Regulatory Activities; Core Data Sheet.

- (a) Subject to the terms and conditions of this Agreement, Licensee (itself and through its Affiliates and Sublicensees, as applicable) shall be solely responsible, [***], for all regulatory activities with respect to the Licensed Products in the Licensee Territory. Under the oversight of the JSC, Licensee shall implement the regulatory strategy formulated and adopted by the JSC and prepare, file, obtain and maintain Regulatory Approvals for the Licensed Products in the Field in the Licensee Territory on behalf of Seagen.
- **(b)** Seagen will maintain a Core Data Sheet applicable to each Licensed Product. All local product information and Regulatory Materials for a Licensed Product in the Licensee Territory shall be consistent with the applicable Core Data Sheet, and any such information or materials that deviate from the Core Data Sheet shall be submitted to the JSC for prior approval.

5.2 Holder of Regulatory Approvals.

- (a) Except as otherwise provided for in this Article 5, the Regulatory Approvals of each Licensed Product in the Licensee Territory shall be applied in the name of [***], and [***] shall be the holder of such Regulatory Approvals. For all [***], Seagen shall appoint Licensee or its applicable Affiliate as Seagen's exclusive distributor of the Licensed Products in the Licensee Territory and also as its regulatory agent to communicate and handle ordinary course regulatory activities with the applicable Regulatory Authorities in the Licensee Territory, and Licensee hereby accepts such appointment and agrees to perform such activities [***]; provided, however, that Licensee shall not have the power or authority (and shall not represent itself to any Third Party or any Governmental Authority as having any power or authority) to enter into agreements on behalf of Seagen or to waive any legal rights of Seagen, in each case without the prior written consent of Seagen. If any regulatory activities in the Licensee Territory are conducted in Seagen's name, subject to the terms of this Article 5, Seagen will have final decision-making authority regarding all such regulatory activities, including the content of regulatory submissions for the Licensed Products in the Licensee Territory and Licensee shall, and shall ensure that its relevant Affiliates and Sublicensees will, conduct all regulatory activities in compliance with Seagen's final decisions.
- **(b)** If Seagen grants a Manufacturing right to Licensee as contemplated by Section 7.3, then following the completion of Manufacturing Technology Transfer pursuant to Section 7.3, Licensee shall apply for Regulatory Approvals (as domestic product) of such Licensed Product that is manufactured in Mainland China in Licensee's name to the extent permitted by Applicable Laws. In such an event, the Parties shall cooperate in good faith to transfer to Licensee or its applicable Affiliate all Regulatory Approvals of such Licensed Product in the Field in the Licensee Territory that were obtained in the name of Seagen (or its designee); provided, however that Seagen shall continue to hold such Regulatory Approval (and the preceding sentences in this Section 5.2 shall continue to apply) to the extent that Seagen is required by Applicable Laws to hold any Regulatory Approval for such Licensed Product in any

Region. In the event and during any period that Seagen holds any Regulatory Approval for Licensee's benefit, (i) Seagen shall not be obligated to perform any activities, bear any obligations, or bear any costs, in each case, in addition to the activities set forth in this Agreement due to Seagen holding such Regulatory Approval; (ii) Seagen shall not assume any liability in connection with Seagen holding such Regulatory Approval; (iii) should Seagen incur any costs or expenses related to holding or transferring any such Regulatory Approval, Licensee shall reimburse Seagen for any and all costs and expenses incurred by or on behalf of Seagen in holding or transferring such Regulatory Approval; and (iv) Licensee shall indemnify and hold Seagen Indemnitees (as defined herein) from and against all Losses to the extent arising from Seagen holding such Regulatory Approval in the Licensee Territory as set forth in Article 15.

- 5.3 Regulatory Materials. Licensee shall provide Seagen with drafts of [***] Regulatory Materials or other material documents to be submitted to a Regulatory Authority in the Licensee Territory sufficiently in advance of submission (and, in any event, no less than [***] for Regulatory Materials other than an MAA or other application for Regulatory Approval, which shall be drafted and reviewed based on a schedule to be agreed by the Parties) so that Seagen may review and comment on such Regulatory Materials or other material documents prior to submission, and Licensee shall use Commercially Reasonable Efforts to incorporate such comments. For clarity, Licensee shall [***] accommodate any comment that could reasonably be expected [***] on the Regulatory Approval for, or Commercialization of the Licensee Compound or Licensed Products outside the Licensee Territory, or on Seagen's retained rights under Section 2.4. Licensee shall not make any statement in any regulatory filing or Regulatory Materials with Regulatory Authority in the Licensee Territory as to which Seagen has advised Licensee that such statement would be inconsistent with the Core Data Sheet or statements made by Seagen in regulatory filings or Regulatory Materials with any Regulatory Authority outside the Licensee Territory. In addition, Licensee shall, as promptly as practicable (and, in any event, within [***] of its receipt), provide Seagen with copies of any Regulatory Materials or other material documents received from any Regulatory Authority in the Licensee Territory.
- **5.4 Regulatory Communications and Meetings.** Licensee shall keep Seagen timely and fully informed of the preparation and Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to the Licensed Products in the Field in the Licensee Territory. Licensee shall provide Seagen with drafts of [***] communications, correspondence or filings to be submitted to a Regulatory Authority in the Licensee Territory sufficiently in advance so that Seagen may review and comment on such Licensee's communications, correspondence and filings prior to submission, and Licensee shall incorporate such comments therein. Licensee shall not make any statement in any communications, correspondence or filings to be submitted to a Regulatory Authority in the Licensee Territory as to which Seagen has advised Licensee that such statement would be inconsistent with the Core Data Sheet or statements made by Seagen in regulatory filings or Regulatory Materials with any Regulatory Authority outside the Licensee Territory. In addition, Licensee shall promptly as practicable (and, in any event, within [***] of its receipt) provide Seagen with copies of all material documents, submissions, filings, information and correspondence received from a Regulatory Authority by Licensee (or its Affiliate or Sublicensee) and upon reasonable request, with copies of any other documents, reports and communications from or to any Regulatory Authority relating to the Licensed Products or activities under this Agreement. Licensee shall provide Seagen with written notice within [***] after its receipt of the meeting notice from a Regulatory Authority of any meeting with such Regulatory Authority in the Licensee Territory (including advisory committee meetings and any

other meeting of experts convened by a Regulatory Authority) regarding a Licensed Product unless expressly prohibited by the Applicable Laws or the applicable Regulatory Authority. Unless expressly prohibited by the Applicable Laws or the applicable Regulatory Authority, Seagen will have the right to have [***] individuals, or more if agreed upon by Licensee and Seagen [***] in all such in-person meetings and material telephone conferences or videoconferences with such Regulatory Authorities in the Licensee Territory, and Licensee shall schedule such meetings in consultation with Seagen [***] to permit such attendance and participation by Seagen [***], as the case may be.

- 5.5 Access to Regulatory Materials. Seagen hereby grants to Licensee (and its Affiliates and Sublicensees, as applicable) the right to access and cross-reference filings made by Seagen or its Affiliates with Regulatory Authorities and Regulatory Materials relating to the Licensed Products, solely to the extent necessary or reasonably useful in connection with regulatory activities with respect to the Licensed Products in the Field in the Licensee Territory, [***]. If and in the event of the transfer of Regulatory Approvals pursuant to Section 5.3, Licensee shall and hereby grants to Seagen and its Affiliates and (sub)licensees the right to access to Data and cross-reference filings made by Licensee and its Affiliates and Sublicensees with Regulatory Authorities and Regulatory Materials relating to the Licensed Products, to the extent necessary or reasonable useful in connection with regulatory activities with respect to the Licensed Products outside the Licensee Territory, at [***]. Each Party shall, promptly upon request of the other Party, file with applicable Regulatory Authorities such letters of access or cross-reference as may be necessary to accomplish the intent of this Section 5.5. If any approval or filing is required by Applicable Law for a Party to share any materials abovementioned in this Section 5.5 with the other Party, the other Party shall use Commercially Reasonable Efforts to obtain such approval or filing at its sole costs and expense. Notwithstanding the foregoing, neither Party shall be obligated to share any personally identifiable information with the other Party, unless reasonably required for such other Party to Develop the Licensed Products in its respective territory and such sharing is permitted by, and in accordance with, the Applicable Laws, including applicable data privacy laws, in which case the Parties shall enter into a separate agreement to address such exchange of personally identifiable information between the Parties.
- 5.6 Pharmacovigilance Agreement. Within [***] of the Effective Date, but in any event, no later than the Initiation of the first clinical trial of which Licensee or its applicable Affiliate acts as the sponsor in the Licensee Territory, if any, the Parties shall enter into a pharmacovigilance agreement regarding the Licensed Compound and Licensed Products (the "Pharmacovigilance Agreement"), which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of safety information sufficient to permit each Party to comply with its regulatory and other legal obligations within the applicable timeframes. Unless otherwise mutually agreed by the Parties, Seagen shall maintain a global safety database for the Licensed Compound and Licensed Products, and Licensee shall provide all such assistance as Seagen may from time to time require in connection therewith. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail and govern, except to the extent such conflicting terms relate directly to the pharmacovigilance responsibilities of the Parties (including the exchange of safety data), in which case the terms of the Pharmacovigilance Agreement shall prevail and govern.
- **5.7 Data Privacy**. If [***], promptly after the Effective Date, the Parties (and, if relevant, Genmab) shall negotiate in good faith and enter into a data protection agreement in

accordance with all Applicable Laws which sets forth, among other things, the responsibilities and obligations of the Parties with respect to the procedures and timeframes for compliance with all Applicable Laws (and each of the Party's policies) pertaining to the collection, use, transfer, storage, destruction, aggregation or other use of study subject health information or other personal data in connection with the Parties' activities under or in connection with this Agreement.

5.8 Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Licensed Product may be subject to any recall, corrective action or other regulatory action in the Licensee Territory by any Governmental Authority or Regulatory Authority (a "Remedial Action"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall collaborate in good faith and endeavor to reach an agreement on Remedial Action related decisions. In the event that the Parties cannot reach an agreement, [***] shall have final decision-making authority with respect to any matters relating to any Remedial Action in the Licensee Territory, including the decision to commence such Remedial Action and the control over such Remedial Action, provided that [***] shall provide advance notice to [***] and [***]. The cost and expenses of any Remedial Action in the Licensee Territory shall be borne solely by Licensee; provided that if and to the extent that a Remedial Action results from Seagen's breach of this Agreement or its negligence or willful misconduct, Seagen shall bear the costs and expenses with respect to such Remedial Action that is attributed to Seagen's breach.

ARTICLE 6 MEDICAL AFFAIRS

- **6.1 General**. Subject to the Medical Affairs Plan, oversight by the JSC, and the terms and conditions of this Agreement, Licensee shall be responsible for Medical Affairs Activities in support of the Licensed Products in the Licensee Territory, at Licensee's own cost and expense, including by performing activities for the Licensee Territory as follows: (a) preparing materials for use in connection with Medical Affairs Activities in the Licensee Territory; and (b) preparing training materials and training programs for personnel engaged in such Medical Affairs Activities and implementing such training; provided, that, in each case ((a) and (b)), such activities shall be consistent with the Medical Affairs Plan, including the tactical and strategic matters described in such plan, and otherwise conducted in accordance with this Agreement.
- **6.2 Medical Affairs Plan**. The Medical Affairs Activities to be conducted by or on behalf of Licensee in support of each Licensed Product in the Field in the Licensee Territory shall be described in a high-level plan and corresponding budget (the "**Medical Affairs Plan**") that describes the Medical Affairs Activities for such Licensed Product in the Licensee Territory, which shall be consistent with Seagen's global medical affairs plan for the Licensed Product (the "**Seagen Global Medical Affairs Plan**"). No later than [***] before the anticipated date of the submission of the first MAA for a Licensed Product in the Licensee Territory, Licensee shall submit to the JSC for review, discussion and approval a Medical Affairs Plan. Following its approval by the JSC, the Medical Affairs Plan shall be updated at least [***], and all updates and amendments shall be reviewed and approved by the JSC to ensure consistency with the Seagen Global Medical Affairs Plan. The Parties shall agree on a timeline for conducting all such

reviews and approvals that accommodates the Parties' respective planning and budgeting purposes.

6.3 Coordination of Medical Affairs Activities.

- (a) Seagen shall keep the JSC reasonably informed of its plans (including any updates and amendment thereto) for the global Medical Affairs Activities for the Licensed Product under the Seagen Global Medical Affairs Plan in sufficient detail in order for Licensee to conform its Medical Affairs Activities for the Licensed Product in the Field in the Licensee Territory to the Seagen Global Medical Affairs Plan. Except as expressly agreed by Seagen in writing, Licensee's Medical Affairs Plan and all Medical Affairs Activities for each Licensed Product in the Field in the Licensee Territory shall be consistent with the Seagen Global Medical Affairs Plan.
- **(b)** The Parties may collaborate with respect to Medical Affairs Activities for any Licensed Product across their territories. If the Parties agree to jointly conduct any specific Medical Affairs Activities for the benefit of a Licensed Product in both Parties' territories, the Parties shall negotiate and agree on the details of such activities, including allocation of responsibilities, budget and cost sharing. Licensee shall not make any statements in the course of Medical Affairs Activities for a Licensed Product that are inconsistent with factual statements made by Seagen outside the Licensee Territory in connection with Medical Affairs Activities for such Licensed Product. For clarity, Licensee shall not conduct any Medical Affairs Activities for any Licensed Product outside the Field or outside Licensee Territory without Seagen's express prior written consent.
- **6.4 Medical Affairs Activities Reports.** Licensee shall keep Seagen informed of its, its Affiliates' and Sublicensees' Medical Affairs Activities with respect to any Licensed Product. Without limiting the foregoing, within [***] after the end of each [***], Licensee shall provide the JSC with a reasonably detailed report summarizing the Medical Affairs Activities performed by or on behalf of Licensee in support of the Licensed Product in the Field in the Licensee Territory. In addition, Licensee shall make available to Seagen such additional information about its Medical Affairs Activities as may be [***] from time to time.

