

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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

OR

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

Date of event requiring this shell company report \_\_\_\_\_

Commission file number 001-38205

**ZAI LAB LIMITED**

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

Cayman Islands

(Jurisdiction of incorporation or organization)

4560 Jinke Road  
Bldg. 1, Fourth Floor  
Pudong  
Shanghai, China 201210

(Address of principal executive offices)

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Chief Executive Officer  
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Pudong  
Shanghai, China 201210  
Telephone: +86 21 6163 2588

(Name, telephone, email and/or facsimile number and address of Company contact person)  
Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class

American depository shares, each representing one  
ordinary share, par value \$0.00006 per share

Name of each exchange on which registered

Nasdaq Global Market

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

None

(Title of Class)

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

None

(Title of Class)

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

50,555,903 ordinary shares were issued and outstanding as of December 31, 2017

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).  Yes  No

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

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

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

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

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

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

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

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

**Zai Lab Limited**  
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## Industry and Market Data

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

## Trademarks and Service Marks

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

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

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to advance our drug candidates into, and successfully complete, clinical trials;
- the ability of our drug candidates to be granted or maintain Category 1 designation with the State Drug Administration, or SDA (formerly known as the CFDA, China Food and Drug Administration), and to receive a faster development, review or approval process;
- our reliance on the success of our clinical-stage drug candidates ZL-2306, ZL-2401, Bemarituzumab and ZL-2301 and certain other drug candidates;
- the timing or likelihood of regulatory filings and approvals;
- the commercialization of our drug candidates, if approved;
- our ability to develop sales and marketing capabilities;
- our ability to contract on commercially reasonable terms with contract research organizations, or CROs, third-party suppliers and manufacturers;

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

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

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

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

**PART I**

**ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

Not applicable.

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

**ITEM 3. KEY INFORMATION**

**A. SELECTED FINANCIAL DATA**

**Our Selected Consolidated Financial Data**

The following selected consolidated statement of operations data for the years ended December 31, 2017, 2016 and 2015 and the selected balance sheet data as of December 31, 2017 and 2016 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. Our historical results for any period are not necessarily indicative of results to be expected for any future period. The selected consolidated financial data should be read in conjunction with, and are qualified in their entirety by reference to, our audited consolidated financial statements and related notes and “Item 5. Operating and Financial Review and Prospects” below. Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP.

	<b>Year Ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
	<b>(in thousands, except share and per share data)</b>		
Research and development expenses	\$ (39,342)	\$ (32,149)	\$ (13,587)
General and administrative expenses	(12,049)	(6,380)	(2,762)
Loss from operations	(51,391)	(38,529)	(16,349)
Interest income	527	403	5
Changes in fair value of warrants	200	(1,920)	(1,980)
Other income	933	2,534	341
Other expense	(403)	—	(39)
Loss before income taxes and share of loss from equity method investment	\$ (50,134)	\$ (37,512)	\$ (18,022)
Income tax expense	—	—	—
Share of loss from equity method investment	(250)	—	—
Net loss	\$ (50,384)	\$ (37,512)	\$ (18,022)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted (1)	21,752,757	9,439,028	8,693,655
Net loss per share, basic and diluted (1)	(2.32)	(3.97)	(2.07)

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

	<b>As of December 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(in thousands)</b>	
<b>Consolidated balance sheet data:</b>		
Cash and cash equivalents	\$ 229,660	\$ 83,949
Total assets	\$ 249,634	\$ 88,907
Total shareholders' equity (deficit)	\$ 235,171	\$ (51,552)
Total current liabilities	\$ 12,069	\$ 5,173
Total non-current liabilities	\$ 2,394	\$ 778

**B. CAPITALIZATION AND INDEBTEDNESS**

Not applicable.

**C. REASONS FOR THE OFFER AND USE OF PROCEEDS**

Not applicable.

**D. RISK FACTORS**

**Risks Related to Our Financial Position and Need for Additional Capital**

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

We are a clinical stage biopharmaceutical company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. To date, we have financed our activities primarily through private placements and our initial public offering in September of 2017. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2014. For the two years ended December 31, 2017 and 2016, we reported a net loss of \$50.4 million and \$37.5 million, respectively.

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

- continue our development and commence clinical trials of our drug candidates;
- seek regulatory approvals for our drug candidates that successfully complete clinical trials;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- complete construction of and maintain our manufacturing facilities;
- hire additional clinical, operational, financial, quality control and scientific personnel;
- establish a sales, marketing and commercialization infrastructure for any products that obtain regulatory approval;
- seek to identify additional drug candidates;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend intellectual property-related claims; and
- acquire or in-license other intellectual property, drug candidates and technologies.

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

***We will likely need substantial additional funding for our drug development programs and commercialization efforts, which may not be available on acceptable terms, or at all. If we are unable to raise capital on acceptable terms when needed, we could incur losses or be forced to delay, reduce or terminate such efforts.***

To date, we have financed our activities primarily through private placements and our initial public offering in September of 2017. Through December 31, 2017, we have raised \$322.3 million in equity financing, including \$157.7 million in net proceeds from our initial public offering. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$32.4 million and \$32.2 million for the years ended December 31, 2017 and 2016, respectively. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our six clinical-stage drug candidates and continue research and development of our preclinical-stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs that may be required for the manufacture of any drug candidate that receives regulatory approval may be substantial as we may have to modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers. We have, and may continue to, incur expenses as we create additional infrastructure to support our operations as a U.S. public company. Accordingly, we will likely need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts.

We believe our cash and cash equivalents as of December 31, 2017 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;
- the cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;
- the cash received, if any, from commercial sales of any drug candidates for which we receive regulatory approval;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangement and the financial terms of such arrangements;
- the extent to which we acquire or in-license other drug candidates and technologies;
- our headcount growth and associated costs; and
- the costs of operating as a public company in the United States.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.***

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances and marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect rights of our security holders. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our American depositary shares, or ADSs, to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

### **Risks Related to Our Business and Industry**

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

We commenced our operations in 2014. Our operations to date have been limited to organizing and staffing our company, identifying potential partnerships and drug candidates, acquiring product and technology rights, and conducting research and development activities for our drug candidates. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials. We have also not yet obtained regulatory approval for, or demonstrated an ability to manufacture or commercialize, any of our drug candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history and/or approved products on the market.

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

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

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

- successful completion of pre-clinical and/or clinical studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;
- successful completion of all safety studies required to obtain regulatory approval in China, the United States and other jurisdictions for our drug candidates;



- adapting our commercial manufacturing capabilities to the specifications for our drug candidates for clinical supply and commercial manufacturing;
- making and maintain arrangements with third-party manufacturers;
- obtaining and maintaining patent, trade secret and other intellectual property protection and/or regulatory exclusivity for our drug candidates;
- launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and alternative drugs;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the drug candidates following regulatory approval.

The success of our business is dependent upon our ability to develop and commercialize our clinical-stage drug candidates, particularly ZL-2306, which in March 2017 received FDA marketing approval and in November 2017 received European Union marketing approval as maintenance treatment for recurrent platinum-sensitive epithelial ovarian cancer. As ZL-2306 has been approved both in the United States and European Union, we plan to commercialize ZL-2306 in Hong Kong in the second half of 2018 and in Macau thereafter. For ZL-2401, we completed the technology transfer stage and started discussions with key opinion leaders on our planned China development activities in preparation for SDA interactions. We initiated a Phase II trial in advanced HCC patients in China to investigate ZL-2301's optimal treatment schedule and dosage as a second-line treatment in the second quarter of 2017. The recruitment for the Phase II study has been completed and the study is ongoing. As a result, our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for, and successfully commercialize ZL-2306, ZL-2401, ZL-2301, Bemarituzumab and our other drug candidates in a timely manner.

We cannot commercialize drug candidates in China without first obtaining regulatory approval from the SDA. Similarly, we cannot commercialize drug candidates in the United States or another jurisdiction outside of China without obtaining regulatory approval from the FDA or comparable foreign regulatory authorities. The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside of China and approval may not be granted. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Even if our drug candidates were to successfully obtain approval or, in the case of ZL-2306, have obtained approval, from the FDA and comparable foreign regulatory authorities, we would still need to seek approval in China and any other jurisdictions where we plan to market the product. For example, we will need to conduct clinical trials of each of our drug candidates in patients in China prior to seeking regulatory approval in China. Even if our drug candidates have successfully completed clinical trials outside of China, there is no assurance that clinical trials conducted with Chinese patients will be successful. Any safety issues, product recalls or other incidents related to products approved and marketed in other jurisdictions may impact approval of those products by the SDA. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, or are imposed on certain drug candidates, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

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

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

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

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the SDA, FDA and European Medicines Agency, or EMA, and other regulatory agencies in China and the United States and by comparable authorities in other countries. We are not permitted to market any of our drug candidates in China, the United States and other jurisdictions unless and until we receive regulatory approval from the SDA, FDA and EMA and other comparable authorities, respectively. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing regulatory approval may also require the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. Although ZL-2306 was approved in the United States and the European Union, we cannot provide any assurance that we will ever obtain regulatory approval for ZL-2306 in China or for any of our other drug candidates in any jurisdiction or that any of our drug candidates will be successfully commercialized, even if we receive regulatory approval.

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

- disagreement with the SDA, FDA and EMA or comparable regulatory authorities regarding the number, design, size, conduct or implementation of our clinical trials;
- failure to demonstrate to the satisfaction of the SDA, FDA and EMA or comparable regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- failure of contract research organizations, or CROs, clinical study sites or investigators to comply with the ICH-good clinical practice, or GCP, requirements imposed by the SDA, FDA and EMA or comparable regulatory authorities;
- failure of the clinical trial results to meet the level of statistical significance required by the SDA, FDA and EMA or comparable regulatory authorities for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;

- the SDA, FDA and EMA or comparable regulatory authorities disagreeing with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from clinical trials to support the submission of an NDA or other submission or to obtain regulatory approval in China, the United States or elsewhere;
- the SDA, FDA and EMA or comparable regulatory authorities not approving the manufacturing processes for our clinical and commercial supplies;
- changes in the approval policies or regulations of the SDA, FDA or comparable regulatory authorities rendering our clinical data insufficient for approval;
- the SDA, FDA or comparable regulatory authorities restricting the use of our products to a narrow population; and
- our CROs or licensors taking actions that materially and adversely impact the clinical trials.

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

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

We plan to develop certain of our drug candidates for use as a combination therapy. For example, Tesaro, Inc., or Tesaro, is currently developing, and we also plan to develop, ZL-2306 as both a monotherapy and in combination with any potential anti-VEGF or PD-1/PD-L1 treatments. However, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any anti-VEGF or PD-1/PD-L1 treatments or any other therapeutic we use in combination with our drug candidates. We may also seek to develop our drug candidates in combination with other therapeutics in the future.

If the SDA, FDA or another regulatory agency revokes its approval of any anti-VEGF or PD-1/PD-L1 treatments or another therapeutic we use in combination with our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any anti-VEGF or PD-1/PD-L1 treatments or any other combination therapeutics, we may not be able to complete clinical development of ZL-2306 and/or another of our drug candidates on our current timeline or at all.

Even if one or more of our drug candidates were to receive regulatory approval for use in combination with any anti-VEGF or PD-1/PD-L1 treatments, as applicable, or another therapeutic, we would continue to be subject to the risk that the SDA, FDA or another regulatory agency could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with one of these combination therapeutics. This could result in ZL-2306 or one of our other products being removed from the market or being less successful commercially.

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

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. For example, there are a number of large pharmaceutical and biotechnology

companies that currently market drugs or are pursuing the development of therapies in the field of poly ADP ribose polymerase, or PARP, inhibition to treat cancer. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to that of our drug candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Specifically, there are a large number of companies developing or marketing treatments for oncology, autoimmune and infectious diseases including many major pharmaceutical and biotechnology companies.

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

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

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

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

There is a risk of failure for each of our drug candidates. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any drug candidate, our drug candidates must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete. The outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Future clinical trials of our drug candidates may not be successful. For example, ZL-2301 failed to meet its primary endpoint of overall survival, or OS, noninferiority for ZL-2301 versus sorafenib in Phase III trials in patients with HCC conducted by Bristol-Myers Squibb Company, or Bristol-Myers Squibb, before we licensed the development rights from them. Although we believe that ZL-2301 has the potential to be an effective treatment for Chinese patients and merits further clinical trials patients, we cannot guarantee that our future clinical trials of ZL-2301 in Chinese patients will be successful.

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

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

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

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

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or, as applicable, the IRBs or the ethics committee of the institutions in which such trials are being conducted, by the data safety monitoring board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the SDA, FDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, inspection of the clinical trial operations or trial site by the SDA, FDA or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the SDA, FDA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

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

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

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

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

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the SDA, FDA or similar regulatory authorities. In particular, we have designed many of our clinical trials, and expect to design future trials, to include some patients with the applicable genomic mutation with a view to assessing possible early evidence of potential therapeutic effect. Genomically defined diseases, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genomic mutation. In addition, for our trials studying ZL-2306 in ovarian cancer patients and certain of our other drug candidates, we plan to focus on enrolling patients who have failed their first or second-line treatments, which limits the total size of the patient population available for such trials. The inability to enroll a sufficient number of patients with the applicable genomic alteration or that meet other applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

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

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;

- the availability of competing therapies also undergoing clinical trials;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which could cause the value of our company to decline and limit our ability to obtain additional financing.