ARTICLE 7 MANUFACTURE & SUPPLY

7.1 Clinical Supply. Seagen shall, by itself or through one or more Seagen CMO(s), use commercially reasonable efforts to supply to Licensee the Licensed Compound and/or the Licensed Products for clinical use at [***]. The Parties shall negotiate in good faith a clinical supply agreement and related quality agreement with such negotiation to be commenced within [***] after the Effective Date and completed no later than [***] after the Effective Date, which clinical supply agreement will be consistent with the Manufacturing plan for the territories outside the Licensee Territory and contain customary language regarding supply of the Licensed Products to Licensee (subject to equitable allocation in the event of disruption to or shortage of product supply). Notwithstanding the foregoing, the Parties shall engage in good faith conversations on clinical volumes as soon as practicable. For clarity, Licensee shall not have the right to Manufacture or have Manufactured any Licensed Product for any purpose unless and

until Seagen agrees to permit Manufacturing of the Licensed Product in Mainland China and after the Manufacture Technology Transfer described in Section 7.3 is completed.

- 7.2 Commercial Supply. With respect to any Licensed Product, unless and until Seagen agrees to permit Manufacturing of the Licensed Product in Mainland China and after the Manufacture Technology Transfer described in Section 7.3 is completed, Seagen shall, by itself or through one or more Seagen CMO(s), use commercially reasonable efforts to supply to Licensee the Licensed Product for commercial use in the Licensee Territory at [***]. The Parties shall negotiate in good faith and enter into a commercial supply agreement and related quality agreement no later than [***] prior to the anticipated First Commercial Sale of a Licensed Product in the Licensee Territory, which will contain customary language ensuring adequate supply of the Licensed Products to Licensee (subject to equitable allocation in the event of disruption to or shortage of product supply). Notwithstanding the foregoing, the Parties shall engage in good faith conversations on commercial market volumes as soon as practicable. For clarity, Licensee shall not have the right to Manufacture or have Manufactured any Licensed Product for any purpose unless and until Seagen agrees to permit Manufacturing of the Licensed Product in Mainland China and after the Manufacture Technology Transfer described in Section 7.3 is completed.
- **7.3 Local Manufacture.** If and after the [***], the Parties will discuss the feasibility of establishing local Manufacturing sources for such Licensed Product in the Licensee Territory and the transfer of Seagen Manufacturing Know-How to Licensee or a Permitted Domestic CMO (the "Manufacture Technology Transfer").
- **(a)** If [***], Seagen will consider in good faith granting Licensee a non-exclusive right to Manufacture the Licensed Compound and/or the applicable Licensed Product in the Licensee Territory. If Seagen decides, in its sole and absolute discretion, to grant Licensee such right, the Parties shall negotiate in good faith and enter into a separate agreement on customary and reasonable terms and conditions regarding the Manufacture of such Licensed Product and/or components thereof by Licensee in the Licensee Territory (the "**Licensee Manufacturing Agreement**").
- **(b)** In addition, subject to the quality audit of and approval by Seagen, in its sole and absolute discretion, of any contract manufacturing organization with suitable qualifications in Mainland China (each a "**Permitted Domestic CMO**") to Manufacture such Licensed Product in the Licensee Territory as proposed by Licensee, Seagen will consider in good faith granting Licensee a non-exclusive right to allow such Permitted Domestic CMO(s) to Manufacture such Licensed Product in the Licensee Territory. If Seagen decides, in its sole and absolute discretion, to grant Licensee such right, the Parties shall negotiate in good faith and enter into a three-way agreement on customary and reasonable terms and conditions among Seagen, Licensee and each Permitted Domestic CMO regarding the Manufacture and supply of such Licensed Product and/or components thereof by the Permitted Domestic CMO(s) to Licensee in the Licensee Territory (the "**CMO Manufacturing Agreement**") (Licensee Manufacturing Agreement and CMO Manufacturing Agreement(s) collectively, the "**Manufacturing Agreements**").
- **(c)** Any Manufacturing Agreement shall be consistent with the terms and conditions of this Agreement and shall include a manufacturing transfer plan pursuant to which the parties to such Manufacturing Agreement shall conduct and cooperate on the applicable Manufacture Technology Transfer, and terms and conditions that are at least as protective of Seagen as those

set forth herein, including (A) Seagen's right to terminate such Manufacturing Agreement commensurate with the termination of this Agreement, (B) Seagen's right to indemnification on the same terms and conditions *mutatis mutandis* as this Agreement, and (C) Seagen's audit and inspection rights, quality assurance requirements and similar matters.

(d) In each case of (a) and (b) above, [***] for the applicable Manufacture Technology Transfer and provision of any support or assistance to enable the Manufacture of such Licensed Product and/or components thereof in the Licensee Territory in accordance with the applicable Manufacturing Agreement.

ARTICLE 8 COMMERCIALIZATION MATTERS

- 8.1 Overview; Diligence. Subject to the terms and conditions of this Agreement (including the diligence obligations set forth below), Licensee (itself and through its Affiliates and Sublicensees, as applicable) shall be solely responsible for Commercialization of the Licensed Products in the Field in the Licensee Territory, under the oversight of the JSC, including: (i) developing and executing a commercial launch and pre-launch plan, (ii) negotiating with applicable Governmental Authorities regarding the price and reimbursement statuses of the Licensed Products; (iii) marketing, advertising and promotion; (iv) booking sales and distribution and performance of related services; (v) handling all aspects of order processing, invoicing and collection, inventory and receivables; (vi) providing customer support, and performing other related functions; and (vii) conforming its practices and procedures to Applicable Laws relating to the marketing, detailing and promotion of the Licensed Products in the Field in the Licensee Territory. Licensee shall [***] in connection with such Commercialization activities. Licensee shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Licensee Territory and to expand annual Net Sales of such Licensed Products in the Licensee Territory. Without limiting the generality of the foregoing, Licensee shall launch the Licensed Products for each indication that has obtained Regulatory Approval for Commercialization in a Region no later than [***] after obtaining the Regulatory Approval for such indication in such Region.
- **8.2 Commercialization Plan.** No later than [***] before the anticipated date of the submission of the first MAA for a Licensed Product in the Licensee Territory, Licensee shall submit to the JSC for review, discussion and approval a written Commercialization plan that sets forth the timeline and details of all major Commercialization activities planned for such Licensed Product in the Licensee Territory (the "**Commercialization Plan**"). The Commercialization Plan shall include an executive summary; [***]. Thereafter, from time to time, but at least [***], Licensee shall prepare updates or amendments to the Commercialization Plan to reflect changes in such plan, including those [***], and submit such updated or amended plan to the JSC for review, discussion and approval. Once approved by the JSC, the Commercialization Plan (including updates and amendments thereto) shall become effective. The Commercialization Plan shall be consistent with the Commercialization plan for the Licensed Product outside the Licensee Territory, and the Commercialization of the Licensed Product in the Licensee Territory shall be conducted in accordance with the Commercialization Plan as amended from time to time.

- **8.3** Coordination of Commercialization Activities. The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of a Licensed Product across their territories. As such, the Parties may coordinate such activities where appropriate, [***]. Licensee shall submit to the JSC for review and approval prior to use materials proposed to be used in connection with the promotion and other Commercialization of each Licensed Product. If the Parties agree to jointly conduct any specific Commercialization activities for the benefit of a Licensed Product in both Parties' territories, the Parties shall negotiate and agree on the details of such activities, including allocation of responsibilities, budget and cost sharing. Licensee shall not make any statements in the course of Commercialization of any Licensed Product that are inconsistent with any factual statement made or promotional materials used by or on behalf of Seagen outside the Licensee Territory in connection with Commercialization of such Licensed Product. For clarity, Licensee shall not conduct any Commercialization of any Licensed Product outside the Licensee Territory without Seagen's express prior written consent.
- **8.4 Pricing.** Without limiting Section 8.2, Licensee shall present to the JSC its proposed pricing for Licensed Products in each Region in the Licensee Territory [***], and thereafter shall provide the JSC detailed updates regarding such pricing discussions and reimbursement matters in the Licensee Territory at each regular meeting of the JSC [***]. Licensee shall consider in good faith [***] comments received from Seagen with respect to pricing and reimbursement of Licensed Products, provided that Licensee shall have the final decision-making authority with respect to such matters provided that such decisions are [***]. [***]. Licensee shall keep Seagen informed regarding the status of any application for pricing or reimbursement approval for Licensed Products in Mainland China and other Regions in the Licensee Territory, including any discussions with Regulatory Authorities with respect thereto.
- **8.5 Commercialization Reports.** Licensee shall keep Seagen informed of its, its Affiliates' and Sublicensees' Commercialization activities with respect to each Licensed Product. Without limiting the foregoing, Licensee shall update the JSC at each regularly scheduled JSC meeting regarding the Commercialization activities with respect to each Licensed Product in the Licensee Territory. Each such update shall be in a form to be agreed by the JSC and shall summarize Licensee's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to each Licensed Product in the Licensee Territory, covering subject matter at a level of detail [***] and sufficient to enable Seagen to understand such activities and to determine Licensee's compliance with its diligence obligations pursuant to Section 6.1. In addition, Licensee shall make available to Seagen such additional information about its Commercialization activities [***] from time to time.
- **8.6** Global Branding Strategies; Trademarks. As between the Parties, Seagen (or Genmab as provided for in the Genmab Agreements) shall own and retain all right, title, and interest in and to all trademarks, logos and trade names associated with any Licensed Product worldwide (including trademarks, logos, and trade names in any local language in the Licensee Territory) and will have the sole right to register and maintain all such trademarks, logos and trade names worldwide, and all goodwill derived from the use by Licensee thereof as permitted under this Section 8.6 shall accrue to Seagen or Genmab, as the case may be. In addition, Seagen (and/or Genmab as provided for in the Genmab Agreements) shall have the right and responsibility in formulating global branding strategies for the Licensed Products. Licensee shall reasonably cooperate with Seagen to implement such global branding strategy for the Licensed Products in the Licensee Territory, and shall conduct Commercialization activities in the

Licensee Territory in accordance with such global branding strategy. Specifically, Licensee shall only use (pursuant to this Section 8.6), and shall cause its Affiliates and Sublicensees to only use, the trademarks Controlled by Seagen in the Licensee Territory [***] (the "**Product Marks**") for the Commercialization of the Licensed Products in the Licensee Territory and in compliance with Applicable Laws. Seagen hereby grants to Licensee, during the Term and subject to the terms and conditions of this Agreement, a royalty-free, fully paid-up, exclusive license solely to use the then-current Product Marks in Commercializing the Licensed Products in the Field in the Licensee Territory. Licensee shall Commercialize the Licensed Products in the Licensee Territory using the Product Marks in a manner consistent with the global branding strategy for the Licensed Products outside the Licensee Territory.

- **8.7 Licensed Products Tracking in the Licensee Territory**. Licensee shall, and shall ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the [***] in the Licensee Territory.
- 8.8 No Diversion. Each Party hereby covenants and agrees that during the Term, and except as expressly permitted by this Agreement, it shall not (and shall cause its Affiliates and Sublicensees and subcontractors not to), either itself or through a Third Party, develop, use, market, promote, import, export, sell or actively offer for sale the Licensed Products in the other Party's territory. Without limiting the generality of the foregoing, except as mutually agreed or contemplated by the then-current Development Plan or Commercialization Plan, each Party shall not (a) engage in any advertising activities relating to the Licensed Products directed primarily to customers in the other Party's territory (it being understood that global marketing efforts by Seagen including digital online campaigns that are not territory specific and participation in conferences, congresses or scientific or medical meetings held throughout the world for example would not be "directed primarily" to customers in the other Party's territory), or (b) actively or intentionally solicit orders from any prospective purchaser located in the other Party's territory. To the extent permitted by Applicable Laws, including applicable antitrust laws, if a Party receives any order for Licensed Products from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to the other Party and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Licensed Products under such order. If a Party should reasonably know that a customer or distributor is actively engaged itself or through a Third Party in the sale or distribution of the Licensed Products in the other Party's territory, then such Party shall (i) within [***] of gaining knowledge of such activities, notify the other Party regarding such activities and provide all information available to such Party that the other Party may reasonably request concerning such activities and pr

ARTICLE 9 PAYMENTS

9.1 Upfront Payment. In partial consideration of Seagen's granting of the licenses and rights to Licensee hereunder, Licensee shall make a one-time, non-refundable, non-creditable payment to Seagen of thirty million U.S. Dollars (US\$30,000,000) (the "**Upfront Payment**") within [***] after the Effective Date.

9.2 Development and Regulatory Milestone Payments. With respect to the milestone events set forth in the table below, promptly following the first achievement, whether by Seagen or any of Seagen's Affiliates or (sub)licensees or by Licensee or any of Licensee's Affiliates or Sublicensees, of the corresponding milestone event by any Licensed Product for the first time, Licensee or Seagen, as the case may be, shall notify the other Party within [***] of such achievement, and Licensee shall pay to Seagen the corresponding non-refundable, non-creditable milestone payment within [***] after the achievement of the applicable milestone event:

Licensed Product Milestone Event	Milestone Payment (in U.S. Dollars)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
- [***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, if milestone event (1) is achieved, milestone event (2) shall be deemed to be achieved concurrently. Each of the milestone payments set forth above in this Section 9.2 shall be payable only once, for the first achievement of the applicable milestone event by any Licensed Product for the first time, regardless of the number of times the milestone is achieved, such that the maximum amount payable by Licensee to Seagen under this Section 9.2 shall be seventy-eight million dollars (\$78,000,000). For clarity, as used in the above table, "[***]" refers to [***], and "[***]" refers to [***], whether or not it also includes any other [***].

9.3 Sales Milestone Payments. Licensee shall pay to Seagen the additional one-time, non-refundable, non-creditable payments set forth in the table below after the first achievement of each milestone event described below:

Sales Milestone Event	(in U.S. Dollars)
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Within [***] any milestone event set forth above in this Section 9.3 for which a milestone payment is payable is achieved, Licensee shall deliver a written notice to Seagen of such achievement, and Licensee shall pay to Seagen the corresponding milestone payment within [***]. For clarity, each of the milestone payments set forth above in this Section 9.3 shall be additive such that if multiple milestone events specified above are achieved in the same Calendar Quarter, then the milestone payments for all such milestone events shall be payable by Licensee.

9.4 Royalties. Licensee shall pay tiered royalties to Seagen on annual Aggregate Net Sales of all Licensed Products in each Calendar Quarter as set forth below, calculated by multiplying the applicable royalty rate by the corresponding portion of annual Aggregate Net Sales of all Licensed Products:

Annual Aggregate Net Sales of all Licensed Products	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

9.5 Royalty Term. Royalties under Section 9.4 shall be payable, on a Region-by-Region and Licensed Product-by-Licensed Product basis, during the period beginning on the date of the First Commercial Sale of such Licensed Product in such Region in the Licensee Territory

and continuing until the latest of: (a) ten (10) years from the date of First Commercial Sale of such Licensed Product in such Region; (b) the expiration of the last-to-expire Valid Claim of the Seagen Patents or the Seagen Manufacturing Patents Covering the Licensed Compound or such Licensed Product, their manufacture, or their use in such Region; and (c) the expiration of the Regulatory Exclusivity of the applicable Licensed Product in such Region (the "**Royalty Term**").

9.6 Royalty Payment Reduction.

- (a) Biosimilar Product. At any time during the Term, if a Biosimilar Product with respect to such Licensed Product is being sold in a Region, then the royalty rate applicable to Net Sales of such Licensed Product in such Region shall be reduced by [***] that would otherwise be owed on such Net Sales of such Licensed Product in [***], solely for so long as sales of such Biosimilar Product [***].
- **(b) Third Party License Payments**. In the event that it is necessary for Licensee to obtain a license under any Patents or Know-How of any Third Party that, in the absence of such license, would be infringed or misappropriated by the practice of the Seagen Technology in connection with the Development or Commercialization of a Licensed Product in a given Region by Licensee or its Affiliate or Sublicensees, and if such license requires the payment of royalties to such Third Party, then the royalties payable by Licensee to Seagen shall be reduced by an amount equal to [***] of the royalties actually paid to such Third Party with respect to such license on the applicable Net Sales.
- **(c)** Lack of Patent Protection. If at any time during the Royalty Term with respect to a Licensed Product, there are no Valid Claims under the Seagen Patents and Seagen Manufacturing Patents Covering the making, using, selling, offering for sale or importing of such Licensed Product in a Region, the royalty rate applicable to Net Sales of such Licensed Product in such Region shall be reduced by [***] of the royalty rate that would otherwise be owed on such Net Sales of such Licensed Product in such Region under Section 9.4.
- **(d) Cumulative Deductions**. Notwithstanding the foregoing, in no event shall the cumulative royalty payment deductions reduce the royalty payments otherwise payable to Seagen as set forth in Section 9.4 with respect to a [***] by more than [***].

ARTICLE 10 PAYMENT; RECORDS; AUDITS

- **10.1 Payment; Reports.** Royalties shall be calculated and reported for each [***] and shall be paid within [***] after the end of each [***]. Each payment shall be accompanied by a report of Net Sales of the Licensed Products by Licensee, its Affiliates and Sublicensees in sufficient detail to permit confirmation of the accuracy of the payment made, [***].
- **10.2 Quarterly Projections**. In order to facilitate planning and budgetary control by the Parties, each Party shall provide to the JSC (or a finance subcommittee if and when established) and to the other Party, no later than [***] before the end of each Calendar Quarter, [***] (for clarity, on behalf of such Party, its Affiliates and (sub)licensees, as applicable), in each case, in such Calendar Quarter.

10.3 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in U.S. dollars. When conversion of payments from any foreign currency is required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange for the currency of the country from which such payments are payable as published by *The Wall Street Journal*, Western U.S. Edition during the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Seagen, unless otherwise specified in writing by Seagen.

10.4 Taxes.

- **(a) Taxes on Income**. Except as otherwise provided in this Section 10.4, Licensee shall be solely responsible for the payment of all value added taxes, fees, duties, surcharges, and other deductions or withholding taxes imposed by or on any entity in the Licensee Territory in connection with the payments and activities contemplated hereunder.
- **(b)** Tax Withholdings. In the event that any withholding tax, fee, duty or surcharge applicable to or assessable in respect of any of the upfront payment, development or sales milestone payments, royalty payments, or any other payments to be made by Licensee to Seagen under this Agreement (collectively, the "License Payments") is required to be withheld and deducted under Applicable Laws ("Tax Withholdings"), Licensee (or its Affiliate paying on behalf of Licensee) shall make such deduction and withholding and will pay the remaining License Payments to Seagen, subject to the following conditions:
 - (i) if the applicable rate of calculating the amount of Tax Withholdings on the portion of License Payments due to [***], then (A) Seagen shall bear the amount of Tax Withholdings that is equal to [***], and (B) Licensee will bear all Tax Withholdings not described in clause (A) (i.e., [***] and the [***]), [***] pursuant to (A)), and shall increase the amount of such payments accordingly to reflect Licensee bearing such amounts (including any increase in respect of such increases in payments (i.e., Seagen will receive no less than [***] of the License Payments after any Tax Withholding). For clarity, Licensee shall bear [***] of amounts of Tax Withholdings in respect of License Payments attributable to [***]; or
 - (ii) if the applicable [***], then (A) the amount of Tax Withholdings that Seagen shall bear will remain as [***], and (B) Licensee shall bear all other amounts of Tax Withholdings not described in the foregoing (A), [***].
- **(c) Tax Cooperation**. Licensee shall make such deduction of Taxes and withholding Tax payments to the applicable taxing authority(ies) in a timely manner and shall promptly provide Seagen with the appropriate proof of payment and relevant receipt(s) with respect to such deduction or withholding. Licensee shall provide Seagen reasonable assistance in order to allow Seagen to obtain the benefit of any present or future treaty against double taxation or refund or reduction in Taxes which may apply to the License Payments. Each Party agrees to use commercially reasonable efforts to cooperate with the other Party in claiming refunds, reductions, or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect. Seagen will provide Licensee with any tax forms or other documentation reasonably necessary in order for Licensee not to withhold or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. If the taxes originally paid or otherwise borne by

- a Party are in whole or in part subsequently determined not to have been chargeable, all reasonably necessary steps will be taken by each Party to obtain a refund of these undue taxes from the applicable Governmental Authority or other fiscal authority and any amount of undue taxes repaid by such authority to the receiving Party will be transferred to the paying Party within [***] of receipt.
- (d) Taxes Resulting From Party's Action. Notwithstanding Section 10.4, if, solely as a result of any action by either Party (or its assignee pursuant to Section 17.6 of this Agreement), including without limitation, assignment or transfer of this Agreement, change in the residence of such Party for tax purposes, change in the entity making such payment, or failure on the part of such Party to comply with Applicable Laws or filing or record retention requirements (each, a "Withholding Tax Action"), the amount of any tax (including Tax Withholdings, value added tax or other similar tax) is increased, then the Party responsible for such Withholding Tax Action shall bear such additional taxes.
- **10.5 Blocked Currency**. In the event that, by reason of Applicable Law in any country or region, it becomes impossible or illegal, after reasonable efforts by Licensee to do so, for Licensee or its Affiliate to transfer, or have transferred on its behalf, payments owed Seagen hereunder, Licensee will promptly notify Seagen of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of Seagen in a recognized banking institution [***].
- 10.6 Records; Audits. Licensee shall keep, and require its Affiliates and Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Seagen pursuant to this Agreement. Such books and records shall be kept for at least [***] following the end of the Calendar Year to which they pertain. Seagen shall have the right to cause an independent, certified public accountant reasonably acceptable to Licensee to audit such records to confirm [***]; provided that (a) such audit shall not be more frequent than [***] period, and (b) once such accountant has conducted a review and audit of any records pursuant to this Section 10.6 in respect of any given period, it may not subsequently re-inspect such records with respect to such period, unless, in each case of (a) and (b), for cause. Such audits may be exercised during normal business hours upon reasonable prior written notice to Licensee. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Seagen shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than [***], in which case, Licensee shall bear the cost of such audit and shall promptly remit to Seagen the amount of any underpayment. Any overpayment by Licensee revealed by an audit shall be fully-creditable against future payment owed by Licensee to Seagen (and if no further payments are due, shall be refunded by Seagen [***]).
- **10.7 Late Payments.** In the event that any payment due under this Agreement is not made [***], the payment shall accrue interest from the date due at a rate per annum that is [***]. The payment of such interest shall not limit Seagen from exercising any other rights it may have as a consequence of the lateness of any payment.

ARTICLE 11 CONFIDENTIALITY

- 11.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party (in such capacity, the "Receiving Party") agrees that, during the Term and for [***] thereafter, it shall keep confidential and shall not publish or otherwise disclose to any Third Party, and shall not use for any purpose other than as expressly provided for in this Agreement or any other written agreement between the Parties, any Confidential Information, including any Know-How, furnished or made available to it by or on behalf of the other Party (in such capacity, the "Disclosing Party"). The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its, and its Affiliates', employees, agents, contractors, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information.
- 11.2 Exceptions. Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is at the time of disclosure, or thereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available to the public or part of the public domain; (b) is known by the Receiving Party and/or any of its Affiliates at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party and/or any of its Affiliates by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party and/or any of its Affiliates, without the use of or reference to Confidential Information of the Disclosing Party.
- **11.3 Authorized Disclosure**. Notwithstanding the provisions of Section 11.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:
 - (a) filing or prosecuting or defending Patents as permitted by this Agreement;
- **(b)** disclosure required in connection with any judicial or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable court orders or governmental regulations or the rules of any recognized stock exchange, including filing or disclosure requirements of SEC;
- **(c)** disclosure to Affiliates, actual and potential licensees and Sublicensees, employees, contractors, consultants or agents of the Receiving Party who have a need to know such information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Affiliate, actual or potential licensee or Sublicensee, employee, contractor, consultant or agent agrees to be bound by terms of confidentiality and non-use comparable in scope to those set forth in this Article 11;
- **(d)** such disclosure is deemed necessary by counsel to the Receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide

advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party (provided, however, that in the case of financial advisers, including investment bankers, the term of confidentiality may be shortened to [***] from the date of disclosure and in the case of attorneys, no written agreement shall be required);

- **(e)** disclosure to existing investors, acquirors or collaborators or potential bona fide investors, acquirors or collaborators in connection with due diligence or similar investigations by such Third Parties; provided, in each case, that any such existing or potential investor, acquiror or collaborator agrees to be bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party (but of duration customary in confidentiality agreements entered into for similar purpose); and
- **(f)** in the case of Licensee's Confidential Information, disclosure to Genmab and its Affiliates by Seagen in connection with the exercise of its rights or performance of its obligations under the Genmab Agreements.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.3(a) or Section 11.3(b), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and cooperate with the other Party to seek and obtain confidential treatment of such information to the extent legally permissible.

11.4 Public Announcements.

(a) Press Releases and Publicity.

- (i) As soon as practicable following the Effective Date, the Parties shall issue a joint press release announcing the execution of this Agreement in a form mutually agreed by the Parties. Except as required by applicable securities laws (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a Party or its Affiliates are traded), neither Party shall make any other public announcement or statement, whether oral or written, concerning this Agreement or the subject matter hereof without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed; provided that each Party may make any public statement in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other Party pursuant to this Section 11.4 and which do not reveal non-public information about the other Party. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.
- (ii) Notwithstanding anything to the contrary in this Section 11.4, Seagen has the right to publicly disclose (A) the achievement of milestones under this Agreement;

- (B) the commencement, completion, material data and key results of clinical trials conducted under this Agreement; and (C) any information relating to any Global Trial. After a Publication has been made available to the public, each Party may post such publication or a link to it on its corporate web site without the prior written consent of the other Party.
- **(b) Filing of this Agreement**. The Parties shall coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC or any stock exchange or other governmental agency.