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

Undesirable side effects caused by our drug candidates could cause us to interrupt, delay or halt clinical trials or could cause regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the SDA, FDA or other regulatory authorities. In particular, as is the case with all oncology drugs, it is likely that there may be side effects, such as fatigue, nausea and low blood cell levels, associated with the use of certain of our oncology drug candidates. For example, the known adverse events for ZL-2306 include thrombocytopenia, anemia and neutropenia and for ZL-2301, the known adverse events include hyponatremia, AST elevation, fatigue, hand-foot skin reaction and hypertension. The results of our drug candidates' trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, trials of our drug candidates could be suspended or terminated and the SDA, FDA or comparable regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, our drug candidates could cause undesirable side effects related to off-target toxicity. For example, many of the currently approved PARP inhibitors have been associated with off-target toxicities. While we believe that the superior selectivity of ZL-2306 has the potential to significantly improve the unfavorable adverse off-target toxicity issues, if patients were to experience off-target toxicity, we may not be able to achieve an effective dosage level (especially in combination therapies), receive approval to market, or achieve the commercial success we anticipate with respect to, any of our drug candidates, which could prevent us from ever generating revenue or achieving profitability. Many compounds that initially showed promise in early stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

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

- the SDA, FDA or other comparable regulatory authorities may withdraw or limit their approval of such drug candidates;
- the SDA, FDA or other comparable regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of our drug candidates;
- the SDA, FDA or other comparable regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS (or analogous requirement), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;

- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates; and
- our reputation may suffer.

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

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

The SDA categorizes domestically-manufactured innovative drug applications as Category 1, provided such drug has a new and clearly defined structure, pharmacological property and apparent clinical value and has not been marketed anywhere in the world. Domestically developed and manufactured innovative drugs will be attributed to Category 1 for their CTA and NDA applications. While some multinational pharmaceutical companies may file CTAs with the SDA prior to approval of a drug in another country in order to take advantage of Category 1 classification, such drug will most likely be assigned to Category 5 for NDA approval purposes because, based on historical observations, multinational pharmaceutical companies will typically not prioritize applying for local manufacturing rights in China, hence subjecting the drug to the imported drug status. Our CTAs for ZL-2306, ZL-2301 and ZL-2302 were approved as Category 1 drugs by the SDA. Other than ZL-3101 and Bemarituzumab, all our other clinical stage drug candidates are eligible for Category 1 designation. These two categories have distinct approval pathways. We believe the local drug registration pathway is a faster and more efficient path to approval in the China market than the imported drug registration pathway. The imported drug registration pathway is more complex and is evolving. Imported drug registration applications in China may only be approved after a drug has obtained an NDA approval and received the Certificate of Pharmaceutical Product granted by a major drug regulatory authority, such as the FDA. A Category 1 designation by the SDA may not be granted for any of our other drug candidates that do not already have a Category 1 designation or may not lead to faster development or regulatory review or approval process. Moreover, a Category 1 designation does not increase the likelihood that our drug candidates will receive regulatory approval.

Furthermore, there has been recent regulatory initiatives in China, including (i) the China's State Council's August 2015 statement, *Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices*, which declared the Chinese government's clear determination to encourage transformation and upgrade of the pharmaceutical industry, (ii) the SDA's November 2015 release, *Circular Concerning Several Policies on Drug Registration Review and Approval*, with aims to accelerate the approval process of clinical trials and (iii) the SDA's December 2017 release, *Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations*, which further clarified that a fast track clinical trial approval or drug registration pathway will be available to certain designated drugs. As such, the regulatory process in China is evolving and subject to change. Any future policies, or changes to current policies, that the SDA approves might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

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

If the SDA, FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions



of safety and other post-marketing information and reports, registration, and continued compliance with cGMPs and GCPs. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV studies for the surveillance and monitoring the safety and efficacy of the drug.

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

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

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

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

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

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

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

On March 17, 2018, China's highest legislative body, the National People's Congress, approved a sweeping government restructuring plan. This is generally considered to be the most comprehensive government restructuring that China has undertaken since its "Open Door" policy in the late 1970s. As part of the new plan, China has established a State Market Regulatory Administration (SMRA), which merges and undertakes the responsibilities previously held by the China Food and Drug Administration, the State Administration for Industry and Commerce (SAIC), General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the Certification and Accreditation Administration (CAC), and the Standardization Administration of China (SAC).

A new State Drug Administration is formed and reports to the SMRA, responsible for the review and approval of drugs, medical devices and cosmetics. The new SDA will maintain its own branches at the provincial level and leave the post-approval enforcement authorities at the local level to the consolidated SMRA branches.

Despite the announcement of key leadership positions at the SMRA and SDA, appointments of working-level officials are still ongoing. The new authorities at the national level are not expected to be fully operational until June 2018, and the reorganization will continue at the provincial and local levels through the first quarter of 2019. This massive restructuring exercise could result in the delay of key decision-making in various sectors, including the pharmaceutical industry. In addition, there could be delays in the SDA's implementation of the new reform initiatives and disruption in the SDA's routine operations due to personnel reshuffle.

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

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

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

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

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

***We have concluded that there was a material weakness in internal control over financial reporting in the past and cannot assure you that additional material weaknesses will not be identified in the future. A material weakness may not be timely eliminated and general reputational harm could result or persist, which could materially and adversely affect our business, operations and financial condition. Our failure to implement and maintain effective internal control over financial reporting could result in material misstatements in our financial statements which could require us to restate financial statements, cause investors to lose confidence in our reported financial information and have a negative effect on our stock price.***

In the course of having our consolidated financial statements audited for the year ended December 31, 2015 and 2016, we and our independent registered public accounting firm identified one material weakness in our internal control over financial reporting as of December 31, 2016. In accordance with the standards established by the Public Company Accounting Oversight Board of the United States, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weakness related to the lack of sufficient accounting personnel with U.S. GAAP knowledge and SEC financial reporting requirements for the purpose of financial reporting, and lack of accounting policies and procedures over financial reporting in accordance with U.S. GAAP.

During 2017, we implemented a number of measures to remedy this material weakness, including adding staff with extensive U.S. GAAP experience to our accounting team and developing, communicating and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes and improving the capabilities of existing financial reporting personnel through training and education in the accounting and reporting requirements under U.S. GAAP and SEC rules and regulations. As of December 31, 2017, based on the measures relating to formal process to identify and address risk of material misstatement related to U.S. GAAP reporting and other controls implemented as described above, we believe we have been able to remediate the identified material weakness as mentioned above, we believe we have been able to remediate the identified material weakness as mentioned above. However, we cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional significant deficiencies or material weaknesses, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. Furthermore, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting as of the end of our fiscal year ending on December 31, 2018. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. The existence of a material weakness could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

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

While we currently have no specific plans to acquire any other businesses, we have, from time to time, evaluated acquisition opportunities and may, in the future, make acquisitions of, or investments in, companies that we believe have products or capabilities that are a strategic or commercial fit with our current drug candidates and business or otherwise offer opportunities for our company. In connection with these acquisitions or investments, we may:

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

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

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

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

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may be unable to generate any revenue.***

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the SDA, FDA and comparable regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

***Reimbursement may not be immediately available for our drug candidates in China, the United States or other countries, which could diminish our sales or affect our profitability.***

The regulations that govern pricing and reimbursement for pharmaceuticals vary widely from country to country. In China, the Ministry of Human Resources and Social Security of the PRC or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the PRC's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, or the NRDL, or provincial or local medical insurance catalogues for the National Medical Insurance Program regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy.

In February 2017, the Ministry of Human Resources and Social Security of the PRC released a new edition of the NRDL, or the 2017 NRDL. The 2017 NRDL expands its scope by including an additional 339 drugs. The 2017 NRDL reflects an emphasis on innovative drugs and drugs that treat cancer and other serious diseases. For instance, most of the innovative chemical drugs and biological products approved in China between 2008 and the first half of 2016 have been included in the 2017 NRDL or its candidate list. Most of our drug candidates targeted at treating oncology diseases, including ZL-2306, are unlikely to be included in the NRDL for the National Medical Insurance Program at least in the short-term. Products included in the NRDL are typically generic and essential drugs. Innovative drugs, like ZL-2306, have historically been more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance. More recently, the government has started to include more innovative drugs in the 2017 NRDL. As a result, if we were to successfully launch commercial sales of our oncology-based drug candidates, including ZL-2306, our revenue from such sales is largely expected to be self-paid by patients, which may make our drug candidates less desirable. On the other hand, if the Ministry of Human Resources and Social Security of the PRC or any of its local counterparts accepts our application for the inclusion of our drug candidates in the NRDL or provincial or local medical insurance catalogues, which may increase the demand for our drug candidates, our potential revenue from the sales of our drug candidates may still decrease as a result of lower prices we may be required to charge for our drug candidates that are included in the NRDL or provincial or local medical insurance catalogues.

In the United States, federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Healthcare Reform Act, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. The Trump administration may also take executive action in the absence of legislative action. For example, in October 2017, the President announced that his administration will withhold the cost-sharing subsidies paid to health insurance exchange plans serving low-income enrollees. Actions by the administration are widely expected to lead to fewer Americans having more comprehensive health insurance compliant with the Healthcare Reform Act, even in the absence of a legislative repeal. Tax reform legislation was also enacted at the end of 2017 that includes provisions that

will affect healthcare insurance coverage and payment, such as the elimination of the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). In a November 2017 report, the Congressional Budget Office estimates that the elimination will increase the number of uninsured by 4 million in 2019 and 13 million in 2027.

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

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

Moreover, eligibility for reimbursement in either China or the United States does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution. Interim U.S. reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by U.S. government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

***Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our drug candidates.***

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

- obtain a pharmaceutical manufacturing permit and GMP certificate for each production facility from the SDA and its relevant branches for trading and distribution of drugs not manufactured by the drug registration certificate holder;
- obtain a drug registration certificate, which includes a drug approval number, from the SDA for each drug manufactured by us;
- obtain a pharmaceutical distribution permit and good supply practice, or GSP, certificate from the SDA and its relevant branches; and
- renew the pharmaceutical manufacturing permits, the pharmaceutical distribution permits, drug registration certificates, GMP certificates and GSP certificates every five years, among other requirements.

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

The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The PRC government has introduced various reforms to the Chinese healthcare system in recent

years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the reform still remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the level we expect, if at all. Moreover, the reform could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

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

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

Our business relies, in large part, on our ability to develop and commercialize drug candidates we have licensed and sublicensed from third parties including ZL-2306 from Tesaro, ZL-2301 from Bristol-Myers Squibb, ZL-2401 from Paratek Bermuda, Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., or Paratek, ZL-3101 from GlaxoSmithKline (China) R&D Co., Ltd., an affiliate of GlaxoSmithKline plc, or GSK, ZL-2302 from Sanofi, ZL-1101 from UCB Biopharma Sprl, an affiliate of Union Chimique Belge, or UCB, FPA144 from Five Prime Therapeutics, Inc., or Five Prime, and ETX2514 from Entasis Therapeutics Holdings, Inc., or Entasis. Because our licenses from Paratek, GSK and UCB are granted to us by a subsidiary or an affiliate of Paratek, GSK or UCB, as applicable, our licenses may not encumber all intellectual property rights owned or controlled by the affiliates of our licensors and relevant to our drug candidates. If we have not obtained a license to all intellectual property rights owned or controlled by such affiliates of our licensors that are relevant to our drug candidates, we may need to obtain additional licenses to such intellectual property rights which may not be available on an exclusive basis, on commercially reasonable terms or at all. In addition, if our licensors breach such agreements, we may not be able to enforce such agreements against our licensors’ parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable drug candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such drug candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such drug candidates and/or maintaining the confidentiality of information we receive from our licensors. For example, under our agreements relating to ZL-2306 and ZL-2301, we are required to use commercially reasonable efforts to conduct the necessary pre-clinical, clinical, regulatory and other activities necessary to develop and commercialize such drug candidates in the licensed territories. We are also obligated to use commercially reasonable efforts to develop and commercialize ZL-2401, ZL-3101, ZL-2302, ZL-1101, FPA144 and ETX2514 in certain of their respective licensed territories, in each case, under their respective license agreements.

If we fail to meet any of our obligations under our license and intellectual property-related agreements, our licensors have the right to terminate our licenses and sublicenses and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses or sublicenses, we will lose the right to develop and commercialize our applicable drug candidates and other third parties may be able to market drug candidates similar or identical to ours. In such case, we may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. For example, if our agreement with Sanofi for ZL-2302 terminates for any reason, we are required to grant Sanofi an exclusive license with respect to certain of our owned patents and know-how that are necessary to exploit ZL-2302 in the field of oncology in the regions where the license is terminated. In addition, if our agreements with UCB for ZL-1101 and Tesaro for ZL-2306 terminate for any reason, we are required to grant UCB or Tesaro, as applicable, an exclusive license to certain of our intellectual property rights that relate to ZL-1101 or ZL-2306, as applicable. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our drug candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such drug candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable drug candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

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

Moreover, certain of our licensors do not own some or all of the intellectual property included in the license, but instead have licensed such intellectual property from a third party, and have granted us a sub-license. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. For example, our licenses from Tesaro and Paratek comprise sublicenses to us of certain intellectual property rights owned by third parties that are not our direct licensors. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our rights to the applicable licensed intellectual property may be terminated or narrowed, our exclusive licenses may be converted to non-exclusive licenses, and our ability to produce and sell our products and drug candidates may be materially harmed. In addition, our license from Paratek is limited to intellectual property rights under the control of Paratek Bermuda, Ltd. To the extent Paratek Bermuda, Ltd. loses control over any of the licensed intellectual property rights for any reason, we will no longer be licensed to such intellectual property rights to use, develop and otherwise commercialize ZL-2401. Also, our license from GSK for ZL-3101 includes license agreements between GSK and third parties, which were assigned to us. If we do not comply with our license agreement with GSK or with such other third parties, any such agreements may be terminated or narrowed and we may lose our rights to the licensed intellectual property rights and be required to cease development and commercialization of ZL-3101. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

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

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

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

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

Existing PRC laws and regulations do not require us to have, nor do we currently, maintain liability insurance to cover product liability claims. We do not have business liability, or in particular, product liability insurance for each of our drug candidates. Any litigation might result in substantial costs and diversion of resources. While we maintain liability insurance for certain clinical trials (which covers the patient human clinical trial liabilities including, among others, bodily injury), this insurance may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with our collaborators.