11.5 Publication.

- **(a)** Seagen will be responsible for a global publication strategy for the Licensed Products, including a strategy for the publication of clinical trial data generated pursuant to this Agreement including from any Global Trial and any Licensee Territory Specific Study.
- **(b)** Seagen will be responsible for publicly presenting or publishing any clinical trial data, non-clinical data or any associated results or conclusions from all Global Trials and otherwise generated by or on behalf of Seagen (each such proposed presentation or publication, a "**Seagen Publication**") in accordance with the global publication strategy and this Section 11.5. Seagen will provide Licensee a copy of each Seagen Publication at the time of the submission or presentation. Seagen agrees to acknowledge the contributions of Licensee in all Seagen Publications as scientifically appropriate.
- (c) If Licensee desires to publicly present or publish any clinical trial data, non-clinical data or any associated results or conclusions generated by or on behalf of Licensee pursuant to the Licensee Territory Specific Studies (each such proposed presentation or publication, a "Licensee Publication"), it shall obtain Seagen's prior written consent and in accordance with the global publication strategy and this Section 11.5. Licensee shall provide Seagen with a copy of such proposed Licensee Publication at least [***] prior to the earlier of its presentation or intended submission for publication; provided that in the case of abstracts, this period shall be at least [***] (such applicable period, the "Review Period"). Licensee agrees that it will not submit or present any Licensee Publication (i) until Seagen has provided written comments during such Review Period on the material in such Licensee Publication or (ii) until the applicable Review Period has elapsed without written comments from Seagen, in which case Licensee may proceed and the Licensee Publication will be considered approved in its entirety. If Licensee receives written comments from Seagen during the applicable Review Period, it shall consider the comments of Seagen in good faith, but will retain the [***] to submit the manuscript for such Licensee Publication; provided that Licensee agrees to (A) delete any Confidential Information of Seagen or Genmab that Seagen identifies for deletion in Seagen's written

comments, (B) delete any clinical trial data, non-clinical data, results, conclusions or other related information that is not specific to or resulting from any Licensee Territory Specific Study, and (C) delay such Licensee Publication for a period of up to an additional [***] after the end of the applicable Review Period to enable Seagen (or Genmab if applicable) to draft and file patents with respect to any subject matter to be made public in such Licensee Publication and to which Seagen (or Genmab if applicable) has the applicable intellectual property rights to file such patents. Licensee shall provide Seagen a copy of the Licensee Publication at the time of the submission or presentation. Licensee agrees to acknowledge the contributions of Seagen, and the employees of Seagen, and Genmab if applicable, in all Licensee Publications as scientifically appropriate. Licensee shall require its Affiliates, Sublicensees and contractors to comply with the obligations of this Section 11.5 as if they were Licensee, and shall be liable for their non-compliance.

- 11.6 Publication and Listing of Clinical Trials. Each Party agrees to comply, with respect to the listing of clinical trials or the publication of clinical trial results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of clinical trials and the publication of clinical trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; provided that any listings or publications made pursuant to this Section 11.6 shall be considered a publication hereunder and shall be subject to Section 11.5.
- 11.7 **Prior Non-Disclosure Agreement**. As of the Effective Date, the terms of this Article 11 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.
- 11.8 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 11. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 11.

ARTICLE 12 REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

- **12.1 Mutual Representations and Warranties**. Each Party represents and warrants to the other that, as of the Effective Date:
- **(a)** it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

- **(b)** it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; and
- (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, (ii) conflict with or result in a breach of any provision of its organizational documents, or (iii) violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.
- **12.2 Additional Seagen Representations and Warranties**. Seagen represents and warrants to Licensee, as of the Effective Date, as follows:
- **(a)** Seagen (i) has sufficient legal and/or beneficial title or ownership or license, free and clear from any mortgages, pledges, liens, security interests, encumbrances, charges or claim of any kind, of the Seagen Technology to grant the License that it purports to grant in Section 2.1; and (ii) has not granted any right to any Third Party with respect to the Seagen Technology that would conflict with the License or rights granted to Licensee hereunder;
- **(b)** Seagen has not received any written notice that any Third Party has taken any action before any applicable patent office in the Licensee Territory, claiming ownership of any Seagen Technology;
- **(c)** Seagen has not received any written notice from any Third Party asserting that the issued patents within the Seagen Patents or the Seagen Manufacturing Patents are invalid or unenforceable;
- **(d)** to the knowledge of Seagen, no litigation, discovery process, interference, reissue, reexamination, interference, invalidity, opposition, post-grant review, or *inter partes* review is pending or threatened with respect to any Seagen Patent or Seagen Manufacturing Patent;
- **(e)** to the knowledge of Seagen, the conduct of any Development, Manufacture or Commercialization with respect to the Licensed Compound or Licensed Product by or on behalf of Seagen or any of its Affiliates, as conducted on or prior to the Effective Date, or as contemplated (as of the Effective Date) to be conducted during the Term in the Licensee Territory, in each case, does not infringe any valid and enforceable claim of any issued Patent of any Third Party in the Licensee Territory or misappropriate any other intellectual property rights of any Third Party in the Licensee Territory; and
- **(f)** there are (i) no written claims, judgments or settlements against, or amounts with respect thereto owed by, Seagen or any of its Affiliates relating to the Seagen Technology and (ii) no written claim or litigation has been brought, or to the knowledge of Seagen, threatened, challenging the validity, enforceability or ownership of any Seagen Technology, in existence as of the Effective Date, in each case (i) and (ii), that relate to the Development, Manufacturing or Commercialization of the Licensed Compound or Licensed Product infringing any Patents of any Third Party or misappropriating any Know-How of any Third Party.
- **12.3 Additional Licensee Representations and Warranties**. Licensee represents and warrants to Seagen, as of the Effective Date:

- (a) Licensee (i) has the right to grant the license that it purports to grant in Section 2.5; and (ii) has not as of the Effective Date, and will not during the Term, grant any right to any Third Party that would conflict with the license or rights granted to Seagen hereunder;
- **(b)** there are no legal claims, judgments or settlements against or owed by Licensee or any of its Affiliates, or pending or threatened legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations;
- **(c)** each of Licensee and its Affiliates is not, and shall not become, a person or entity with whom U.S. persons or entities is restricted from doing business with under regulations of the Office of Foreign Asset Control ("**OFAC**") of the Department of the Treasury (including, but not limited to, those named on OFAC's Specially Designated and Blocked Persons list) or under any statute, executive order, sanctions, or other governmental action;
- **(d)** Licensee 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
- **(e)** Licensee 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, of the Licensed Products in the Licensee Territory.
- **12.4 Mutual Covenants**. In addition to any covenants made by the Parties elsewhere in this Agreement, each Party hereby to the other that:
- (a) (i) all patient authorizations and consents required under Applicable Laws (in connection with any applicable clinical study) permit the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 4.5, and (ii) it will comply with Applicable Laws in transferring personal and other Data in connection with the granting of access of Data that such Party is required to provide to the other Party pursuant to Section 4.5. Each Party will obtain all the necessary authorizations, consents and approvals in order for such Party to grant access to its Data with the other Party, including obtaining the necessary patient authorizations and consents, and obtaining the necessary approvals from and completing all necessary filing procedures with the applicable Governmental Authorities in the Licensee Territory (including any HGR Approval);
- **(b)** it will not knowingly, during the Term, employ or use the services of any person who is debarred or disqualified in connection with activities relating to the Licensed Compound or Licensed Products; and in the event that it becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to it with respect to any activities relating to the Licensed Compound or Licensed Products, it will immediately notify the other Party in writing and it will cease employing, contracting with, or retaining any such person to perform any services relating to the Licensed Compound or Licensed Products;
- (c) it shall conduct, and shall cause its Affiliates, (sub)licensees (in the case of Seagen), and Sublicensees (in the case of Licensee) to conduct all activities under this Agreement (including, with respect to Licensee, as set forth in the Development Plan(s), Medical

Affairs Plan(s) and Commercialization Plan(s) with respect to the Licensed Products in the Field in the Licensee Territory) in compliance with all Applicable Laws (including all applicable data privacy laws, anti-bribery and anti-corruption laws), all applicable national and international guidelines (including GCP, GMP, GLP, all applicable ICH guidelines and other good scientific, laboratory, manufacturing and clinical practices under the Applicable Laws of the region in which such activities are conducted), and any Regulatory Authority and Governmental Authority health care programs having jurisdiction, each as may be amended from time to time;

- (d) with respect to any human tissue, human cell lines, human clinical isolates or similar human-derived materials (collectively, "Human Materials") that will be collected or used in connection with the Development of Licensed Compound or Licensed Product, it covenants that it (i) will comply with all Applicable Laws, guidelines and regulations relating to the collection or use of the Human Materials, and (ii) will obtain all necessary approvals and appropriate informed consents, including HGR Approvals, in writing, for the collection or use of such Human Materials. It shall provide documentation of such approvals and consents upon the other Party's request. It further represents, warrants and covenants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities who contributed the Human Materials, including any obligations of compensation to such individuals or entities for the intellectual property associated with, or commercial use of, the Human Materials for any purpose;
- **(e)** it has in place an anti-corruption and anti-bribery policy and in connection with the performance of its obligations under this Agreement, and it shall comply and shall cause its and its Affiliates' employees to comply with its policy;
- (f) it shall, and shall ensure that its Affiliates, (sub)licensees (in the case of Seagen), and Sublicensees (in the case of Licensee) and its and their respective employees and contractors will, not cause the other Party to be in violation of the FCPA, Export Control Laws, or any Applicable Law, including any other applicable anti-corruption and anti-bribery laws, in connection with the performance of its obligations under this Agreement; including without limitation, it shall not, in connection with the performance of its obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a public official or entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including itself, nor will it directly or indirectly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a public official or entity or any other person in connection with the performance of its obligations under this Agreement; and
- **(g)** it shall immediately notify the other Party if it has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any Applicable Law, including any other applicable anti-corruption and anti-bribery laws, in connection with the performance of its obligations under this Agreement.
- **12.5 Licensee Covenants.** In addition to any covenants made by Licensee elsewhere in this Agreement, Licensee hereby covenants to Seagen as follows:

- (a) Licensee will conduct its obligations with respect to each Development Plan, Medical Affairs Plan, and Commercialization Plan in strict adherence with the study design set forth therein, each as may be amended from time to time, and for clarity Licensee shall not have the right to Develop the Licensed Compound or any Licensed Product in a form, presentation, dosage form, or formulation except as set forth in the applicable Development Plan, unless the Parties otherwise agree in writing; and
- **(b)** Licensee shall not take (and shall procure its Affiliates and Sublicensees not to take) any action that will or is reasonably expected to cause Seagen to breach or violate any term or condition under any Genmab Agreement.
- **12.6 Performance by Affiliates, Sublicensees and Subcontractors**. Licensee may perform some or all of its obligations under this Agreement through one or more Affiliates, subcontractors or Sublicensees; *provided*, in each case, that (a) none of Seagen's rights hereunder are diminished or otherwise adversely affected as a result of such delegation or subcontracting, and (b) each such Affiliate, subcontractor or Sublicensee undertakes in writing obligations of confidentiality and non-use regarding Confidential Information and ownership of Inventions which are substantially the same as those set forth in Article 11 and Section 13.1; and *provided, further*, that Licensee shall at all times be fully responsible for the performance and payment of such Affiliate, subcontractor or Sublicensee.
- 12.7 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY SEAGEN TO LICENSEE HEREUNDER ARE PROVIDED "AS IS," AND SEAGEN EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OBTAINING SUCCESSFUL RESULTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE 13 INTELLECTUAL PROPERTY

13.1 Ownership.

(a) Product and Platform Inventions. As between the Parties, any and all Inventions, Data (excluding any Data generated under clinical studies, the ownership of which is set forth in Section 4.5), and Know-How generated, developed, conceived or reduced to practice (constructively or actually) by or on behalf of either Seagen or Licensee alone (including its Affiliates and (sub)licensees, or any of its or their employees, agents and contractors) or jointly by both Seagen and Licensee (including jointly by their Affiliates and respective (sub)licensees, or any of its or their employees, agents and contractors) during the Term (i) pertaining to an Antibody to TF, the Licensed Compound, or any Licensed Product (collectively, "Product Inventions"), and any Patents filed claiming or disclosing such Product Inventions (collectively, "Product Invention Patents"), or (ii) pertaining to the Seagen Platform (collectively, "Platform Inventions"), and any Patents filed claiming or disclosing such Platform Inventions (collectively, "Platform Invention Patents"), shall be owned by Seagen [***]. The Product Invention Patents and the Platform Invention Patents shall be included in the Seagen Technology. For all such Product and Platform Inventions generated, developed, conceived or

reduced to practice by or on behalf of Licensee (including its Affiliates), Licensee shall disclose in writing to Seagen all such Inventions promptly (and in any event no later than [***]) following the generation, development, conception or reduction to practice thereof.

- **(b)** Other Inventions. As between the Parties, inventorship of (i) any Inventions, Data, and Know-How generated, developed, conceived or reduced to practice (constructively or actually) solely by or on behalf of a Party or its Affiliates and (sub)licensees, including their employees, agents and contractors that do not pertain to an Antibody to TF, the Licensed Compound, or any Licensed Product or the Seagen Platform ("Solely Owned Other Inventions"), and any Patents that claim or disclose such Solely Owned Other Inventions ("Solely Owned Other Inventions"), and (ii) any Inventions, Data, and Know-How generated, developed, conceived or reduced to practice (constructively or actually) jointly by or on behalf of Licensee and Seagen, their Affiliates and respective (sub)licensees, including their employees, agents and contractors, that do not pertain to an Antibody to TF, the Licensed Compound, or any Licensed Product or the Seagen Platform ("Jointly Owned Other Inventions"), and any Patents that claim or disclose such Jointly Owned Other Inventions ("Jointly Owned Other Invention Patents"), will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. For clarity, Solely Owned Other Inventions and Jointly Owned Other Inventions do not include Product Inventions or Platform Invention, and Solely Owned Other Patents and Jointly Owned Other Patents do not include Product Invention Patents or Platform Invention Patents.
- **Disclosures**; Cooperation. Each Party shall ensure that each of its Affiliates, (sub)licensees (in the case of Seagen), Sublicensees (in the case of Licensee) and subcontractors under this Agreement has a contractual obligation to disclose to such Party all Data and Inventions generated, invented, discovered, developed, made or otherwise created by them or their employees, agents or independent contractors, and to provide sufficient rights with respect thereto, so that such Party can comply with its obligations under this Section 13.1. With respect to any activities of a Party under this Agreement that are subcontracted to a person that is not an employee of such Party, such Party shall include in the applicable subcontract (i) an assignment to such Party of all of such subcontractor's rights, title and interest in any Inventions, Data, Know-How generated by subcontractor resulting from such activities; and (ii) to the extent that such subcontractor uses or incorporates its pre-existing intellectual property or improvements thereon in performing such activities, a license to such Party that is sublicensable to the other Party of any such pre-existing intellectual property to the extent reasonably necessary for the other Party and, where Seagen is the other Party Genmab, to exploit such Inventions and Know-How, and Develop and Commercialize the Licensed Compound and Licensed Products in its territory. Each Party shall ensure that any employees or contractors who perform any activities under this Agreement, or who conceive, reduce to practice, discover, develop or otherwise make any Know-How or Inventions by or on behalf of such Party or its Affiliates, (sub)licensees (in the case of Seagen), or Sublicensees (in the case of Licensee) under or in connection with this Agreement agree to and are bound by a written inventor reward and remuneration policy or agreement that is legally sufficient under Applicable Laws, including a specific waiver of pre-emption rights, including, as applicable, Article 847 of the Civil Code of the People's Republic of China and Article 326 of the PRC Contract Law, such that such employees or contractors shall not have any additional right or claim in or to any Know-How, Inventions, Patents and other intellectual property rights derived from their work other than the reward and remuneration they are entitled to under the inventor reward and remuneration policy or agreement. As between the Parties, each Party shall incur the costs associated with paying all such inventor rewards and

remuneration, and shall make, and shall cause its Affiliates, (sub)licensees (in the case of Seagen) and Sublicensees (in the case of Licensee) to make, timely payments to its or their respective employees and contractors in accordance with its or their respective inventor reward and remuneration policy or agreement with its employees for such rewards and remuneration.

(d) Notwithstanding the foregoing, a Party's (sub)licensees (in the case of Seagen), Sublicensees (in the case of Licensee) and subcontractors will not be required to assign any (i) technology that they independently developed without the use of or reliance upon Licensee's, Seagen's, Genmab's, or their respective Affiliates' Confidential Information or intellectual property ("Sublicensee/Subcontractor Background Technology") and (ii) improvements to such Sublicensee/Subcontractor Background Technology which (A) primarily relate to the conduct of their business, (B) does not pertain an Antibody to TF, to the Licensed Compound, a Licensed Product or the Seagen Technology, and (C) do not make use of or rely upon Licensee's, Seagen's, Genmab's, or their respective Affiliates' Confidential Information or intellectual property. In addition, Licensee will use diligent, good faith efforts to obtain the present assignments set forth in Section 2.2(c), and Section 13.1(c) from subcontractors that are hospitals or clinical trial sites. If, after using such diligent, good faith efforts to obtain such present assignment from such hospitals or clinical trial sites, then Licensee will use diligent, good faith efforts to obtain an exclusive, royalty-free, fully paid-up, perpetual, irrevocable, worldwide, transferable, and sublicensable (through multiple tiers) license back to Licensee under the relevant Data, Inventions and Know-How. If, after using such diligent, good faith efforts, Licensee is unable to obtain such license from such hospitals or clinical trial sites, then (1) Licensee will provide prompt written notice to Seagen, (2) the Parties will discuss in good faith the nature of the intellectual property that may be generated by such subcontractor and how engaging such Sublicensee or subcontractor may affect the Parties' intellectual property, and (3) Licensee will not engage such subcontractor unless Seagen approves such engagement in writing.

13.2 Patent Prosecution and Maintenance.

- **(a) Definition**. For purposes of this Section 13.2, the terms "prosecute," "prosecuting" and "prosecution," when used in reference to any Patent, shall be deemed to include, without limitation, control of any interferences, reissue proceedings, post-grant proceedings, oppositions and reexaminations with respect to such Patent.
- (b) Seagen Patents, Seagen Platform Patents, Seagen Manufacturing Patents, and Jointly Owned Other Invention Patents. As between the Parties.
 - (i) With respect to Seagen Platform Patents and Seagen Manufacturing Patents, Seagen shall have the sole right, but not the obligation, at its own expense, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Seagen Platform Patents and Seagen Manufacturing Patents worldwide.
 - (ii) Subject and subordinate to clause (i) above (i.e. with respect to Seagen Patents other than Seagen Platform Patents and Seagen Manufacturing Patents), as between the Parties, Seagen (or Genmab if applicable) shall have the first right, but not the obligation, at its own expense, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance

of such Seagen Patents and Jointly Owned Other Invention Patents worldwide. Seagen shall keep Licensee reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of such Seagen Patents and Jointly Owned Other Invention Patents in the Field in the Licensee Territory. Seagen will notify Licensee of all warning letters, conflict proceedings, reexaminations, reissuance, oppositions, revocation proceedings or any other material challenge relating to such Seagen Patent or a Jointly Owned Other Invention Patent in the Field in the Licensee Territory, Seagen will consult with, and consider in good faith the requests and suggestions of, Licensee with respect to strategies for filing and prosecuting such Seagen Patents and Jointly Owned Other Invention Patents in the Field in the Licensee Territory. In the event that Seagen desires to abandon or cease prosecution or maintenance of any such Seagen Patent or Jointly Owned Other Invention Patent in the Field in the Licensee Territory, Seagen shall provide reasonable prior written notice to Licensee of such intention (which notice shall, in any event, be given no later than [***] prior to the next deadline for any action that may be taken with respect to such Patent with the applicable patent office), and upon Licensee's written election provided no later than [***] after such notice from Seagen, and subject to the Parties mutual agreement to a budget for such prosecution and/or maintenance Seagen shall continue prosecution and/or maintenance of such Patent at Licensee's direction and expense. If Licensee does not provide such election within [***] after such notice from Seagen or fails to pay for prosecution or maintenance of any such Seagen Patent or Jointly Owned Other Invention Patent in the Licensee Territory, with respect to which it has previously made such election, Seagen may, in its sole discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent. The provisions of this Section 13.2(b) are subject to, if any, the rights of Seagen's licensor Genmab and other licensee(s) with respect to the applicable Patents.

- (iii) As between the Parties, Seagen (or Genmab if applicable) shall have the sole right to obtain and maintain and shall have the final decision-making power with respect to patent term extensions for the Seagen Patents, Seagen Manufacturing Patents, and Jointly Owned Other Invention Patents in the Licensee Territory.
- **(iv)** As between the Parties, Seagen (or Genmab if applicable) shall have the final decision-making power with respect to patent listings of Seagen Patents, Seagen Manufacturing Patents, and Jointly Owned Other Invention Patents in the Licensee Territory.
- **(c) Solely Owned Other Invention Patents**. As between the Parties, each Party shall have the sole right, but not the obligation, at its own expense, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all Solely Owned Other Invention Patents that are owned or Controlled by such Party or its Affiliates worldwide.
- **(d)** Cooperation of the Parties. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Seagen Patents, Seagen Manufacturing Patents, and Joint Invention Patents under this Section 13.2 and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect thereto respectively. Such cooperation includes, but is not limited to: (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and

instruments, so as to enable Seagen (or Genmab if applicable) to apply for and to prosecute patent applications in any country or region as permitted by this Section 13.2; and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

13.3 Infringement by Third Parties.

- (a) Notice. In the event that either Seagen or Licensee becomes aware of any infringement or threatened infringement by a Third Party of any Seagen Patent or Seagen Manufacturing Patent, and any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any Seagen Patent or Seagen Manufacturing Patent ("Product Infringement"), it shall notify the other Party in writing to that effect.
- (b) Jointly Owned Other Invention Patents and Seagen Patents other than Seagen Platform Patents. Subject to subsection (c) below, with respect to Jointly Owned Other Invention Patents and Seagen Patents other than Seagen Platform Patents, as between the Parties, [***] shall have the first right, but not the obligation, to bring and control any action or proceeding with respect to Product Infringement of any such Patent in the Field in the Licensee Territory at [***] and by counsel of its own choice, and, to the extent any such Product Infringement is in the Field and the Licensee Territory, [***] shall have the right, at [***], to be represented in any such action by counsel of its own choice. If [***] fails to bring any such action or proceeding with respect to such Product Infringement within [***] following the notice of such Product Infringement, [***] shall have the right to bring and control any such action at its own expense and by counsel of its own choice but only to the extent such Product Infringement is in the Field and the Licensee Territory, provided that [***] shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Seagen Patent without the prior written consent of [***]. Seagen (and Genmab if applicable) shall have the right, at its own respective expense, to be represented in any such action by counsel of its own respective choice. Neither Party shall enter into any settlement admitting the invalidity of, or otherwise impairing, any Jointly Owned Other Invention Patent without the prior written consent of the other Party. The provisions of this Section 13.3(b) are subject to, if any, the rights of Genmab and Seagen's licensee(s) with respect to the Licensed Products, whether in or outside the Field and whether in or outside the Licensee Territory.
- **(c) Seagen Platform Patents and Seagen Manufacturing Patents**. For clarity, as between the Parties, Seagen shall have the sole right, but not the obligation, to bring and control any action or proceeding with respect to Product Infringement of any Seagen Platform Patent or Seagen Manufacturing Patent anywhere in the world (whether in or outside the Field).
- **(d) Cooperation**. At the request of the Party bringing an action related to Product Infringement, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action, at the sole cost and expense of the Party bringing an action.
- **(e) Solely Owned Other Invention Patents**. Each Party shall have the sole right, but not the obligation, to bring and control any action or proceeding with respect to infringement of any Solely Owned Other Invention Patent that is owned or Controlled by such Party or its Affiliates at its own expense and by counsel of its own choice.

- (f) Cooperation; Award. In the event a Party brings an infringement action in accordance with this Section 13.3, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party. Except as provided for explicitly elsewhere in this Section 13.3, neither Party shall enter into any settlement or compromise of any action under this Section 13.3 which would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld. Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized by a Party as a result of any action or proceeding pursuant to this Section 13.3, whether by way of settlement or otherwise, shall be applied first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining amounts shall be [***]; provided, however, that any recovery realized by Licensee as a result of any action or proceeding brought and controlled by Licensee (after reimbursement of the Parties' documented out-of-pocket legal expenses relating to the action or proceeding) shall be [***].
- 13.4 Infringement of Third Party Rights. 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 Development, Manufacture, use, Commercialization or importation of the Licensed Products in the Field in the Licensee Territory, each Party shall promptly notify the other Party in writing of such claim, and 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. Unless otherwise agreed in the joint defense agreement, each Party shall have the right to defend any such claims against it in the Licensee Territory at its own expense as it reasonably determines appropriate; provided that the defending Party shall not enter into any settlement, consent judgment or other disposition of any action or proceeding that would: (a) admit the invalidity of, or otherwise impair, any Seagen Technology without the prior written consent of Seagen, or (b) impose any liability or obligation on the other Party.
- **13.5 Marking**. To the extent required by law, Licensee shall, and shall cause its Affiliates and their Sublicensees to, mark the Licensed Products sold under this Agreement with the number of each issued Seagen Patent that applies to the Licensed Products.

ARTICLE 14 TERM: TERMINATION

- **14.1 Term.** The term of this Agreement (the "**Term**") shall commence on the Effective Date, and unless terminated earlier as provided in this Article 14, shall expire upon the expiration of the final Royalty Term with respect to all Licensed Products.
 - 14.2 Termination.
- **(a) Termination by Licensee for Convenience**. Licensee shall have the right during the Term to terminate this Agreement in its entirety without cause upon [***] prior written notice to Seagen.