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

Our internal discovery programs are at an early stage of development and will require significant investment and regulatory approvals prior to commercialization. We currently have no drug candidates beyond pre-clinical trials under our internal discovery programs. Each of our drug candidates will require additional clinical and preclinical development, management of clinical, preclinical and manufacturing activities, obtaining regulatory approval, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before they generate any revenue from product sales. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the SDA, the FDA or comparable regulatory authorities, and we may never receive such regulatory approval for any such drug candidates.

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

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

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



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

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

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

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

#### **Risks Related to Our Dependence on Third Parties**

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for some of our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Administrative Regulations on Experimental Animals or the Animal Welfare Act requirements. We and our CROs are required to

comply with GCP regulations and guidelines enforced by the SDA, and comparable foreign regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the SDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with ICH-GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

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

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

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

We rely on third-party vendors and CROs for some of our preclinical studies and clinical trials related to our drug development efforts. Switching or adding additional CROs involves additional cost and requires management time and focus. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs are terminated, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms, and we may not be able to meet our desired clinical development timelines.

***We have no experience manufacturing our drug candidates on a large clinical or commercial scale and have built or just started building our manufacturing facilities. We may be dependent on third party manufacturers for the manufacture of our drug candidates as well as on third parties for our supply chain, and if we experience problems with any of these third parties, the manufacture of our drug candidates or products could be delayed, which could harm our results of operations.***

In early 2017 we built a small molecule facility capable of supporting clinical and commercial production and expect to complete construction of a large molecule facility capable of supporting clinical production of our drug candidates in the first half of 2018. If either of these two facilities is unable to meet our intended production capacity in a timely fashion, we may have to engage a CMO for the production of clinical supplies of our drug candidates.

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

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

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

Furthermore, because of the complex nature of our compounds, we or our manufacturers may not be able to manufacture our compounds at a cost or in quantities or in a timely manner necessary to make commercially successful products. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical study and commercial manufacturing capacity. We have no experience manufacturing pharmaceutical products on a commercial scale and some of our current suppliers will need to increase their scale of production to meet our projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met.

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

We have licensed and sublicensed patent rights from third parties for some of our development programs, including ZL-2306 from Tesaro, ZL-2401 from Paratek, ZL-2301 from Bristol-Myers Squibb, ZL-2302 from Sanofi, FPA144 from Five Prime and ETX2514 from Entasis. As a licensee and sublicensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under certain of our license agreements. In addition, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. We cannot be certain that these patents and patent applications have been or will be prepared, filed, prosecuted or maintained by such third parties in compliance with applicable laws and regulations, in a manner consistent with the best interests of our business, or in a manner that will result in valid and enforceable patents or other intellectual property rights that cover our drug candidates. If our licensors or such third parties fail to prepare, prosecute, or maintain such patent applications and patents, or lose rights to those patent applications or patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drug candidates that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. For example, under our agreement with Bristol-Myers Squibb for ZL-2301, Bristol-Myers Squibb has the first right to enforce the licensed patents in China, Hong Kong and Macau, subject to certain exceptions. Similarly, under our agreement with Five Prime for FPA144, Five Prime has the first right to enforce the licensed patents in China, Hong Kong, Macau and Taiwan, subject to certain exceptions. In addition, with respect to the patent portfolio for ZL-2401, which we sub-license from Paratek, Paratek has the first right to enforce such patent portfolio in territories outside of China, Hong Kong, Macau and Taiwan. Similarly, with respect to the patent portfolio for ZL-2306, which we sub-license from Tesaro, we have the first right to enforce such patent portfolio within China, Hong Kong and Macau. However, Tesaro maintains the right to enforce such patent portfolio in all other territories or, if we fail to bring an action within 90 days within China, Hong Kong or Macau, Tesaro can control such enforcement actions in those areas as well. In the case where Tesaro controls such enforcement actions, although we have rights to consult with Tesaro on such actions within China, Hong Kong and Macau, rights granted by Tesaro under ZL-2306 to another licensee, such as Janssen Biotech, Inc. to whom Tesaro has granted an exclusive right to develop ZL-2306 for the treatment of prostate cancer, could potentially influence Tesaro's interests in the exercise of its prosecution, maintenance and enforcement rights in a manner that may favor the interests of such other licensee as compared with us, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

#### **Other Risks and Risks Related to Doing Business in China**

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

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

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

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

Substantially all of our operations are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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

We conduct our business primarily through our subsidiaries in China. PRC laws and regulations govern our operations in China. Our subsidiaries are generally subject to laws and regulations applicable to foreign investments in China, which may not sufficiently cover all of the aspects of our economic activities in China. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not always be aware of any potential violation of these policies and rules. Such unpredictability regarding our contractual, property and procedural rights could adversely affect our business and impede our ability to continue our operations. Furthermore, since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties could materially and adversely affect our business and results of operations.

In January 2015, the Ministry of Commerce of the PRC, or the MOFCOM, published a discussion draft of the proposed Foreign Investment Law. The MOFCOM has solicited comments on this draft and substantial uncertainties exist with respect to its enactment timetable, interpretation and implementation. If enacted as proposed, the Foreign Investment Law may materially impact our current corporate governance practice and business operations in many aspects and may increase our compliance costs. For instance, the proposed Foreign Investment Law would impose stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable foreign invested entities. Depending on the seriousness of the circumstances, non-compliance with the information reporting obligations, concealment of information or providing misleading or false information could result in monetary fines or criminal charges. In addition, the draft Foreign Investment Law embodies an expected PRC regulation trend of rationalizing the foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments.

Additionally, the SDA's recent reform of the drug and approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner.

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

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

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

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

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

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

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

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

We will request PRC residents who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not be informed of the identities of all the PRC residents holding direct or indirect interest in our company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our PRC resident shareholders to comply with the registration procedures set forth in these regulations may subject us to

finances and legal sanctions, restrict our cross-border investment activities, limit the ability of our wholly foreign-owned subsidiaries in China to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

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

PRC regulations and rules concerning mergers and acquisitions including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of PRC promulgated on August 30, 2007 and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the Prior Notification Rules issued by the State Council in August 2008, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors, or the Security Review Rules issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to the security review, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

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

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We received approximately \$0.19 million and \$2.41 million in financial incentives from local governments in China relating to our business operations in 2017 and 2016, respectively. We also received approximately \$0.75 million and \$0.37 million in financial incentives from local governments in Australia as part of its tax incentive program in 2017 and 2016. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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

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

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

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

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

We are a holding company, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries, each of which is a wholly foreign-owned enterprise may pay dividends only out of its respective accumulated profits as determined in accordance with PRC



accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund.

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

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

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

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

The indirect transfer of equity interest in PRC resident enterprises by a non-PRC resident enterprise, or Indirect Transfer, is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. SAT Circular 7 sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding PRC assets directly or indirectly in the course of a group's overseas restructuring, and the factors to consider in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under PRC laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the PRC taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in China, or 90% or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the PRC taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-PRC tax payable on the gain derived from the indirect transfer of the PRC taxable assets is lower than the potential PRC income tax on the direct transfer of such assets. Nevertheless, a non-resident enterprise's buying and selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 and will not be subject to PRC tax pursuant to SAT Circular 7.

However, as these rules and notices are relatively new and there is a lack of clear statutory interpretation, we face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchange or other transactions involving the transfer of shares in our company by investors that are non-PRC resident enterprises, or the sale or purchase of shares in other non-PRC resident companies or other taxable assets by us. For example, the PRC tax authorities may consider that our current offering involves an indirect change of shareholding in our PRC subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Although we believe no SAT Circular 7 reporting is required on the basis that the current offering has commercial purposes and is not conducted for tax avoidance, the PRC tax authorities may pursue us to report under SAT Circular 7 and request that we and our PRC subsidiaries assist in the filing. As a result, we and our subsidiaries may be required to expend significant resources to provide assistance and comply with SAT Circular 7, or establish that we or our non-resident enterprises should not be subject to tax under SAT Circular 7, for the current offering or other transactions, which may have an adverse effect on our and their financial condition and day-to-day operations.

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

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

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

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

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

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

## Risks Related to Intellectual Property

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

Our success depends, in part, on our ability to protect our drug candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing PRC and international patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. We also seek to protect our proprietary position by in-licensing intellectual property relating to our technology and drug candidates. We do not own or exclusively license any issued patents with respect to certain of our drug candidates in all territories in which we plan to commercialize our drug candidates. For example, we do not own or exclusively license any issued patents covering ZL-2306 in Hong Kong and Macau. Additionally, we do not own or exclusively license any issued patents covering ZL-2302 in the PRC, but we do in-license a pending patent application relating to ZL-2302 in the PRC. However, we cannot predict whether such patent application or any of our other owned or in-licensed pending patent applications will result in the issuance of any patents that effectively protect our drug candidates. If we or our licensors are unable to obtain or maintain patent protection with respect to our drug candidates and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, our license and intellectual property-related agreements may not provide us with exclusive rights to use our in-licensed intellectual property rights relating to the applicable drug candidates in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. For example, under our agreements with Tesaro for ZL-2306, Paratek for ZL-2401, Bristol-Myers Squibb for ZL-2301 and with Entasis for ETX2514, our exclusive licenses are limited to China, Hong Kong, Macau, in the case of our agreement for ZL-2401, FPA144 and ETX2514, Taiwan, and in the case of ETX2514, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Patents may be invalidated and patent applications, including our in-licensed patent application relating to ZL-2302, may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or in-licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, the PRC and, recently, the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology, which we invented.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we are found to infringe a third party's patent rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to:

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

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

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

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

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

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

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

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

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

Although we also intend to develop drug candidates through our own internal research, our near-term business model is predicated, in large part, on our ability to successfully identify and acquire or in-license drug candidates to grow our drug candidate pipeline. However, we may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such drug candidates from third parties on commercially reasonable terms or at all, including because we are focusing on specific areas of care such as oncology and inflammatory and infectious diseases. In that event, we may be unable to develop or commercialize such drug candidates. We may also be unable to identify



drug candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such drug candidates. Any of the foregoing could have a materially adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, no patent term extension system has been established in the PRC. As a result, the patents we have in-licensed or own in the PRC are not eligible to be extended for patent term lost during the regulatory review process. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

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

***Intellectual property rights do not necessarily address all potential threats.***

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

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

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

**Risks Related to Our ADSs**

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

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

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

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

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

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

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

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

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

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

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq Stock Market listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for

general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. We follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following: (i) the majority independent director requirement under Section 5605(b)(1) of the Nasdaq Stock Market listing rules, (ii) the requirement under Section 5605(d) of the Nasdaq Stock Market listing rules that a compensation committee comprised solely of independent directors governed by a compensation committee charter oversee executive compensation, (iii) the requirement under Section 5605(e) of the Nasdaq Stock Market listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors and (iv) the requirement under Section 5605(b)(2) of the Nasdaq Stock Market listing rules that our independent directors hold regularly scheduled executive sessions. Cayman Islands law does not impose a requirement that our board of directors consist of a majority of independent directors. Nor does Cayman Islands law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

***We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.***

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2018. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the U.S. and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on January 1, 2019, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq Stock Market listing rules. As a U.S. listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer, and accounting, reporting and other expenses in order to maintain a listing on a U.S. securities exchange.

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

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

In May 2013, the PCAOB announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or CSRC, and the Ministry of Finance, which establishes a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by the PCAOB in the United States or the CSRC or the Ministry of Finance in the PRC. The PCAOB continues to be in discussions with the CSRC and the Ministry of Finance to permit joint inspections in the PRC of audit firms that are registered with PCAOB and audit Chinese companies that trade on U.S. exchanges.

This lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating audits and quality control procedures of any auditors operating in China, including our auditor. As a result, investors may be deprived of the benefits of PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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

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

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

The market price for our ADSs has been volatile. From September 20, 2017 to April 27, 2018, the closing price of our ADSs ranged from a high of \$35.74 to a low of \$17.86 per ADS.