- **(b) Material Breach**. A Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within [***] (or [***] with respect to any breach of payment obligations hereunder) after written notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of the applicable curing period unless the breaching Party has cured such breach prior to the end of such curing period. If the breaching Party disputes in good faith (i) whether it has materially breached this Agreement, (ii) whether such material breach is reasonably curable within the applicable cure period, or (iii) whether it has cured such material breach within the applicable cure period, in each case by giving written notice of such dispute to the non-breaching Party within [***] after receipt of notice of the applicable material breach, the dispute will be resolved pursuant to Section 16.2, and this Agreement may not be terminated and the Parties shall continue to perform all of their respective obligations hereunder during the pendency of such dispute resolution procedure.
- (c) Patent Challenge. Seagen shall have the right to terminate this Agreement immediately upon written notice to Licensee if Licensee or any of its Affiliates or Sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of, or the grant of a supplementary protection certificate with respect to, any Seagen Patent or any Seagen Manufacturing Patent. Notwithstanding the foregoing, Seagen will not have the right pursuant to this Section 14.2(c) to terminate this Agreement if, with respect to a proceeding involving a Third Party's challenge to a Seagen Patent or Seagen Manufacturing Patent, Licensee or its Affiliate or Sublicensee has been compelled by order of a court or patent office to respond to or participate in a proceeding, including by a discovery request or other requirement under such court order to provide testimony in the proceeding (provided that (A) such proceeding is not itself a patent challenge brought or assisted directly or indirectly by Licensee or its Affiliate or Sublicensee, or (B) such order is not an enforcement of, by specific performance or otherwise, or otherwise based on a contractual obligation or voluntary commitment for Licensee or its Affiliate or Sublicensee to bring or assist in, directly or indirectly, a patent challenge, and Licensee's or its Affiliate's or Sublicensee's involvement in such proceeding is limited to such compelled response, request, or required participation).
- **(d) Bankruptcy**. A Party shall have the right to terminate this Agreement upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, dissolution, liquidation or winding up of such other Party, or the making or seeking to make or arrange an assignment of a substantial portion of such other Party's assets for the benefit of creditors of such other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy against such other Party, or is adjudged bankrupt, or the appointment of a receiver or trustee of such other Party's property, in each case that is not discharged within [***].

14.3 Effect of Expiration or Termination.

(a) Effect of Expiration. Upon expiration (but not earlier termination) of the Royalty Term for a given Licensed Product in a given Region, and provided that Licensee has paid all payments payable with respect to such Licensed Product, the License with respect to such Licensed Product in such Region shall survive on a non-exclusive, fully paid, irrevocable, perpetual basis, and all other rights and obligations of the Parties with respect to such Licensed Product in such Region under this Agreement shall terminate, except as provided elsewhere in this Section 14.3 or in Section 14.4.

- **(b) Effect of Termination**. Upon any termination of this Agreement, [***]. [***].
- **(c) Additional Effects of Termination**. Upon any termination of this Agreement, the following provisions shall apply:
 - (i) Licensee shall, and it hereby does, effective as of such termination, grant to Seagen [***].
- (ii) As promptly as practicable (and in any event within [***]) after such termination, Licensee shall: (A) to the extent not previously provided to Seagen, deliver to Seagen true, correct and complete copies of all regulatory filings and registrations (including Regulatory Approvals) for the Licensed Products in the Field in the Licensee Territory, and disclose to Seagen all Licensee Know-How (including all preclinical, clinical data, efficacy data and safety data) not previously disclosed to Seagen; (B) transfer or assign, or cause to be transferred or assigned, to Seagen or its designee (or to the extent not so assignable, take all reasonable actions to make available to Seagen or its designee the benefits of) all regulatory filings and registrations (including Regulatory Approvals) for the Licensed Products in the Field in the Licensee Territory, whether held in the name of Licensee or its Affiliate, or as directed by Seagen in its sole discretion, provide Seagen with a right of reference with respect to any such regulatory filings and registrations at no cost to Seagen; and (C) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section 14.3(c)(ii) to Seagen.
- (iii) Licensee shall, as directed by Seagen, either (A) [***] with respect to the Licensed Products in the Field in the Licensee Territory in a manner as directed by Seagen, or (B) [***]. In the event such Development, Manufacturing (if any), and Commercialization activities are to be transferred to Seagen or its designee, Licensee shall use Commercially Reasonable Efforts to transfer and to assist Seagen to assume responsibility for and control of such Development, Manufacturing (if any), and Commercialization activities. Without limiting the generality of the foregoing, [***].
- **(iv)** At Seagen's option and request, Licensee shall assign to Seagen any Third Party contract that relates to the Development, Manufacture, or Commercialization of the Licensed Compound or Licensed Products, or otherwise relates to Licensee's performance of its obligations hereunder, or to the extent any such Third Party contract is not assignable to Seagen, reasonably cooperate with Seagen to arrange to continue to provide such services for a reasonable time after termination.
- **(v)** At Seagen's election and request, Licensee shall (A) transfer to Seagen or its designee some or all inventory of the Licensed Products (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or control of Licensee, its Affiliates or Sublicensees; provided that, Seagen shall pay Licensee a price equal to [***]. [***].
- **(vi)** Any existing, permitted sublicense granted by Licensee under Section 2.2 of this Agreement (and any further sublicenses thereunder) shall, if and upon the written

request of Seagen, remain in full force and effect, provided that (A) such Sublicensee is not then in breach of its sublicense agreement (and, in the case of termination by Seagen for breach by Licensee, that such Sublicensee and any further sublicensees did not cause the breach that gave rise to the termination by Seagen); and (B) and such Sublicensee agrees that Seagen shall assume the rights, but not the obligations, of Licensee under the terms and conditions of such sublicense agreement.

- **(d) Confidential Information.** Upon expiration or termination of this Agreement in its entirety, except to the extent that a Party retains a license from the other Party as provided in this Article 14, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations under Article 11.
- **14.4 Accrued Obligations; Survival**. Neither expiration nor any termination of this Agreement shall relieve either Party of any obligation or liability accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the Parties' rights and obligations under Sections 2.2(b) and 2.2(d), 2.3, 2.4, 4.4(f), 4.4(g), 4.4(h), 4.4(i), 4.4(j), 4.5, 5.3, 5.4, 5.5, 5.8, 8.6 (to the extent related to ownership and management of intellectual property and goodwill), 10.1 (solely with respect to payments accrued prior to expiration or termination), 10.3, 10.4, 10.5, 10.6, 10.7, 12.6, 12.7, 14.3, 14.4, and 14.5 and Articles 1, 9 (solely with respect to payments accrued prior to expiration or termination), 11 (for the time period as set forth in Section 11.1), 13, 15, 16 and 17 of this Agreement shall survive expiration or any termination of this Agreement.
- 14.5 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the U.S. (collectively, the "Bankruptcy Laws"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the other Party copies of all Know-How and other information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

ARTICLE 15 INDEMNIFICATION

- **15.1 Indemnification of Seagen**. Licensee shall indemnify and hold harmless each of Seagen and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the "**Seagen Indemnitees**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**"), incurred by any Seagen Indemnitee as a result of any claims, demands, actions, suits or proceedings brought by a Third Party ("**Third Party Claims**") arising directly or indirectly out of: (a) the practice by Licensee or its Affiliates or Sublicensees of the License; (b) the research, Development, Manufacture or have Manufactured (in the event Seagen grants Licensee the right to Manufacture or have Manufactured in the Licensee Territory), use, handling, storage, Commercialization or other disposition of the Licensed Compound or the Licensed Products by Licensee or its Affiliates or Sublicensees in the Field in the Licensee Territory; (c) the negligence or willful misconduct of any Licensee Indemnitee; or (d) any breach of any representations, warranties or covenants by Licensee under this Agreement; except, in each case, to the extent such Third Party Claims fall within the scope of the indemnification obligations of Seagen set forth in Section 15.2.
- **15.2 Indemnification of Licensee**. Seagen shall indemnify and hold harmless each of Licensee and its Affiliates and their respective directors, officers, employees, consultants, agents and successors and assigns of any of the foregoing (the "**Licensee Indemnitees**"), from and against any and all Losses incurred by any Licensee Indemnitee as a result of any Third Party Claims arising directly or indirectly out of: (a) the practice by Seagen or its Affiliates of the license granted to Seagen under Section 2.5; (b) the Development, Manufacture, use, handling, storage, sale or other disposition of the Licensed Compound or Licensed Products by Seagen or its Affiliates outside the Licensee Territory or in the Licensee Territory outside of the Field; (c) the negligence or willful misconduct of any Seagen Indemnitee; or (d) any breach of any representations, warranties or covenants by Seagen under this Agreement; except, in each case, to the extent such Third Party Claims fall within the scope of the indemnification obligations of Licensee set forth in Section 15.1.
- 15.3 Procedure. If any Seagen Indemnitee or Licensee Indemnitee intends to claim indemnification under this Article 15 (the "Indemnitee"), Seagen or Licensee, as the case may be, shall promptly notify the indemnifying Party (the "Indemnitor") in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Article 15 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 15 if and to the extent the Indemnitor is actually prejudiced thereby. Seagen or Licensee, as the case may be, and the Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by these indemnification provisions. The Indemnitor shall not settle any Third Party Claim without the prior written consent of the Indemnitee if the settlement is reasonably expected to: (a) result in or impose any obligation (including any payment obligation) on the Indemnitee, or (b) result in any admission of wrong-doing or fault by the Indemnitee.

- **15.4 Insurance**. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.
- 15.5 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 15.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 15.1 OR 15.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11 OR A PARTY'S BREACH OF SECTION 2.7.

ARTICLE 16 DISPUTE RESOLUTION

16.1 Disputes. Subject to Section 16.3, upon the written request of either Party to the other Party, any claim, dispute, or controversy as to the breach, enforcement, interpretation or validity of this Agreement (a "**Dispute**") will be referred to the Executive Officers for attempted resolution. In the event such executives are unable to resolve such Dispute within [***] after the initial written request, then, upon the written demand of either Party and subject to Section 16.3 below, the Dispute shall be finally resolved by binding arbitration administered by the International Chamber of Commerce ("**ICC**") (or any successor entity thereto) pursuant to its arbitration rules and procedures then in effect (the "**Rules**"), as modified by Section 16.2 below. For clarity, any decisions that are subject to the final decision-making authority of a Party (or mutual agreement of the Parties, as applicable), or the JSC in each case as expressly set forth in this Agreement, will not be subject to the provisions of this Article so long as such decisions are made in accordance with this Agreement.

16.2 Arbitration.

(a) Procedure. The arbitration shall be conducted by a panel of three arbitrators experienced in the business of pharmaceuticals (including biologicals). If the issues in dispute involve scientific, technical or commercial matters, the arbitrators chosen hereunder shall engage experts having educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. Within [***] after initiation of arbitration, each of the Parties shall select one arbitrator and a third arbitrator will be mutually agreed upon. If a Party fails to select an arbitrator or if the Parties are unable or fail to agree upon the third arbitrator within such [***] period, any unselected arbitrator or third arbitrator, as the case may be, shall be appointed in accordance with the Rules. The place of arbitration shall be San Francisco, California, and all proceedings and communications shall be in English. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrators may disclose the existence, content, or results of arbitration without the prior written consent of both Parties. In no event shall an

arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

- **(b) Arbitrators' Award**. Prior to the arbitrators being selected, either Party, without waiving any remedy under this Agreement, may seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party until final resolution of the issue by the arbitrator or other resolution of the controversy between the Parties. Once the arbitrators have been selected, either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved, and either Party may apply to a court of competent jurisdiction to enforce interim injunctive relief granted by the arbitrators. The arbitrators shall, within [***] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the arbitrators shall be final and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction. The arbitrators shall be authorized to award compensatory damages, but shall not be authorized (i) to award non-economic damages, (ii) to award punitive damages or any other damages expressly excluded under this Agreement, or (iii) to reform, modify or materially change this Agreement or any other agreements contemplated hereunder; provided, however, that the damage limitations described in subsections (i) and (ii) of this sentence will not apply if such damages are statutorily imposed.
- (c) Costs. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the ICC and the arbitrator.
- **16.3 Court Actions.** Nothing contained in this Agreement shall deny either Party the right to bring an action in any court of competent jurisdiction to resolve any dispute, controversy or claim that concerns (a) the validity, enforceability or infringement of any Patents or other intellectual property rights, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, and no such claim shall be subject to arbitration as a Dispute pursuant to Section 16.2.

ARTICLE 17 MISCELLANEOUS

17.1 Governing Law; English Language. This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflicts of law provisions thereof. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. All notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties

regarding this Agreement shall be in the English language. In addition, unless otherwise agreed by Seagen, in each and every instance in this Agreement where Licensee is to deliver or provide access to any documents, records, materials, data, communication, information, or any other written or electronic materials to Seagen (including to the JSC), Licensee shall deliver or provide access to copies of the same in their original format and language, and accurate (and where reasonably requested certified) English translations of all such documents, records, materials, data, communication, information, or any other written or electronic materials. Translations into English shall be the responsibility of, and at the sole cost and expense of, Licensee.

- 17.2 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth all of the agreements and understandings between the Parties with respect to the subject matter hereof and thereof, and supersedes and terminates all prior agreements and understandings between the Parties with respect to the subject matter hereof and thereof. There are no other agreements or understandings with respect to the subject matter hereof, either oral or written, between the Parties. Except as expressly set forth in this Agreement, no subsequent amendment, modification or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.
- 17.3 Further Assurances. Each Party will 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 any other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.
- **17.4 Relationship Between the Parties**. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship or legal entity of any type between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever. Neither Party shall treat or report the relationship arising under this Agreement as a partnership for United States tax purposes unless otherwise required pursuant to a determination within the meaning of Section 1313 of the Internal Revenue Code of 1986, as amended.
- 17.5 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.
- **17.6 Assignment**. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by a Party without the prior written consent of the other Party (which shall not be unreasonably withheld, conditioned or delayed), except to (a) an Affiliate, provided that this Agreement shall be assigned in whole, and the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate, (b) Genmab or its Affiliate, provided that this Agreement shall be assigned in

whole, and Genmab or its Affiliate shall be liable and responsible for the performance and observance of all such duties and obligations after such assignment, or (c) a Third Party in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, sale of stock, sale of assets, reorganization, or other transaction or series of related transactions. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Section 17.6. Any assignment not in accordance with this Agreement shall be void.

- **17.7 Third Party Beneficiaries**. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, provided however that [***].
- 17.8 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part. The Parties shall use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) in a way that, to the extent practicable and legally permissible, implements the original intent of the Parties.
- 17.9 Notices. Any notice to be given under this Agreement must be in writing in the English language and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if delivered by overnight courier, [***] after delivery; or (c) if sent by facsimile, upon electronic confirmation of receipt.

if to Seagen:	Seagen Inc.

21823 30th Drive St Bothell, WA 98021 United States

Attention: General Counsel

Facsimile No.: [***]

with a copy to: Goodwin Procter (Hong Kong) LLP

38th Floor, Edinburgh Tower

The Landmark

15 Queen's Road Central

Hong Kong
Attention: [***]
Facsimile No.: [***]

and a copy to: Goodwin Procter LLP

1900 N Street NW Washington, DC 20036

United States
Attention: [***]
Facsimile No.: [***]

if to Licensee: Zai Lab (Hong Kong) Limited

Room 2301, 23/F., Island Place Tower

510 King's Road, North Point

Hong Kong

Attention: Chief Business Officer, Jonathan Wang

with an electronic copy to [***]

with a copy to: Cooley LLP

3175 Hanover Street Palo Alto, CA 94303 Attention: Lila Hope

with an electronic copy to [***]

17.10 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control including but not limited to acts of God, fire, flood, explosion, earthquake, or other natural forces, regional or worldwide epidemic, war, civil unrest, acts of

terrorism, accident, destruction or other casualty (a "Force Majeure Event"). Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to a Force Majeure Event must be given to the other Party within [***] after its occurrence. The Party affected by a Force Majeure Event will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto. If any such failure or delay in a Party's performance hereunder continues for more than [***], the other Party may terminate this Agreement upon written notice to the delayed Party.

- 17.11 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means "including without limitation," whether or not specifically stated. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. The words "pharmaceuticals" or "drugs" include biologics unless expressly indicated otherwise. All references to days in this Agreement shall mean calendar days, unless otherwise specified. All references to any Applicable Law in this Agreement shall mean such Applicable Law as amended, restated, supplanted or otherwise modified from time to time. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.
- **17.12 Export.** Each Party acknowledges that the laws and regulations of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without appropriate United States and foreign government licenses.
- **17.13 Construction**. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.
- **17.14 Notification and Approval**. If this Agreement or the transaction(s) set forth herein are subject to notification or regulatory approval in one or more countries or jurisdiction(s), then development and commercialization in such country(ies) or jurisdiction(s) will be subject to such notification or regulatory approval. The Parties will reasonably cooperate with each other with respect to such notification and the process required thereunder, including

in the preparation of any filing. Licensee will be responsible for any and all costs, expenses, and filing fees associated with any such filing.

17.15 Counterparts; Electronic Signatures. This Agreement may be executed in two (2) or more counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one and the same instrument. Electronic, facsimile or PDF image signatures shall be treated as original signatures, with the understanding that each Party expressly agrees that such Party shall be bound by its own electronically transmitted signature and shall accept the electronically transmitted signature of the other Party (including through the use of eSignature platforms such as DocuSign®). No Party will raise the use of electronic delivery to transmit a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of electronic delivery as a defense to the formation of a contract.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

In Witness Whereof, the Parties hereto have duly executed this **Collaboration and License Agreement** as of the Effective Date.

Seagen Inc. Zai Lab (Hong Kong) Limited

By: /s/ Natasha HerndayBy: /s/ Samantha DuName: Natasha HerndayName: Samantha Du

Title: EVP, Corp Dev & Alliance Management Title: CEO

Exhibit A Schedule of Seagen Patents

[***]

Exhibit B

Description of Chemical Structure of tisotumab vedotin

[***]

Exhibit C

Initial Development Plan

[***]

Exhibit D

Participating Global Trial Cost Sharing Illustration for Global Trials Other Than TV-301 Global Trial

[***]

Name:	[]
Number of Restricted Share Units subject to Award:	[]
Date of Grant:	[]

ZAI LAB LIMITED

2022 EQUITY INCENTIVE PLAN

RESTRICTED SHARE UNIT AWARD AGREEMENT

This agreement (this "<u>Agreement</u>") evidences an award (the "<u>Award</u>") of Restricted Share Units granted by Zai Lab Limited (the "<u>Company</u>") to the individual named above (the "<u>Grantee</u>"), pursuant to and subject to the terms of the Zai Lab Limited 2022 Equity Incentive Plan (as amended from time to time, the "<u>Plan</u>").

- 1. <u>Grant of Restricted Share Unit Award</u>. The Company grants to the Grantee on the date set forth above (the "<u>Date of Grant</u>") the number of Restricted Share Units (the "<u>Restricted Share Units</u>") set forth above giving the Grantee the conditional right to receive, without payment and pursuant to and subject to the terms set forth in this Agreement and in the Plan, one ADS (each, a "Share") with respect to each Restricted Share Unit forming part of the Award, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof. Each ADS represents the right to receive [__] ([_]) Ordinary Shares (subject to any Share dividend, Share split or combination of Shares (including a reverse Share split)).
- 2. <u>Meaning of Certain Terms</u>. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:
 - (a) "Beneficiary" means, in the event of the Grantee's death, the beneficiary named in the written designation (in a form acceptable to the Administrator) most recently filed with the Administrator by the Grantee prior to the Grantee's death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Grantee's estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Grantee's death, of an instrument of revocation in a form acceptable to the Administrator.
 - 3. <u>Vesting</u>; <u>Cessation of Employment</u>.
 - (a) <u>Vesting</u>. Unless earlier terminated, forfeited, relinquished or expired, the Restricted Share Units will vest as follows, subject to the Grantee remaining in continuous Employment from the Date of Grant through each such vesting date:
 - (i) [Specific vesting terms to be specified in each grant.]

- (b) <u>Forfeiture</u>. Automatically and immediately upon the cessation of the Grantee's Employment (i) the unvested portion of the Award will terminate and be forfeited for no consideration, and (ii) the vested portion of the Award, if any, will terminate and be forfeited for no consideration if the Grantee's Employment is terminated in connection with an act or failure to act constituting Cause (as the Administrator, in its sole discretion, may determine), or such termination of Employment occurs in circumstances that in the determination of the Administrator would have entitled the Company and its subsidiaries to terminate the Grantee's Employment for Cause.
- 4. <u>Delivery of Shares</u>. Subject to Section 5 below, the Company shall, as soon as practicable upon the vesting of any portion of the Award (but in no event later than 30 days following the date on which such Restricted Share Units vest), effect delivery of the Shares with respect to such vested Restricted Share Units to the Grantee (or, in the event of the Grantee's death following the vesting of such portion of the Award, to the Grantee's Beneficiary). No Shares will be issued pursuant to the Award unless and until all legal requirements applicable to the issuance or transfer of such Shares have been complied with to the satisfaction of the Administrator.
- 5. <u>Forfeiture; Recovery of Compensation</u>. The Administrator may cancel, rescind, withhold or otherwise limit or restrict the Award at any time if the Grantee is not in compliance with all applicable provisions of this Agreement and the Plan. By accepting, or being deemed to have accepted, the Award, the Grantee expressly acknowledges and agrees that his or her rights, and those of any Beneficiary or permitted transferee of the Award, under the Award, including the right to any Shares acquired under the Award or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). Nothing in the preceding sentence may be construed as limiting the general application of Section 8 of this Agreement.
- 6. <u>Dividends; Other Rights</u>. The Award may not be interpreted to bestow upon the Grantee any equity interest or ownership in the Company or any subsidiary prior to the date on which the Company delivers Shares to the Grantee. The Grantee is not entitled to vote any Shares by reason of the granting of the Award or to receive or be credited with any dividends declared and payable on any Share prior to the date on which any such Share is delivered to the Grantee hereunder. The Grantee will have the rights of a shareholder only as to those Shares, if any, that are actually delivered under the Award.
 - 7. <u>Nontransferability</u>. The Award may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

8. Withholding.

- (a) The Grantee expressly acknowledges that the vesting or settlement of the Restricted Share Units acquired hereunder may give rise to "wages" subject to withholding. The Grantee expressly acknowledges and agrees that the Grantee's rights hereunder, including the right to receive Shares following the vesting of any portion of the Award, are subject to the Grantee promptly paying to the Company in cash (or by such other means as may be acceptable to the Administrator in its discretion) all taxes required to be withheld. No Shares will be delivered pursuant to the Award unless and until the Grantee (or the Grantee's Beneficiary or permitted transferee of the Award) has remitted to the Company an amount in cash sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Grantee authorizes the Company and its subsidiaries to take the following actions with respect to withholding tax requirements: (i) withhold such amount from any amounts otherwise owed to the Grantee, (ii) cause the Grantee to tender a cash payment; (iii) permit or require the Grantee to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "FINRA Dealer") whereby the Grantee irrevocably elects to sell a portion of the Shares to be delivered in connection with the Restricted Share Units to satisfy the withholding taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the withholding taxes directly to the Company and/or its affiliates; or (iv) withhold Shares from the Shares issued or otherwise issuable to the Grantee in connection with the Award with a Fair Market Value (measured as of the date Shares are issued to pursuant to Section 4) equal to the amount of such withholding taxes; provided, however, that the number of such Shares so withheld will be at least the minimum amount necessary to satisfy the Company's required tax withholding but in no event more than the maximum permitted withholding under applicable law; and provided, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Securities Exchange Act of 1934, if applicable, such share withholding procedure will be subject to the express prior approval of the Company's Compensation Committee. Notwithstanding the foregoing, nothing in the preceding sentence may be construed as relieving the Grantee of any liability for satisfying his or her obligation under the preceding provisions of this Section.] [The Grantee expressly acknowledges and agrees that he or she shall be responsible for satisfying and paying all taxes arising from or due in connection with the grant or vesting of the Restricted Share Units and/or the delivery of any Shares hereunder. The Company shall have no liability or obligation relating to the foregoing. 12
- (b) The Grantee expressly acknowledges that because this Award consists of an unfunded and unsecured promise by the Company to deliver Shares in the future, subject to the terms hereof, it is not possible to make a so-called "83(b) election" under U.S. federal tax laws with respect to the Award.
- 9. <u>Effect on Employment</u>. Neither the grant of the Award, nor the issuance of Shares upon the vesting of the Award, will give the Grantee any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to discharge the Grantee at any time, subject to the terms and conditions of an effective employment or other individual agreement, if any, between the Grantee and the Company or any of its subsidiaries, or affect any right of the Grantee to terminate his or her Employment at any time, subject to the terms and conditions of an effective employment or other individual agreement, if any, between the Grantee and the Company or any of its subsidiaries.

¹ To be used if the Grantee is an employee.

² To be used if the Grantee is a non-employee director or other independent contractor.

- 10. <u>Provisions of the Plan</u>. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished or made available to the Grantee. By accepting, or being deemed to have accepted, all or any portion of the Award, the Grantee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.
- 11. <u>Acknowledgements</u>. The Grantee acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii) this Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Grantee.

[Signature page follows.]

	ZAI LAB L	ZAI LAB LIMITED	
	By:		
	Name:		
	Title:		
Agreed and Accepted:			
By: [Name of Grantee]			
Dated: []			

The Company, by its duly authorized officer, and the Grantee have executed this Agreement as of the date first set forth above.

Signature Page to Restricted Share Unit Award Agreement

ZAI LAB LIMITED

2022 EQUITY INCENTIVE PLAN

RESTRICTED SHARE AWARD AGREEMENT

This award evidences the grant of Restricted Shares represented by [ADSs / Ordinary Shares] (the "Award") by Zai Lab Limited (the "Company"), on [] to [] (the "Grantee") pursuant to and subject to the terms of the Zai Lab
Limited 2022 Equity Incentive Plan (as from time to time in effect, the "Plan"). Except as otherwise defined herein, all capitalized
terms used herein have the same meaning as in the Plan.
1. Grant of Restricted Shares. The Company grants to the Grantee on the date set forth above (the "Date of Grant") [] Restricted Shares represented by [] ADSs (the "Shares"). Each ADS represents the right to receive [] ([]) Ordinary Shares (subject to any Share dividend, Share split or combination of Shares (including a reverse Share split)). No Shares can be acquired by the Grantee pursuant to this Award unless, within 14 days of the Date of Grant, the Grantee has acknowledged and accepted the Award and thereby agreed to its terms by signing a copy of this instrument in the space indicated below and returning it to [].