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

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

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. For example, since August 2008, multiple exchanges in the United States and other countries and regions, including China, experienced sharp declines in response to the growing credit market crisis and the recession in the United States. As recently as February 2018, the exchanges in China experienced a sharp decline. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs, which would also negatively affect the trading prices for our ADSs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As discussed in "Material United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations," we believe that our Hong Kong subsidiary, Zai Lab (Hong Kong) Limited, was a PFIC for its taxable year ended July 12, 2017 and that the Company and its other subsidiaries were not PFICs for the taxable year ended December 31, 2017 and we do not expect that the Company and its subsidiaries will be treated as PFICs for the current taxable year, although no assurance can be provided in that regard. Notwithstanding the foregoing, the determination of whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year and which depends on the composition of our income and the composition and value of our

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

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

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

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

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

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

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



***You may have difficulty enforcing judgments obtained against us.***

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

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

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

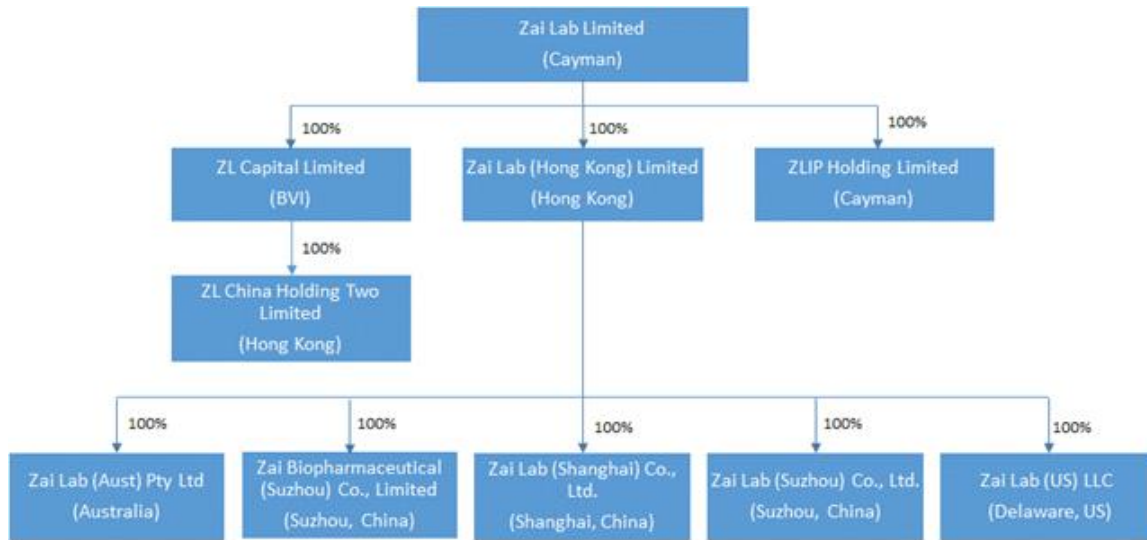
ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depository may refuse to deliver, transfer or register transfers of ADSs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

**ITEM 4. INFORMATION ON THE COMPANY**

**A. History and Development of the Company**

Our company was founded in the Cayman Islands on March 28, 2013 as an exempted company with limited liability under the Companies Law, Cap 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands. Our principal executive offices are located at 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210. Our telephone number at that address is +86 21 6163 2588. The address of our registered office in the Cayman Islands is Harbour Place 2nd Floor, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands. Our agent for service of process in the United States is Law Debenture Corporate Services Inc., located at 400 Madison Avenue 4th Floor, New York, New York 10017.

The chart below shows our principal subsidiaries as of March 31, 2018.



Since our founding, we have raised approximately \$164.6 million in private equity financing. In September 2017, we completed our initial public offering in the United States, listing on the Nasdaq Global Market. We raised approximately \$157.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering. In addition, we have received government grants totaling approximately \$4.1 million since our inception.

To date, we have in-licensed five late-stage clinical drug candidates for development in China, Hong Kong, Macau and, in certain instances, Taiwan, Australia, New Zealand and other countries throughout Asia, through partnerships with Tesaro, Bristol-Myers Squibb, Paratek, Five Prime and Entasis. We have also obtained global development and commercialization rights to two drug candidates, including one late-stage clinical and one preclinical drug candidates, through partnerships with GSK and Sanofi. To date, we have made upfront, milestone and clinical cost reimbursement payments totaling approximately \$37.1 million since our inception in connection with these licensing arrangements. In early 2017, we built a small molecule drug product facility in Suzhou, China capable of supporting clinical and commercial production and have begun construction of a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. The cost to complete the small molecule facility was approximately \$6.7 million and was paid with cash on hand. The construction of the large molecule facility is expected to be completed in the first half of 2018, which we expect will cost approximately \$13.0 million to complete and has been, and we expect will continue to be, financed with cash.

## Business

### Overview of Our Business

We are an innovative biopharmaceutical company based in Shanghai focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China market, including in the fields of oncology, autoimmune and infectious diseases. We believe there exists a significant opportunity to build an organization that not only addresses such unmet needs but leverages underutilized resources in China to foster innovation. As part of that effort, we have assembled a management team with global experience and an extensive track record in navigating the regulatory process to develop and commercialize innovative drugs in China. Our mission is to leverage our expertise and insight to address the expanding needs of Chinese patients in order to transform their lives and eventually utilize our China-based competencies to impact human health worldwide.

Furthermore, Zai Lab was built on the vision that, despite having a significant addressable market and sizable growth potential, China has historically lacked access to many innovative therapies available in other parts of the world and its drug development infrastructure has been underutilized. There remains the need to bring new and transformative therapies to China. In recent years, the Chinese government has focused on promoting local innovation through streamlining regulatory processes, improving drug quality standards and fostering a favorable environment, which we believe creates an attractive opportunity for the growth of China-based, innovation-focused companies.

We have assembled an innovative pipeline consisting of seven drug candidates through partnerships with global biopharmaceutical companies. These include five late-stage assets targeting fast growing segments of China's pharmaceutical market and two assets addressing global unmet medical needs. We believe that our management's extensive global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, opportunities to partner with global companies aiming to bring innovative products to market in China efficiently.

To date, we have in-licensed six clinical stage drug candidates for development in China, Hong Kong, Macau and, in certain instances, Taiwan, Australia, New Zealand, and other countries throughout Asia. Our CTAs for three of these drug candidates have been accepted as Category 1 drugs by the SDA. Our CTA for ZL-2301 also has been accepted as a Category 1 drug by the SDA. This classification provides us with a competitive advantage as Category 1 drugs benefit from an expedited review of CTAs and NDAs as well as commercial benefits.

Our lead drug candidate is ZL-2306, an oral, once-daily small molecule PARP 1/2 inhibitor being developed and commercialized by our partner Tesaro. In March 2017, ZL-2306 received FDA marketing approval and in November 2017 received European Union marketing approval as a maintenance treatment for recurrent platinum-sensitive epithelial ovarian cancer and, in April 2017, commercially launched the product in the United States under the commercial name Zejula. ZL-2306 is the first PARP inhibitor approved by the FDA for ovarian cancer that does not require BRCA mutation or other biomarker testing. We believe ZL-2306 is uniquely suited for the China marketplace where BRCA biomarker diagnostic tests are not widely available. We intend to develop ZL-2306 for Chinese patients across multiple tumor types. We initiated the first of two Phase III studies of ZL-2306 in patients with ovarian cancer in September 2017 and anticipate initiating the second study in the first half of 2018. In addition, we intend to pursue ZL-2306 in other indications.

As part of our licensing strategy, we have also obtained global development and commercialization rights to two drug candidates, including one late-stage clinical and two preclinical drug candidates, through partnerships with GSK and Sanofi. We intend to leverage our resources and competitive advantages in China, including our ability to access China's large patient population and conduct efficient clinical trials, to rapidly and cost-effectively establish proof of concept for such candidates prior to pursuing further late-stage development for the global market.

In the longer term, we plan to build a premier, fully integrated drug discovery and development platform that brings both in-licensed and internally-discovered medicines to patients in China and globally. Our in-house research and development team had previously been directly involved in the discovery and development of several innovative drug candidates at Hutchison Medi-Pharma, including fruquintinib and savolitinib. These assets were out-licensed to Eli Lilly and AstraZeneca, respectively. Our in-house discovery team is currently focused on exploring immuno-oncology and targeted therapy approaches to treating cancer, and we have identified one immune-oncology candidate that is currently under preclinical development. We have collaborations with academic institutions in China, including Tsinghua University and Shanghai Institute of Materia Medica, to expand our in-house research projects. We believe this team and our discovery strategy will enable us to achieve our long-term goal of commercializing our internally discovered innovative medicine for patients worldwide.

As our business grows, we plan to build our own commercial team to launch our portfolio of drug products. Part of our strategy to become a fully integrated biopharmaceutical company is the ability to produce both large and small molecule therapeutics under global standard cGMP. To this end, in the first half of 2017 we built a small molecule drug product facility capable of supporting clinical and commercial production and have also begun construction of a large molecule facility. Construction of the large molecule facility is expected to be completed in the first half of 2018.

## Our Innovative Pipeline

We have a broad pipeline of proprietary drug candidates that range from discovery stage to late-stage clinical programs. These include five drug candidates with greater China rights and two primary drug candidates with global rights. The following table summarizes our drug candidates and programs:

Program	Commercial rights	Indication	Zai Lab clinical stage
ZL-2306	 China, HK, Macau	Ovarian cancer	Phase III
		Lung cancer	Phase III
		Breast cancer	CTA approved for Phase III (Protocol currently under discussion with CFDA)
ZL-2401	 China, HK, Macau, Taiwan	ABSSSI	Phase III
		CABP	Phase III
FPA144	 China, HK, Macau, Taiwan	Gastric Cancer / GEJ	Phase III
ETX2514	 Asia Pacific	A. Baumannii	Preparing for CTA Submission for Phase III
ZL-2301	 China, HK, Macau	HCC	Phase II
ZL-3101	 Global	Eczema, Psoriasis	Phase II
ZL-2302	 Global	NSCLC	CTA Approved for Phase I

## Our Greater China Rights Drug Candidates

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

- ZL-2306**, a highly potent and selective oral, small molecule PARP 1/2 inhibitor with the potential to be a first-in-class drug for treatment across multiple solid tumor types in China including ovarian and certain types of lung and breast cancers. We have licensed ZL-2306 from Tesaro, which in March 2017 received FDA marketing approval and in November 2017 received European Union marketing approval for ZL-2306 (Zejula®) as maintenance treatment for women with recurrent platinum-sensitive epithelial ovarian cancer. ZL-2306 was commercially launched in the United States in April 2017. ZL-2306 does not require BRCA mutation or other biomarker testing as is necessary for other approved PARP inhibitors which, we believe, significantly expands its availability to ovarian cancer patients in China. As ZL-2306 has been approved both in the United States and EU, we plan to commercialize ZL-2306 in Hong Kong in the second half of 2018, and in Macau thereafter. In China, our CTA for ZL-2306 has been approved as a Category 1 drug by the SDA. We initiated the Phase III study of ZL-2306 in patients with recurrent platinum-sensitive ovarian cancer as a second-line maintenance therapy in September 2017, and intend to initiate the second Phase III study as a first-line maintenance therapy in patients with platinum-responsive ovarian cancer in the first half of 2018. These studies are similar in design to Tesaro's clinical studies of ZL-2306 in ovarian cancer. We also anticipate beginning a Phase III study in patients with platinum responsive small cell lung cancer as maintenance therapy in the first half of 2018. We continue to explore ZL-2306 in patients with gBRCA+ breast cancer, triple negative breast cancer, and squamous-type non-small cell lung cancer in China. In addition to ZL-2306 monotherapy in the potential indications stated, we also intend to explore the combination of ZL-2306 with other potential therapies such as immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

- **ZL-2401** is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. We have licensed ZL-2401 from Paratek where it is primarily being developed for ABSSSI, CABP and UTI. ZL-2401 is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. If approved, ZL-2401 is expected to be available in IV and PO once-daily formulations. The competitive drugs have only IV formulation but ZL-2401 has both IV and PO formulations that makes the treatment convenient for patients. Paratek has reported the results of three pivotal Phase III studies of ZL-2401 in ABSSSI and CABP. All these studies achieved their primary endpoints. In February 2018, Paratek submitted an NDA, and in April 2018, the FDA granted priority review for ZL-2401. Zai has completed the technology transfer and engaged in discussions with the SDA and key opinion leaders on our planned China development strategy in preparation for our NDA filing.
- **FPA144** is a humanized monoclonal antibody (IgG1 isotype) specific to the human fibroblast growth factor receptor 2, or FGFR2b, in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastroesophageal cancer. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually. Zai Lab has licensed FPA144 from Five Prime. In December 2017, Five Prime initiated dosing in the Phase I safety lead-in portion of its Phase I/III clinical trial of FPA144 in combination with the mFOLFOX6 chemotherapy regimen in patients with previously untreated, advanced gastric or gastroesophageal cancer. The randomized, controlled Phase III portion of the trial evaluating FPA144 plus chemotherapy is expected to start in the second half of 2018 and would serve as a global registrational study for the treatment of front-line gastric and gastroesophageal cancers.
- **ETX2514** is a novel  $\beta$ -lactamase inhibitor of class A, C, and D beta-lactamases. In combination with sulbactam, ETX2514 reduces the minimum inhibitory concentration, or MIC, against this organism and restores susceptibility to sulbactam. It is being developed by Entasis as ETX2514SUL, a combination of ETX2514 and sulbactam. The microbiologic efficacy of this combination was demonstrated in large studies of well-characterized MDR Acinetobacter isolates from diverse regions, including Asia. The FDA has granted ETX2514SUL QIDP, Fast Track and Priority Review status. Entasis plans to develop ETX2514SUL for the treatment of severe A. baumannii infections. Entasis anticipates initiating a Phase II cUTI trial starting in 2018 and a pivotal Phase III trial in MDR Acinetobacter infections in 2019.
- **ZL-2301** is an oral, small molecule dual target TKI which blocks both vascular endothelial growth factor, or VEGFR, and fibroblast growth factor receptor, or FGFR. ZL-2301 was studied by our partner Bristol-Myers Squibb mainly for the treatment of HCC, the most common type of liver cancer. In these trials, ZL-2301 demonstrated anti-tumor activity and a generally well-established safety profile in HCC patients. In 2012, Bristol-Myers Squibb terminated its development program of ZL-2301 after it missed the primary endpoints in two Phase III trials with advanced HCC patients. Based on our review of the results from Bristol-Myers Squibb's development program for ZL-2301, our understanding of the etiology and current standard of care of HCC in Chinese patients and our ongoing research, we believe that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical trials. The SDA has approved our CTA for ZL-2301 as a Category 1 drug, and in the second quarter of 2017 we initiated a Phase II trial of ZL-2301 as a second-line treatment for advanced HCC patients in China. The recruitment for the Phase II study is ongoing. Preliminary anti-tumor activity has been observed with second line HCC patients treated with ZL-2301. Safety profile to date appears to be tolerable and manageable in general. Pending results of this Phase II study, a Phase III clinical trial in second line HCC patients is anticipated to start in the second half of 2018.

For our late-stage oncology drug candidates with greater China rights, our near-term development plan focuses on specific patient segments. These patient segments have an estimated annual incidence of nearly 900,000 patients in China. We expect that the commercial success of our products will be driven by their differentiated clinical profiles, efficacy in Chinese patients and ability to provide clinical benefit over existing standards of care in a market where targeted therapies are either unavailable or less utilized relative to more developed markets.

In addition to the opportunities available for our oncology products, we believe that, through our development of ZL-2401, we have the chance to introduce into China a new broad-spectrum antibiotic with excellent activity not only against common Gram-positive and Gram-negative bacteria, but also against several MDR pathogens. The profile of ZL-2401 includes MRSA, enterococci, ESBL-E. coli and many Acinetobacter isolates. In addition, availability of an IV and oral formulation allows treatment of hospital- and community-acquired infections. The prevalent overuse of antibiotics, evolution of resistant bacteria and state of current treatment practices are expected to lead to an increase in drug-resistant infection rates. A 2015 study indicated that the total antibiotic usage in China in 2013 accounted for about half of the global antibiotic usage, with a per-capita use of antibiotics in China being more than five times that in Europe and the United States. Based on our estimates, in 2015 there was an incidence of approximately 2.8 million ABSSSI patients and 16.5 million CABP patients in China.

In addition to mainland China, we intend to seek registration and commercialization of the above drug candidates, where we have applicable rights, in Hong Kong, Macau and Taiwan. For Hong Kong and Macau, products with existing approvals by the FDA, EMA or a comparable regulatory agency are eligible for an expedited registration process that does not require conducting local clinical trials. In the case of ZL-2306, we intend to pursue expedited registration, expect to launch and commercialize ZL-2306 in Hong Kong in the second half of 2018, and in Macau thereafter.

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

### ***Our Global Rights Drug Candidates***

Our primary drug candidates for which we retain global rights include:

- **ZL-3101** is a novel steroid-sparing topical product for the treatment of eczema and psoriasis. We are developing ZL-3101 as a botanical formulation to offer patients with eczema and psoriasis a natural alternative to topical steroid treatments, which are currently the main forms of treatment and are known to have many side effects associated with long-term use. We licensed the exclusive worldwide rights to ZL-3101 from GSK in 2016. We initiated a Phase II study of ZL-3101 in patients with eczema in China in the second quarter of 2017. Pending results of this Phase II study, we plan to initiate a Phase III global, multi-center clinical trial.
- **ZL-2302** is a multi-targeted TKI with activity against both ALK mutation and crizotinib-resistant ALK mutations being developed for the treatment of patients with non-small cell lung cancer who have ALK mutations and who have developed crizotinib resistance and/or brain metastasis. We licensed the exclusive worldwide rights to ZL-2302 from Sanofi in 2015. Our preclinical studies demonstrated that ZL-2302 has ability to penetrate the blood-brain barrier, which could make ZL-2302 an effective therapy for a subset of patients who have non-small cell lung cancer with ALK mutations and brain metastasis. Such patients typically have limited treatment options, poor prognosis and low quality of life. Our CTA for ZL-2302 has been accepted as a Category 1 drug and has been approved for clinical study by the SDA, and we are currently in the process of preparing for Phase I clinical trials in China.

### ***Our Clinical Pipeline***

#### ***ZL-2306***

ZL-2306 is a highly potent and selective oral, once-daily small molecule poly (ADP-ribose) polymerase 1/2, or PARP 1/2, inhibitor with the potential to be a first-in-class category 1 drug for treatment across multiple solid tumor types in China. ZL-2306 was approved in March 2017 by the FDA, and in November 2017 by EMA, as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer. Maintenance therapy is for those women who have had prior treatment but are expected to see their cancer return, with the purpose of avoiding or slowing a recurrence if the cancer is in remission after the prior treatment. A platinum-sensitive cancer is one that responded to initial platinum-based chemotherapy and remained in remission post-chemo therapy for more than six months.

ZL-2306 is the first PARP inhibitor to be approved by the FDA for ovarian cancer that does not require BRCA mutation or other biomarker testing. This makes ZL-2306 suitable for a wide patient population and significantly more accessible to patients in China where BRCA biomarker diagnostic tests are not widely available. If approved by the SDA, ZL-2306 may potentially be the first category 1 PARP inhibitor on the China market approved for second-line maintenance treatment in all recurrent platinum-sensitive ovarian cancer patients.

We obtained an exclusive license for the development and commercialization of ZL-2306 in China, Hong Kong and Macau in 2016. As ZL-2306 has been approved in both the United States and the EMA, we anticipate commercializing ZL-2306 in Hong Kong in the second half of 2018, and in Macau thereafter. In addition, our CTA for ZL-2306 has been approved as a Category 1 drug. To date, we have completed the enrollment of the pharmacokinetics, or PK study, with data anticipated in mid-2018. The Phase III trial for ZL-2306 as a second-line maintenance treatment in patients with recurrent platinum-sensitive ovarian cancer in China had been initiated in September 2017. The second Phase III trial for ZL-2306 as a first-line maintenance treatment in patients with platinum-responsive ovarian cancer in China is anticipated to initiate in the first half of 2018. In addition, we anticipate beginning a Phase III study in patients with platinum responsive small cell lung cancer as maintenance therapy in mid-2018. We also intend to study ZL-2306 in patients with other lung cancer and breast cancer in China, either as a monotherapy or in combination.

Our currently targeted indications for ZL-2306 include the following:

### ***Ovarian Cancer***

Ovarian cancer had an estimated annual incidence of 52,000 patients in China in 2015, which is more than double that of the 21,300 patients in the United States and has seen increasing mortality rates. Since early symptoms of ovarian cancer are non-specific and difficult to detect, a majority of women with ovarian cancer are diagnosed when the disease is at an advanced stage, when prognosis is poor. Finding effective therapeutic approaches for advanced ovarian cancer patients represents a large unmet medical need. Given the broad applicability of ZL-2306 across all patient populations, regardless of gBRCA mutation status, we are currently targeting the entire platinum sensitive ovarian cancer patient population. This represents a significant advantage for patient convenience and access, given that there is no need for patients to utilize diagnostic tests to determine their gBRCA mutation status, particularly in China where such tests are not widely available.

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

### ***Lung Cancer***

Lung cancer has the highest total incidence as well as the highest mortality rate of any cancer in China. Annual incidence was estimated at 733,300 patients in China in 2015, which is more than triple the 221,200 patients in the United States. We intend to explore ZL-2306's efficacy in patients with squamous-type non-small cell lung cancer and small cell lung cancer based on the large unmet need for effective treatment for such patients in China. According to the American Cancer Society, approximately 80% to 85% of lung cancers are non-small cell lung cancer and squamous cell carcinoma is about 25% to 30% of lung cancers. Based on an assumption of 80% share of non-small cell lung cancer and 30% of cancers being squamous, we estimate a potential target patient population of 176,000 patients with squamous-type non-small cell lung cancer and 147,000 in small cell lung cancer in China.

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

We believe ZL-2306 has first-in-class potential in both indications in China, by representing an attractive addition to the current standard of care in small cell lung cancer and squamous type non-small cell lung cancer. While globally monoclonal antibodies, which block the interaction between checkpoint molecules PD-1 on immune cells and PD-L1 on cancer cells, have been used to successfully treat non-small cell lung cancer, these drugs have yet been launched in China and remain in clinical trials. Given the relatively limited therapy options for Chinese physicians and patients we believe that a small molecule PARP inhibitor will offer an attractive addition to the standard of care with an attractive price level relative to large molecule drugs.

In addition to ZL-2306 monotherapy in the potential indications stated above, we also intend to explore the combination of ZL-2306 with other potential therapies such as immuno-oncology therapy, targeted therapy and chemotherapy in the clinically relevant indications.

### ***Breast Cancer***

Breast cancer is one of the leading causes of cancer death among women in China, with a total estimated annual incidence of 268,600 female patients in 2015, which is nearly 16% larger than the incidence of 231,840 female patients in the United States. Breast cancer has also seen an increasing mortality rate. We contemplate seeking indications in patient sub-groups, such as BRCA+ and triple negative breast cancer patients. If approved for usage in BRCA+ and triple negative breast cancer patients, we estimate a target patient pool of approximately 68,000 people, representing about a quarter of total breast cancer incidence in China.

There is no single standard treatment in patients with metastatic breast cancer who have previously failed anthracycline and taxane treatments. Furthermore, there are no approved treatments for patients with BRCA mutations, and patients are only treated according to the status of their hormone receptor and human epidermal growth factor receptor 2, or HER2, status, where Herceptin is the recommended targeted therapy. Therefore, more effective therapies that specifically address the gBRCA+ patient population are needed.

We believe ZL-2306 could bring significant benefits to gBRCA+ metastatic breast cancer patients in China based on available clinical results from ZL-2306 and further clinical validation from other PARP inhibitors. In a Phase I dose-escalation and confirmation study in participants with advanced solid tumors, two of the four breast cancer patients carrying gBRCA mutations had partial response as best response (response rate in patients with gBRCA mutations: 50%; 95% CI: 7%, 93%). The clinical potential of PARP inhibitors in this patient population has also been established by the results of a positive Phase III study of AstraZeneca's olaparib. In February 2017, AstraZeneca announced that olaparib improved progression-free survival versus standard chemotherapy in patients with gBRCA+ metastatic breast cancer, according to findings from its Phase III trial.

Epidemiologic studies of BRCA 1/2 mutations in Chinese breast cancer patients performed in China, Hong Kong, Taiwan, and Singapore have shown a prevalence of BRCA 1/2 gene mutation in familial breast cancer and early-onset breast cancer patients that ranged from 8.0% to 13.5% and from 8.7% to 11.4%, respectively. In addition, triple-negative breast cancer accounts for 10%—20% of all invasive breast cancer subtypes.

In the case of triple negative breast cancer patients, since tumor cells lack the necessary receptors, common treatments like hormone therapy and drugs that target HER-2 are ineffective. While chemotherapy is used as standard treatment, there is unmet need for other treatment options that can improve patient survival and overcome the long-term issue of chemoresistance. Global clinical data has suggested that the combination of a PARP inhibitor and chemotherapy might be more effective than chemotherapy alone, and we intend to explore usage of ZL-2306 in this patient segment.

### ***Our Clinical Trial Designs and Strategy for ZL-2306 in the China Market***

#### ***Ovarian Cancer***

We plan to conduct three clinical studies of ZL-2306 in ovarian cancer patients in China. One is a PK study for ZL-2306 in patients with platinum-sensitive ovarian cancer. The enrollment for the PK study has been completed with data anticipated by mid-2018. The Phase III trial for ZL-2306 as a second-line maintenance treatment in patients with recurrent platinum-sensitive ovarian cancer in China was initiated in September 2017. The second Phase III trial for ZL-2306 as a first-line maintenance treatment in patients with platinum-responsive ovarian cancer in China is anticipated to initiate in the first half of 2018. If approved, ZL-2306 may potentially be the first category 1 PARP inhibitor on the China market approved as a second-line maintenance therapy in all recurrent platinum-sensitive ovarian cancer patients, and we would look to rapidly expand ZL-2306 to be available as a first-line maintenance therapy.

Our Phase I PK study is intended to establish the PK profile of ZL-2306 in Chinese patients. We initiated this study in November 2017. The enrollment for the PK study has been completed with data anticipated by mid-2018.

Our first Phase III study, which was initiated in September 2017, will evaluate ZL-2306 as a second-line maintenance therapy in patients with recurrent platinum-sensitive ovarian cancer. Patients with recurrent platinum sensitive ovarian cancer who have responded to a second line platinum-containing treatment will be enrolled in the study. Patients will be randomly assigned in a 2:1 ratio to receive ZL-2306 or placebo once daily. Patients will be stratified by gBRCA status. The primary endpoint is progression-free survival. The primary analysis will be conducted in the entire study population, regardless of gBRCA mutation status. If the primary analysis meets the statistical significance, the study will be ended. If it does not, the study will continue for gBRCA mutation positive patients with the second-step primary analysis conducted in this population.

Our second Phase III study is expected to evaluate ZL-2306 as a first-line maintenance therapy in patients with platinum-responsive ovarian cancer. The study design of this clinical trial has been discussed and agreed with the SDA. We plan to initiate this trial in the first half of 2018. Tesaro is also evaluating ZL-2306 in the PRIMA trial, a Phase III clinical trial in the first-line maintenance setting in platinum responsive ovarian cancer patients.