- pledged, assigned or otherwise encumbered or disposed of except as provided below and in the Plan.
 - 3. <u>Vesting; Forfeiture</u>. The vesting and forfeiture provisions applicable to the Award are set forth in <u>Exhibit A</u> hereto.

Nontransferability of Shares. The Shares acquired by the Grantee pursuant to this Award shall not be sold, transferred,

- 4. <u>Compliance with Plan Restrictions; Recovery of Compensation.</u>
- (a) By accepting the Award, the Grantee expressly acknowledges and agrees that in addition to the vesting and forfeiture provisions set forth in Exhibit A hereto, the Award (whether or not vested) is subject to forfeiture, and the Grantee and any permitted transferee will be obligated to return to the Company the value received with respect to the Award (including any gain realized on a subsequent sale or disposition of Shares) in accordance with any clawback or similar policy maintained by the Company, as such policy may be amended and in effect from time to time.
- (b) The Grantee hereby (i) appoints the Company as the attorney-in-fact of the undersigned to take such actions as may be necessary or appropriate to effectuate a transfer of the record ownership of any Shares that are unvested and forfeited hereunder, (ii) agrees to deliver to the Company, as a precondition to the issuance of any certificate or certificates with respect to unvested Shares hereunder, one or more stock powers, endorsed in blank, with respect to such Shares, and (iii) agrees to sign such other powers and take such other actions as the Company may reasonably request to accomplish the transfer or forfeiture of any unvested Shares that are forfeited hereunder.

- 5. <u>Dividends</u>. The Grantee shall be entitled to receive any and all dividends or other distributions paid with respect to those Shares of which the Grantee is the record owner on the record date for such dividend or other distribution; <u>provided</u>, <u>however</u>, that any property or cash (including, without limitation, any regular cash dividends) distributed with respect to a Share (the "<u>associated share</u>") acquired hereunder, including without limitation a distribution of Shares by reason of a Share dividend, Share split or otherwise, or a distribution of other securities with respect to an associated share, shall be subject to the restrictions of this Award in the same manner and for so long as the associated share remains subject to such restrictions, and shall be promptly forfeited if and when the associated share is so forfeited; and <u>further provided</u>, that the Administrator may require that any cash distribution with respect to the Shares be placed in escrow. Any cash amounts that would otherwise have been paid with respect to an associated share shall be accumulated and paid to the Grantee, without interest, only upon, or within thirty (30) days following, the date on which such associated share vests hereunder (the "<u>Vesting Date</u>") and any other property distributable with respect to such associated share shall also vest on the Vesting Date.
- 6. <u>Retention of Certificates</u>. Any certificates representing unvested Shares shall be held by the Company. If unvested Shares are held in book entry form, the undersigned agrees that the Company may give stop transfer instructions to the depository to ensure compliance with the provisions hereof.
- 7. <u>Legends</u>. Any certificates representing unvested Shares will bear such legends as determined by the Company that discloses the restrictions on transferability imposed on such Shares as a result of this Award and the Plan. As soon as practicable following the vesting of any such Shares, the Company shall cause a certificate or certificates covering such Shares, without the aforesaid legend, to be issued and delivered to the undersigned. If any Shares are held in book-entry form, the Company may take such steps as it deems necessary or appropriate to record and manifest the restrictions applicable to such Shares.

8. Certain Tax Matters.

- (a) The Grantee has been advised to confer promptly with a professional tax advisor to consider whether the Grantee should make a so-called "83(b) election" with respect to the Shares. Any such election, to be effective, must be made in accordance with applicable regulations and within thirty (30) days following the date this Award is granted, and the Grantee must provide the Company with a copy of the 83(b) election prior to filing. The Company has made no recommendation to the Grantee with respect to the advisability of making such an election.
- (b) The Grantee expressly acknowledges and agrees that he or she shall be responsible for satisfying and paying all taxes arising from or due in connection with the grant or vesting of the Award. The Company shall have no liability or obligation relating to the foregoing.

- 9. <u>Effect on Service</u>. The grant of the Shares will not give the Grantee any right to be retained in the service of the Company or any of its affiliates, affect the right of the Company or any of its affiliates to discharge or discipline such Grantee at any time, or affect any right of such Grantee to terminate his or her service at any time.
- 10. <u>Provisions of the Plan</u>. This Award is subject to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant of this Award has been furnished or made available to the Grantee. By accepting this Award, the Grantee agrees to be bound by the terms of the Plan and this Award. All initially capitalized terms used herein will have the meaning specified in the Plan, unless another meaning is specified herein.

[Signature page follows.]

	ZAI LAB LIMITED
	Ву
	Dated: []
The undersigned hereby acknowledges the terms set forth above and in Exhibit A, and in the Plan, and agrees to be bound thereby:	
[Name of Grantee]	

IN WITNESS WHEREOF, the Company has caused this instrument to be executed by its duly authorized officer.

Signature Page to Restricted Share Award Agreement

Dated: [____]

Exhibit A

[Specific vesting and forfeiture terms to be specified in each grant.]

Name:	[]
Number of ADSs subject to the Stock Option:	[]
Exercise Price Per ADS:	[]
Date of Grant:	[]
Vesting Commencement Date	[]

ZAI LAB LIMITED 2022 EQUITY INCENTIVE PLAN

NON-STATUTORY STOCK OPTION AWARD AGREEMENT

This agreement (this "<u>Agreement</u>") evidences a stock option granted by Zai Lab Limited (the "<u>Company</u>") to the individual named above (the "<u>Optionee</u>"), pursuant to and subject to the terms of the Zai Lab Limited 2022 Equity Incentive Plan (as from time to time amended and in effect, the "<u>Plan</u>").

- 1. <u>Meaning of Certain Terms</u>. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:
 - (a) "Beneficiary": In the event of the Optionee's death, the beneficiary named in the written designation (in a form acceptable to the Administrator) most recently filed with the Administrator by the Optionee prior to the Optionee's death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Optionee's estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Optionee's death, of an instrument of revocation in a form acceptable to the Administrator.
 - (b) "Option Holder": The Optionee or, if at the relevant time the Stock Option has passed to a Beneficiary, the Beneficiary.
- 2. <u>Grant of Stock Option</u>. The Company grants to the Optionee on the date set forth above (the "<u>Date of Grant</u>") an option (the "<u>Stock Option</u>") to purchase, pursuant to and subject to the terms set forth in this Agreement and in the Plan, up to the number of ADSs (the "Shares") with an exercise price per Share as set forth above, in each case, subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof. Each ADS represents the right to receive [___] ([__]) Ordinary Shares (subject to any Share dividend, Share split or combination of Shares (including a reverse Share split)).

The Stock Option evidenced by this Agreement is a non-statutory option (that is, an option that does not qualify as an incentive stock option under Section 422 of the Code) and is granted to the Optionee in connection with the Optionee's Employment.

- 3. <u>Vesting; Method of Exercise; Cessation of Employment.</u>
 - (a) <u>Vesting</u>. The term "vest" as used herein with respect to the Stock Option or any portion thereof means to become exercisable, and the term "vested" as applied to any outstanding Stock Option means that the Stock Option is then exercisable, subject, in each case, to the terms of the Plan.
 - (i) [Specific vesting terms to be specified in each grant.]
 - (b) Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and must be in written or electronic form acceptable to the Administrator, signed (including by electronic signature) by the Optionee (or in such other form as is acceptable to the Administrator). Each such written or electronic exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full of the exercise price as provided in the Plan. The latest date on which the Stock Option or any portion thereof may be exercised is the 10th anniversary of the Date of Grant (the "<u>Final Exercise Date</u>") and, if not exercised by such date, the Stock Option or any remaining portion thereof will thereupon immediately terminate.
 - (c) <u>Cessation of Employment</u>. If the Optionee's Employment ceases, except as expressly provided for in an employment or other individual agreement between the Optionee and the Company or any of its subsidiaries, the Stock Option, to the extent not already vested, will be immediately forfeited, and any vested portion of the Stock Option that is then outstanding will be treated as provided in the Plan.
- 4. <u>Forfeiture; Recovery of Compensation</u>.
 - (a) The Stock Option, and the proceeds from the exercise or disposition of the Stock Option or the Shares, will be subject to forfeiture and disgorgement to the Company, with interest and related earnings, if at any time the Optionee is not in compliance with all applicable provisions of this Agreement and the Plan.
 - (b) By accepting, or being deemed to have accepted, the Stock Option, the Optionee expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of the Stock Option, under the Stock Option, including the right to any Share acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a) (5) of the Plan (including any successor provision). Nothing in the preceding sentence may be construed as limiting the general application of Section 8 of this Agreement.
- 5. <u>Nontransferability</u>. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

- 6. Withholding. [The exercise of the Stock Option will give rise to "wages" subject to withholding. The Optionee expressly acknowledges and agrees that the Optionee's rights hereunder, including the right to be issued Shares upon exercise, are subject to the Optionee promptly paying to the Company in cash or by check (or by such other means as may be acceptable to the Administrator) all taxes required to be withheld. No Shares will be issued pursuant to the exercise of the Stock Option unless and until the person exercising the Stock Option has remitted to the Company an amount in cash sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Optionee authorizes the Company and its subsidiaries to take the following actions with respect to withholding tax requirements: (i) withhold such amount from any amounts otherwise owed to the Optionee, (ii) cause the Optionee to tender a cash payment; (iii) permit or require the Optionee to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "FINRA Dealer") whereby the Optionee irrevocably elects to sell a portion of the Shares to be delivered in connection with the exercise of the Stock Option to satisfy the withholding taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the withholding taxes directly to the Company and/or its affiliates; or (iv) withhold Shares from the Shares issued or otherwise issuable to the Optionee in connection with the exercise of the Stock Option with a Fair Market Value (measured as of the date Shares are issued pursuant to Section 3) equal to the amount of such withholding taxes; provided, however, that the number of such Shares so withheld will be at least the minimum amount necessary to satisfy the Company's required tax withholding but in no event more than the maximum permitted withholding under applicable law; and provided, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Securities Exchange Act of 1934, if applicable, such share withholding procedure will be subject to the express prior approval of the Company's Compensation Committee. Notwithstanding the foregoing, nothing in the preceding sentence may be construed as relieving the Optionee of any liability for satisfying his or her obligation under the preceding provisions of this Section.]¹ [The Optionee expressly acknowledges that he or she is responsible for satisfying and paying all taxes arising from, or due in connection with, the Stock Option, its exercise or a disposition of Shares acquired upon exercise of the Stock Option. The Company will have no liability or obligation related to the foregoing. 12
- 7. <u>Effect on Employment</u>. Neither the grant of the Stock Option, nor the issuance of Shares upon exercise of the Stock Option, will give the Optionee any right to be retained in the employ or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to terminate the Optionee's Employment at any time, subject to the terms and conditions of an effective employment or other individual agreement, if any, between the Optionee and the Company or any of its subsidiaries, or affect any right of the Optionee to terminate his or her Employment at any time, subject to the terms and conditions of an effective employment or other individual agreement, if any, between the Optionee and the Company or any of its subsidiaries.
- 8. <u>Provisions of the Plan</u>. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished or made available to the Optionee. By accepting, or being deemed to have accepted, all or any part of the Stock Option, the Optionee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

¹ To be used if the Optionee is an employee.

² To be used if the Optionee is a non-employee director or other independent contractor.

9. Acknowledgements. The Optionee acknowledges and agrees that (i) this Agreement may be executed in two or r	more
counterparts, each of which will be an original and all of which together will constitute one and the same instrument, (ii)	this
Agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in	each
case, will constitute an original signature for all purposes hereunder, and (iii) such signature by the Company will be binding ago	ainst
the Company and will create a legally binding agreement when this Agreement is countersigned by the Optionee.	

[Signature page follows.]

	ZAI	ZAI LAB LIMITED	
	By:		
	Nam	e:	
	Title		
Agreed and Accepted:			
By:			
[Name of Grantee]			
Dated: []			

The Company, by its duly authorized officer, and the Optionee have executed this Agreement as of the Date of Grant.

Signature Page to Non-Statutory Stock Option Award Agreement

Certification by the Principal Executive Officer Pursuant to Exchange Act Rule 13a-14(a), As Adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Samantha (Ying) Du, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 of Zai Lab Limited;
- 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 registrant as of, and for, the periods presented in this report;
- 4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: November 9, 2022 /s/ Samantha (Ying) Du

Samantha (Ying) Du Chief Executive Officer (Principal Executive Officer)

Certification by the Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a), As Adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Billy Cho, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 of Zai Lab Limited;
- 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 registrant as of, and for, the periods presented in this report;
- 4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: November 9, 2022 /s/ Billy Cho

Billy Cho

Chief Financial Officer

(Principal Financial and Accounting Officer)

Certification by the Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 of Zai Lab Limited (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha (Ying) 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: November 9, 2022 /s/ Samantha (Ying) Du

Samantha (Ying) Du Chief Executive Officer (Principal Executive Officer)

Certification by the Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 of Zai Lab Limited (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2022 /s/ Billy Cho

Billy Cho

Chief Financial Officer

(Principal Financial and Accounting Officer)