## *Lung Cancer*

We anticipate beginning a Phase III study in patients with platinum responsive small cell lung cancer as maintenance therapy in mid-2018. The study design has been discussed and agreed with SDA. We also intend to initiate Phase II clinical trials to evaluate the efficacy of ZL-2306 in squamous-type non-small cell lung cancer patients in China. Details of the clinical trial designs are being discussed with the SDA and key opinion leaders.

## *Breast Cancer*

We continue to explore ZL-2306 in patients with gBRCA+ breast cancer, triple negative breast cancer, and squamous-type non-small cell lung cancer in China.

## **Background on PARP Inhibitors**

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

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

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

## **ZL-2306 Mechanism of Action**

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

ZL-2306 is designed to be a highly potent, selective inhibitor of PARP-1 and PARP-2. In an ovarian cancer patient-derived xenograft model, where tumor models are established from transplantation of a human tumor specimen from a cancer patient directly into a mouse, ZL-2306 has been shown to have greater tumor concentration, allowing it to deliver sustained anti-tumor activity as compared to olaparib, an FDA-approved PARP inhibitor marketed by AstraZeneca for gBRCA+ ovarian cancer patients who have received at least three prior lines of chemotherapy.

## **ZL-2306 Clinical Results**

*NOVA, a Phase III maintenance study of ZL-2306 versus placebo in patients with recurrent platinum-sensitive ovarian cancer.*

In March 2017, the FDA approved ZL-2306 as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer, regardless of BRCA mutation or biomarker status, three months ahead of the FDA's scheduled decision date (PDUFA date). ZL-2306's FDA approval followed the release of successful results from Tesaro's NOVA trial in which ZL-2306 demonstrated a clinically meaningful increase in progression-free survival in women with recurrent ovarian cancer, regardless of gBRCA mutation or biomarker status. Treatment with ZL-2306 reduced the risk of disease progression or death by 73% in gBRCA mutation positive patients (hazard ratio = 0.27) and by 55% in patients without gBRCA mutations (hazard ratio = 0.45). Hazard ratio is the probability of an event (such as disease progression or death) occurring in the treatment arm divided by the probability of the event occurring in the control arm of a study, with a ratio of less than one indicating a lower probability of an event occurring for patients in the treatment arm. P-value is a measure of the probability of obtaining the observed sample results, with a lower value indicating a higher degree of statistical confidence in these studies. The magnitude of benefit was similar for patients entering the trial with a partial response or a complete response to platinum treatment.

The NOVA trial was a phase III randomized double-blind trial that assessed the effectiveness of ZL-2306 compared with placebo to delay tumor progression following a platinum containing chemotherapy regimen. Patients enrolled into one of two independent cohorts based on gBRCA mutation status. A total of 553 patients were enrolled in the NOVA study at 107 centers worldwide. The study population has 203 patients assigned to the gBRCA mutation positive cohort and 350 patients assigned to the gBRCA mutation negative cohort. Among the patients in the gBRCA mutation negative cohort, 162 had tumors that were tumors deficient in homologous recombination, or HRDpos, and 134 had tumors did not have a homologous recombination deficiency, or HRDneg. The homologous recombination deficiency status was not determined for 54 patients. The gBRCA mutation negative cohort analyses included all patients randomized, regardless of homologous recombination deficiency status.

Within each cohort, patients were randomized 2:1 to receive ZL-2306 or placebo, and were continuously treated with placebo or ZL-2306 until progression. The primary endpoint of this study was progression free survival. Secondary endpoints included patient-reported outcomes, chemotherapy free interval length, and OS. This trial successfully achieved its primary endpoint in both cohorts, showing that ZL-2306 treatment significantly prolonged progression free survival, compared to control in patients who were gBRCA mutation positive and in patients who were gBRCA mutation negative. In addition, within the gBRCA mutation negative cohort, ZL-2306 treatment significantly prolonged progression free survival compared to placebo for the prospectively defined patient population with HRDpos tumors. A high proportion of patients in both treatment groups in both cohorts had received three or four prior lines of chemotherapy. The most common treatment-emergent grade 3/4 adverse events in the ZL-2306 arm of the NOVA study, based on the National Cancer Institute's Common Terminology Criteria for Adverse Event, or CTC, which is a set of criteria for the standardized classification of adverse effects of drugs used in cancer therapy (with one and two being relatively mild and higher numbers (up to five) being more severe), were thrombocytopenia, anemia, and neutropenia.

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

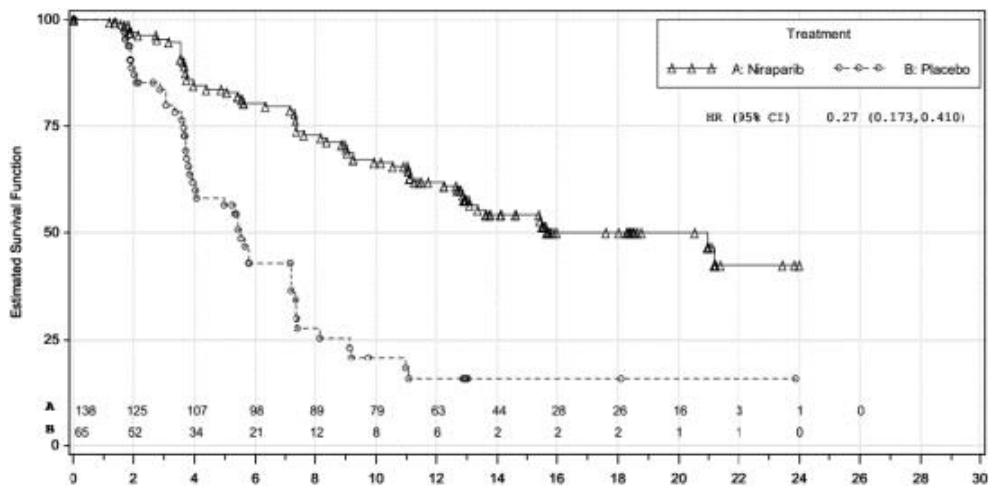
Figure 1: Progression free survival was significantly longer for patients who received ZL-2306 compared to those who received placebo for all primary efficacy populations.

Treatment	Median PFS (95% CI) (Months)	Hazard Ratio (95% CI) p Value	Disease Progression Free (%)		
			6 Months	12 Months	18 Months
<b>gBRCAmut Cohort</b>					
Niraparib (N = 138)	21.0 (12.9, NE)	0.27 (0.173, 0.410) p <0.0001	80%	62%	50%
Placebo (N = 65)	5.5 (3.8, 7.2)		43%	16%	16%
<b>HRDpos Subgroup</b>					
Niraparib (N = 106)	12.9 (8.1, 15.9)	0.38 (0.243, 0.586) p <0.0001	69%	51%	37%
Placebo (N = 56)	3.8 (3.5, 5.7)		35%	13%	9%
<b>Non-gBRCAmut Cohort</b>					
Niraparib (N = 234)	9.3 (7.2, 11.2)	0.45 (0.338, 0.607) p <0.0001	61%	41%	30%
Placebo (N = 116)	3.9 (3.7, 5.5)		36%	14%	12%

Source: Tesaro.

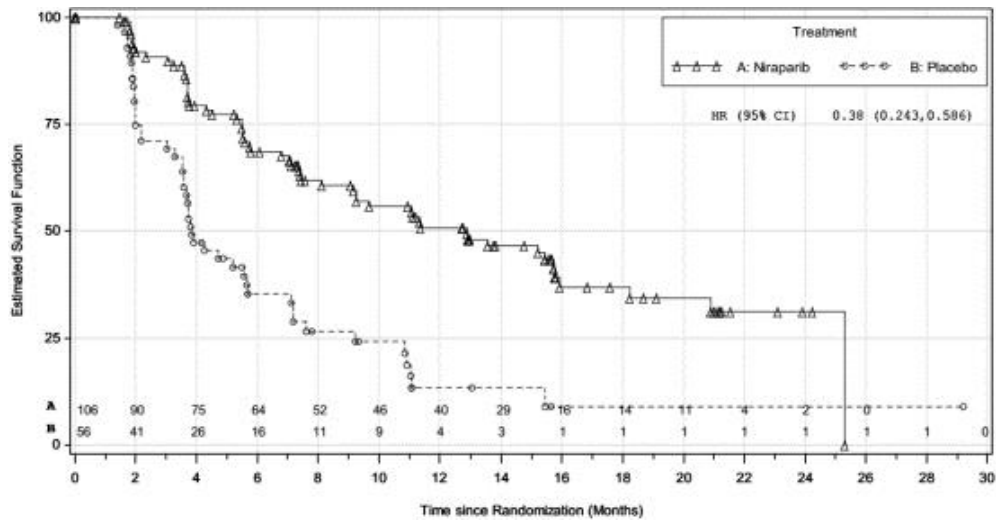
Notes: gBRCAmut = gBRCA mutation positive; non-gBRCA mut = gBRCA mutation negative

Figure 2: Progression free survival in the gBRCA mutation positive cohort of patients treated with ZL-2306 versus placebo



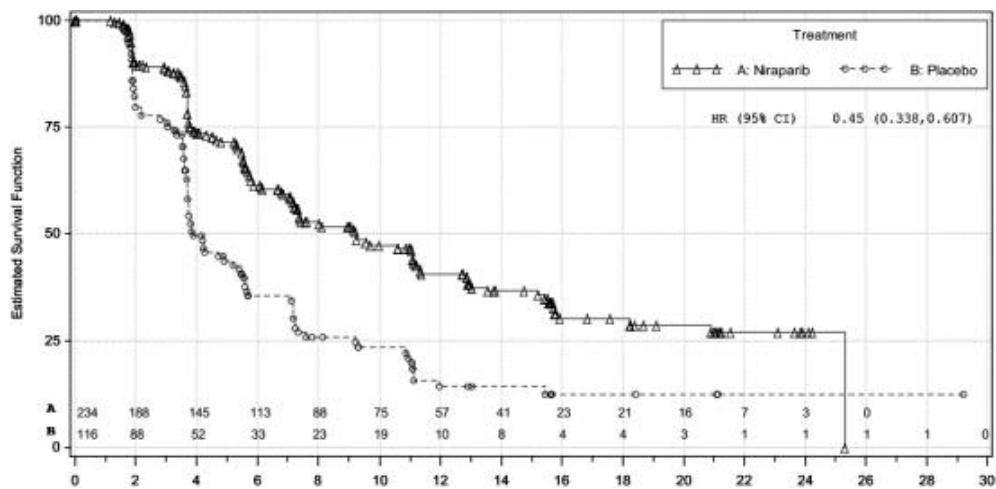
Source: Tesaro.

Figure 3: Progression free survival in the HRDpos group of the gBRCA mutation negative cohort of patients treated with ZL-2306 versus placebo



Source: Tesaro.

Figure 4: Progression free survival in the overall gBRCA mutation negative cohort of patients treated with ZL-2306 versus placebo



Source: Tesaro.

Within the gBRCA mutation positive cohort, the median progression free survival was 21.0 months on ZL-2306 versus 5.5 months on placebo (hazard ratio=0.27;  $p < 0.0001$ ). As shown in the chart above, ZL-2306’s treatment effect started very early during treatment as seen by the two curves being separated at first efficacy assessment. Progression free survival was also significantly longer with ZL-2306 in the HRDpos group of the gBRCA mutation negative cohort (median, 12.9 months versus 3.8 months; hazard ratio=0.38;  $p < 0.0001$ ) and in the overall gBRCA mutation negative cohort (median, 9.3 months versus 3.9 months; hazard ratio = 0.45;  $p < 0.0001$ ). Additionally, in an exploratory pooled analysis that evaluated all patients in both cohorts combined, progression free survival was longer with ZL-2306 (median 11.3 months versus 4.7 months, hazard ratio = 0.38, 95% confidence interval: 0.303, 0.488;  $p < 0.0001$ ).

As it is maintenance therapy, quality of life is important to patients receiving treatment. Patient-reported outcome data from validated survey tools indicated that ZL-2306-treated patients reported no significant difference from placebo in measures associated with symptom specific and general quality of life.

Furthermore, ZL-2306 treatment did not reduce the effectiveness of subsequent therapies, and continued to show carry-over of the beneficial treatment effect in the secondary efficacy measure of second objective disease progression, which is time from randomization to objective tumor progression on next-line treatment or death from any cause. OS data, while immature, showed no negative impact of ZL-2306 treatment.

The incidences of CTC grade 3/4 treatment-emergent adverse events (74% vs 23%), serious adverse events (30% vs 15%), treatment-emergent adverse events leading to treatment interruption (69% vs 5%), treatment-emergent adverse events leading to dose reduction (67% vs 15%), and treatment-emergent adverse events leading to treatment discontinuation (15% vs 2%) were higher for ZL-2306 versus placebo. There were no on-treatment deaths reported.

The most commonly observed hematologic treatment-emergent adverse events (all CTC grades) related to ZL-2306 were thrombocytopenia (61%), anemia (50%) and neutropenia (30%). Although CTC grade 3/4 hematologic laboratory events were common at the initiation of treatment, no severe clinical sequelae were observed and relatively few patients discontinued due to these adverse events. Dose adjustment based on individual tolerability during the first cycles substantially reduced the incidence of these events beyond the third 28-day treatment cycle, indicating the overall effectiveness of the approach to dose modification. Overall the treatment-emergent adverse events were manageable, with no negative impact on quality of life.

### **ZL-2306 Preclinical Development**

As discussed below, Merck and our partner Tesaro have completed various preclinical trials to evaluate the pharmacodynamics, pharmacokinetics and toxicology profile of ZL-2306.

**Pharmacodynamics.** In preclinical trials studying ZL-2306's pharmacodynamics, ZL-2306 was found to be a potent and selective PARP-1 and PARP-2 inhibitor that displayed at least a 100-fold selectivity over other PARP-family members PARP-3, v-PARP, and Tankyrase-1. A commonly used quantitative measure of potency is IC<sub>90</sub>, which represents the concentration of a drug that is required to suppress 90% of the target enzyme. The IC<sub>90</sub> of ZL-2306 for PARylation in BRCA-deficient tumor cells correlates with functional suppression of single strand breakage repair and anti-tumor effects on BRCA mutation positive tumor cells.

Normal primary cells were resistant to ZL-2306 with the most sensitive cells (megakaryocytes) exhibiting a 13-fold selectivity margin as compared to BRCA mutation positive tumor cells *in vitro*. Maximal *in-vivo* efficacy was achieved in BRCA 1 mutation positive ovarian tumor models with once-daily oral administration of ZL-2306 at a dose sufficient to suppress 90% of the PARP enzymatic activity in the tumor at eight hours after the dose, which translated to greater than 50% inhibition of PARP activity in peripheral blood mononuclear cells at eight hours post dose.

The therapeutic potential of ZL-2306 was evaluated in a study designed to examine the benefit of ZL-2306 in maintenance setting, *i.e.*, daily ZL-2306 treatment following a regression induced with a platinum-based regimen. In this study, tumors in mice receiving maintenance ZL-2306 therapy became undetectable whereas regrowth was observed in those receiving only the chemotherapy regimen. These data support the concept that maintenance ZL-2306 therapy after tumor response to chemotherapeutic agents may prolong recurrence-free survival.

ZL-2306 showed no significant observable effects in nonclinical safety pharmacology studies at clinically relevant doses across the species evaluated.

**Pharmacokinetics.** ZL-2306 elicited desirable and consistent pharmacokinetic profiles in nonclinical species *in vivo*. The oral absorption in rats and dogs was rapid, with moderate to high bioavailability. The compound is readily distributed to the brains of rats and monkeys to a modest extent, suggesting additional therapeutic potential.

Elimination of ZL-2306 and its metabolites was fecal and renal in rats, while mainly renal in dogs. The potential risk for drug—drug interactions was determined to be minimal for ZL-2306, due to the lack of the interactions between ZL-2306 and the hepatic drug-metabolizing CYP enzymes, the major hepatic and renal uptake transporters (OATP1B1, OATP1B3, OAT1, OAT3, and OCT2), and BSEP, an efflux transporter known to be associated with hepatotoxicity. The *in vitro* metabolic results, combined with the *in vivo* pharmacokinetic findings, demonstrated that ZL-2306 had a desirable disposition profile with a minimal potential for drug—drug interactions, consistent with the development of ZL-2306 as an anticancer agent.

**Toxicology.** A comprehensive preclinical toxicology program was conducted to support the administration of ZL-2306 in patients with cancer. This program included oral repeat-dose toxicity studies (up to three-months duration) in dogs and rats, genotoxicity and phototoxicity studies. The results obtained from the general toxicity studies in rats and dogs indicated that ZL-2306 causes bone marrow suppression which leads to decreases in circulating white and red blood cells. Infections and septicemia were a consequence of bone marrow suppression and lymphoid depletion. These findings are linked to pharmacology of ZL-2306 and showed reversibility.

#### **ZL-2306—Pharmacokinetics**

The pharmacokinetic profile of ZL-2306 has been evaluated in multiple clinical studies, with an overall ZL-2306-dosed population of 526 patients.

**Absorption.** ZL-2306 exhibited linear pharmacokinetic, dose proportional exposure, and dose-independent absorption and clearance. Following repeat administrations of the daily recommended dose of 300 mg, ZL-2306 accumulation on day 21 was consistent for both the area under the plasma concentration-time curve and maximum concentration (approximately two- to three-fold). ZL-2306 was shown to be highly orally bioavailable (F ~73%). Bioavailability is a measure of the absorption of drug and is expressed as a percentage of the administered dose of the drug which reaches the patient's system. ZL-2306 can be administered with or without food.

**Distribution.** ZL-2306 was moderately protein bound to human plasma (83.0%). The apparent volume of distribution was 1220 L, indicating an extensive tissue distribution of ZL-2306.

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

**Elimination.** In an absorption, metabolism and elimination study in cancer patients using <sup>14</sup>C-radioactive ZL-2306, a mean measured total of 86.2% of the radioactive dose was recovered in urine and fecal samples collected daily from 0 to 504 hours (21 days) post dose after single oral administration of <sup>14</sup>C-ZL-2306. It suggests minimal long-term retention of ZL-2306 or its metabolites in body. Moreover, hepatobiliary clearance and renal excretion are the major routes of elimination in humans.

**Intrinsic Effects.** Population pharmacokinetic analysis identified no intrinsic factors such as age, race, hepatic impairment, renal impairment would have significant impact on the pharmacokinetic of ZL-2306.

#### **ZL-2401**

ZL-2401 is a broad-spectrum antibiotic in a new class of tetracycline derivatives, known as aminomethylcyclines. ZL-2401 is primarily being developed for ABSSSI, CABP and UTIs in both the hospital and community settings and is designed to overcome the two major mechanisms of tetracycline resistance, known as pump efflux and ribosome protection. ZL-2401 has been granted QIDP status in the U.S. by the FDA and has been granted Fast Track status by the FDA. The drug has been administered to over 1,500 patients and has an established safety profile. If approved, ZL-2401 is expected to be available in IV and oral once-daily formulations.

Paratek had previously reached an agreement with the FDA under a Special Protocol Assessment, or SPA, whereby if both the IV to oral Phase III ABSSSI and CABP studies are positive, Paratek could seek approval for both indications. In June 2016, Paratek announced positive top-line efficacy data in a Phase III registration study in ABSSSI which demonstrated the efficacy and safety of IV to oral once-daily ZL-2401 compared to linezolid. In April 2017, Paratek announced positive top-line results from a global, pivotal Phase III clinical study in CABP which demonstrated the efficacy, general safety and tolerability of IV to oral ZL-2401 compared to moxifloxacin. In July 2017, Paratek also announced positive top-line results from a Phase III study comparing oral-only administration of ZL-2401 in ABSSSI compared to oral-only linezolid, which met all of its primary endpoints.

Paratek received priority review for its NDA in the U.S. in April 2018 for ABSSSI and CABP, and plans its EMA submission later in 2018. In addition to its Phase III program for ZL-2401, a Phase Ib study in UTIs was initiated in May 2016 and positive top-line PK proof-of-principle data was reported in November 2016.

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

#### *Our Clinical Trial Designs and Strategy for ZL-2401 in the China market*

We have completed the technology transfer stage and started discussions with key opinion leaders on our planned China development activities in preparation for SDA interactions. We have submitted documents and filed for an IND with Chinese Health Authorities in January 2018. We have completed a microbiology study investigating the activity of ZL-2401 against pathogens obtained from Chinese/Asian patients. In this pilot trial of 3,832 isolates, ZL-2401 activity was essentially identical to the susceptibility results obtained in a larger 2016 surveillance study of 21,000 isolates conducted outside China (mainly U.S. and Europe). Our data have been accepted for publication.

Zai has already engaged in discussions with the SDA and key opinion leaders on our planned China development strategy in preparation for our NDA filing.

We are preparing for our first clinical study in China, a PK study, the design of which we plan to discuss with Center for Drug Evaluation, or CDE, as part of our bridging plan for regulatory approval in China.

#### *Background on Tetracycline Antibiotics*

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

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

#### *ZL-2401 – Pharmacokinetics*

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

#### *ZL-2401 Clinical Results*

##### *Phase III Pivotal Trial—ABSSSI / OASIS—ABSI 1108*

ZL-2401 was statistically non-inferior to linezolid IV/PO in a direct comparison study following a protocol established under an SPA agreed to with the FDA as well as the criteria outlined by the EMA. In this trial, patients with wound infections, major abscesses, and erysipelas/cellulitis were enrolled in equal numbers. On average, patients received IV ZL-2401 for 4.4 days, and oral ZL-2401 for 5.5 days.

*S. aureus* (both MSSA and MRSA) was the predominant pathogen isolated from patients followed by streptococci. Clinical response and bacterial eradication rates showed the high efficacy of ZL-2401 against skin pathogens including MRSA.

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

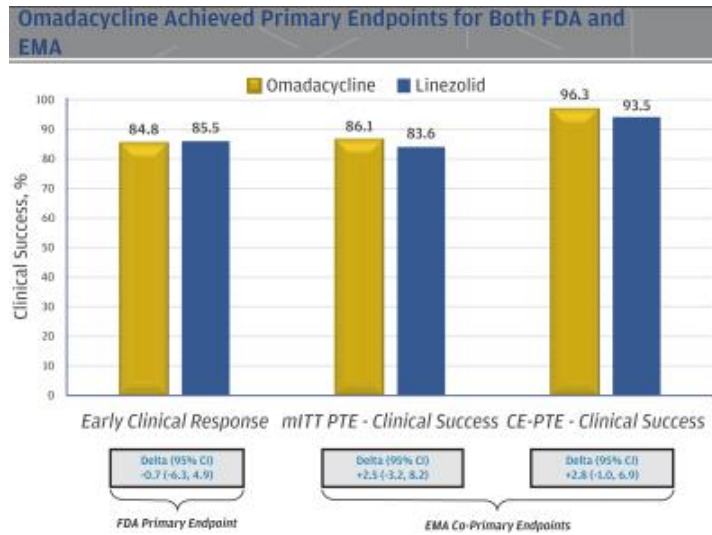
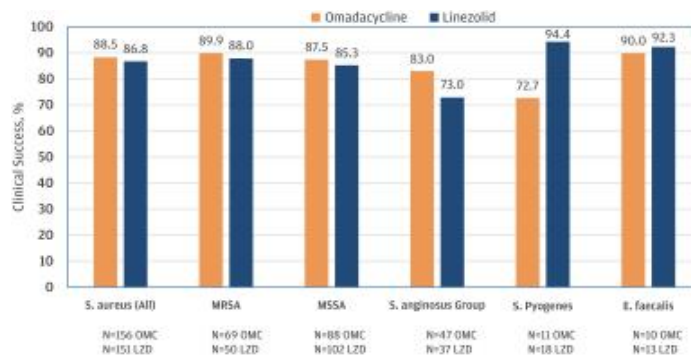


Figure 6: Early Clinical Success by Pathogen—micro-mITT Population



The safety / tolerability profile was very similar between the treatment arms with only a slightly higher rate of gastrointestinal side effects and infusion site reactions in ZL-2401 recipients. There was no significant imbalance in treatment emergent adverse events, or TEAEs, serious TEAEs, premature discontinuations or deaths.

Figure 7: Study ABSI-1108: Most Frequent TEAEs (> 3%)—Safety Population

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



ZL-2401 was non-inferior to moxifloxacin IV/oral in this direct comparison study following a protocol established under an SPA agreed with the FDA as well as the criteria outlined by the EMA. In this trial, patients with PORT Class II—IV were recruited; less than 25% of patients had received non-study antibiotics before enrollment.

*S. pneumoniae* and *Mycoplasma pneumoniae* were the predominant pathogens isolated, followed by *H. influenzae*, *H. parainfluenzae*, *Legionella* and *Chlamydia*. The clinical response rates were high for all respiratory pathogens isolated at entry and very similar between ZL-2401 and moxifloxacin, a powerful respiratory fluoroquinolone.

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

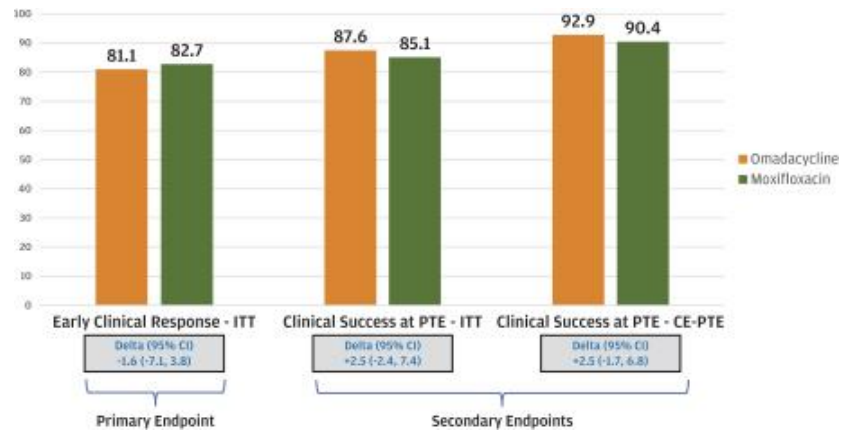


Figure 9: CABP Study—OPTIC: Primary Efficacy Results—EMA Analysis

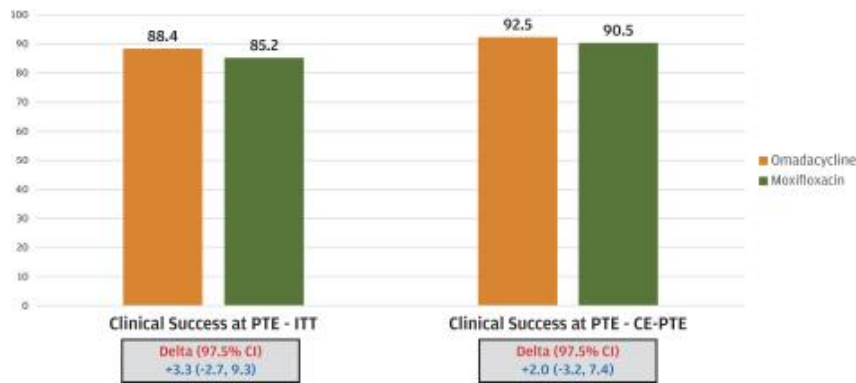


Figure 10: CABP Study—OPTIC: Clinical Success at PTE by Baseline Pathogen

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

\*10 or More Isolates for Omadacycline

Neither gastrointestinal side effects nor IV infusion reactions occurred more frequently in the ZL-2401 arm than in the comparator arm. Cardiovascular signs and symptoms and liver function test abnormalities occurred in both study arms with similar frequency.

Figure 11: TEAEs in CABP Trial

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

Phase III trial – ABSSSI /OASIS-2

Paratek’s third Phase III clinical study (OASIS-2) was an oral-only administration of ZL-2401 in ABSSSI compared to oral-only linezolid. Oral, once daily ZL-2401 met the FDA-specified primary efficacy endpoint of statistical non-inferiority in the modified intent-to-treat, or mITT, population (10% non-inferiority margin, 95% confidence interval) compared to oral, twice daily linezolid at the early clinical response, or ECR, 48-72 hours after initiation of therapy. The ECR rates for the ZL-2401 and linezolid treatment arms were 87.5% and 82.5%, respectively. In addition, ZL-2401 met specified co-primary endpoints for the EMA, which are key secondary endpoints for the FDA. For these endpoints, non-inferiority in the mITT and clinically evaluable populations in at the post treatment evaluation, seven to 14 days after end of treatment, ZL-2401 demonstrated a high response rate and met statistical non-inferiority to linezolid for both populations using a pre-specified 95% confidence interval. High success rates were observed with response rates of 84.2% (ZL-2401) vs. 80.8% (linezolid) and 97.9% (ZL-2401) vs. 95.5% (linezolid), respectively.

The most common TEAEs in ZL-2401-treated patients (occurring in  $\geq 3\%$  of patients) were gastrointestinal adverse events of ZL-2401 vs. linezolid included: vomiting (16.8% vs. 3.0%), nausea (30.2% vs. 7.6%), diarrhea (4.1% vs. 2.7%). In addition, alanine aminotransferase, or ALT, increase (5.2% with ZL-2401 vs. 3.0% with linezolid), aspartate aminotransferase increases (4.6% with ZL-2401 vs. 3.3 for linezolid) and headache (3.5% with ZL-2401 vs. 2.2% with linezolid). Drug-related TEAEs were 37.8% for ZL-2401 vs. 14.2% for linezolid (including gastrointestinal events). Discontinuation for TEAEs was uncommon, 1.6% for ZL-2401 vs. 0.8% for linezolid. Serious TEAEs occurred in 1.4% of ZL-2401 patients and 1.4% of linezolid patients; only one serious TEAE was considered related to the study drug and the event occurred in a linezolid patient. The mortality rate was 0.0% with ZL-2401 and 0.3% with linezolid. Drug-related serious TEAEs leading to premature discontinuation of test articles were 0.8% with ZL-2401 and 0.5% with linezolid.

### *Phase II studies*

In a small study (N=111) conducted in cSSSI patients ZL-2401 showed comparable efficacy and safety to linezolid IV/PO  $\pm$  aztreonam. However, the design of the Phase II study (and a truncated Phase III study with 68 patients) was no longer consistent with newer FDA guidance issued for ABSSSI in 2008 which required, among other changes, an early efficacy read-out at 48-72 hours.

In addition, this early ZL-2401 program used a 200 mg oral step-down dose that proved to not be bioequivalent to the 100 mg IV dose. Hence, these data are considered exploratory and cannot be merged easily with the larger pivotal program trials in ABSSSI and CABP that were conducted with FDA guidance and bioequivalent IV to oral step-down dosing.

### *Phase I studies*

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

ZL-2401 has a very favorable PK profile. It was absorbed well; its plasma T<sub>1/2</sub> of 14-20 hours permitted once-daily dosing. The drug was not metabolized and drug-drug interactions were minimal. In contrast to other tetracyclines, which paradoxically display dose-dependent increases in protein binding, 80% of ZL-2401 remained available as free drug. Excretion was via biliary and urinary routes. Data from hepatic and renal impairment studies showed that dose adjustments are not needed for patients with either condition.

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

ZL-2401 was negative on hERG testing and had no appreciable effect on cardiac conduction in a Thorough QT trial at supra-therapeutic doses. However, in animal tests and during Phase I, a dose-dependent elevation of blood pressure (systolic and diastolic) and heart rate were observed. ZL-2401 was found to be an acetylcholine antagonist for muscarinic receptor subtype M2, essentially acting as a vagolytic agent. In subsequent patient studies, these effects were less pronounced or absent and clinically asymptomatic. All Phase II and III studies included systematic cardiovascular pre- and post-dose monitoring of blood pressure and heart rate to further characterize these effects both qualitatively and quantitatively.

An ELF study showed excellent penetration of ZL-2401 into bronchoalveolar lavage fluid and into alveolar macrophages.

A cystitis (uUTI) study was conducted to obtain PK information for different oral dosing regimens of ZL-2401.

### **FPA144**

#### *Overview*

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

FPA44, which we licensed from Five Prime, is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastroesophageal cancer. In December 2017, Five Prime initiated dosing in a Phase I safety lead-in portion of its Phase I/III clinical trial of FPA144 in combination with the mFOLFOX6 chemotherapy regimen in patients with previously untreated, advanced gastric or gastroesophageal cancer. The randomized, controlled Phase III portion of the trial evaluating FPA144 plus chemotherapy is expected to start in the second half of 2018 and would serve as a global registrational study for the treatment of front-line gastric and gastroesophageal cancers. We and Five Prime intend to use the proposed global pivotal Phase III study and additional supportive data from clinical and nonclinical development to form the basis of an eventual marketing application for FPA144 both within and outside of China.

#### *Our Clinical Trial Designs and Strategy for FPA144 in the China market*

As FPA144 is a targeted biologic, the clinical development of FPA144 will ultimately be in selected patients with alterations in the fibroblast growth factor receptor 2, or FGFR2, pathway that are most likely to respond to this novel agent. The tumor types most relevant to date include gastric, bladder, and possibly cholangiocarcinoma. Each of these cancers needs new therapeutic options. The FIGHT (FPA144-004) study is designed to evaluate the efficacy, safety, and PK of FPA144 in combination with modified FOLFOX (infusional 5-FU, leucovorin, and oxaliplatin) (mFOLFOX6) chemotherapy treatment. Patients with gastrointestinal (GI) tumors will be enrolled in a Phase I safety run in, while the Phase III will enroll gastric cancer patients specifically selected for FGFR2 expression and/or FGFR2 gene amplification (FGFR2 selected) who are eligible for first-line mFOLFOX6 chemotherapy. The primary endpoint for Phase I part is the incidence of Grade 2 or higher AEs assessed as related to FPA144 by the Investigator and the incidence of clinical laboratory abnormalities defined as DLTs. The primary endpoint for the Phase III part is the OS, defined as time from enrollment until death from any cause.

China will be participating the Phase III part of above global trial and contributing largely on patient enrollment. The global Phase III data will support the NDA submissions both in China and outside China.

#### *FPA144 Mechanism of Action*

FPA144 is a humanized monoclonal antibody (IgG1 isotype) specific to the human FGFR2b receptor (National Center for Biotechnology Information; NCBI; reference sequence ID NP\_001138385.1) that blocks FGF ligand binding to the receptor. FPA144 is directed against the third Ig region of the FGFR2b receptor isoform, the region that is alternatively spliced and regulates ligand specificity. This antibody is glycosylated, but is produced in a Chinese hamster ovary (CHO) cell line that lacks the *FUT8* gene ( $\alpha$ 1,6-Fucosyltransferase) and therefore lacks a core fucose in the polysaccharide portion of the antibody. The absence of the core fucose results in higher affinity for the Fc receptor Fc $\gamma$ RIIIa compared to the fucosylated molecule and potentially enhances immune cell-mediated tumor cell killing. The antibody has thus been glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). FPA144 inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation in cell culture in FGFR2b overexpressing gastric and breast cancer cell lines. FPA144 also inhibits tumor growth in FGFR2b overexpressing gastric and breast xenograft models. The 3 potential mechanisms of action of FPA144 thus include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and enhancing ADCC.

FPA144 can produce complete and durable tumor growth inhibition in FGFR2b-overexpressing and FGFR2 gene-amplified gastric cancer xenografts in immune-compromised mice where FGFR2b is considered a driver of tumor growth. In addition, FPA144 demonstrates recruitment of natural killer (NK) cells and concomitant tumor growth inhibition in the 4T1 syngeneic tumor model with modest expression of FGFR2b. These data suggest that ADCC may be efficacious in patients without FGFR2 gene amplification with moderate FGFR2b overexpression, and that ADCC activity may be a major contributor to the mechanism of action in these patients.

Additionally, since FPA144 is specific for the FGFR2b receptor, it does not interfere with signaling of the other FGFs/ FGFRs, including FGFR2c. In contrast to the FGFR tyrosine kinase inhibitors (TKIs), FPA144 does not inhibit FGF23 signaling. FGF23 is a ligand involved in calcium/phosphate metabolism. Thus, treatment with FPA144 is not expected to cause the dose-limiting hyperphosphatemia associated with the FGFR TKIs.

#### *FPA144 Preclinical and Clinical Background*

##### *Nonclinical Pharmacology*

The nonclinical pharmacology program for FPA144 has been designed to assess the *in vitro* and *in vivo* pharmacologic action of FPA144 with particular focus on efficacy and safety. *In vitro* pharmacodynamic (PD) studies have been performed to characterize the binding affinity of FPA144 to FGFR2b *in vitro*, as well as to assess the ability

of FPA144 to inhibit FGFR2b ligand binding, downstream signaling, and cell proliferation. In addition, the ability of FPA144 to induce ADCC has been determined *in vitro*. The *in vivo* pharmacology of FPA144 has been studied in animal models of tumor growth. Safety pharmacology studies including CNS, cardiovascular, and respiratory rate assessments have been incorporated into the toxicology studies. FPA144 inhibits FGF ligand-stimulated FGFR2b phosphorylation and cell proliferation of FGFR2b-overexpressing gastric and breast cancer cell lines. FPA144 also inhibits tumor growth in FGFR2b-overexpressing gastric and breast xenograft models, including regression in some models. In addition, Five Prime has demonstrated *in vitro* that FPA144 mediates ADCC in cells expressing FGFR2b.

#### *Nonclinical Pharmacokinetics*

The PK characteristics of FPA144 were investigated as a part of both nonclinical TK and PK studies in rat and cynomolgus monkey. Single-dose and repeat-dose studies evaluated FPA144 doses of 1–150 mg/kg. In those studies, FPA144 was administered intravenously, either as a bolus injection or a 30-minute infusion, and given weekly in the repeat-dose studies. Determination of serum concentrations of FPA144 and anti-FPA144 antibodies were performed using immunoassay methods developed by Five Prime and validated for use in GLP toxicology studies in rat and monkey.

Between rat and cynomolgus monkey, FPA144 demonstrated consistent PK behavior following IV administration, and the PK characteristics observed were consistent across all studies. Half-life was dose-dependent ranging from approximately 20–40 hours at low doses (1–1.5mg/kg) to 100–200+ hours at the highest doses (100–150 mg/kg) tested in cynomolgus monkey. Estimates of the initial volume of distribution approximated the plasma volume, suggesting that FPA144 did not distribute beyond the plasma compartment immediately after dosing, which is typical of large proteins including antibodies.

The majority of antibodies demonstrate dose-dependent elimination consistent with target-mediated elimination, where clearance decreases as a function of dose (eg, trastuzumab, rituximab, gemtuzumab, and panitumumab). FPA144 demonstrated dose-dependent, nonlinear PK, similar to what has been observed for other mAbs. This was marked by a faster clearance at the terminal phase of the plasma concentration-time profile, a greater than dose-proportional increase in exposure with increasing dose, and a longer half-life with increasing dose. Target-mediated clearance was saturable at doses  $\geq 10$  mg/kg for single doses and doses  $\geq 5$  mg/kg following repeat doses, marked by dose-proportional increases in exposure at doses exceeding this level when dosed at weekly intervals. Since FPA144 binds equivalently to rat, monkey, and human FGFR2b, the nonclinical data provide a solid foundation to understanding the profile in clinical studies with FPA144.

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

#### *Nonclinical Toxicology*

Six nonclinical *in vivo* toxicology studies were performed using FPA144: two studies in rat and four studies in monkey. In rat, a dose-range finding, repeat-dose toxicology study (four weekly doses of 1.5, 30, or 150 mg/kg and a repeat-dose GLP toxicity study of 13 weekly doses of 1, 5, or 100 mg/kg with a nine-week recovery phase) were performed. In monkey, a single-dose PK/tolerability study (single dose of 10 mg/kg), a dose-range finding, repeat-dose toxicology study (four weekly doses of 1.5, 30, or 150 mg/kg), an ophthalmic-focused, repeat-dose tolerability study (four weekly doses of 1.5, 5, 15, 30, or 150 mg/kg), and a repeat-dose GLP toxicology study (13 weekly doses of 1, 5, or 100 mg/kg with a 15-week recovery phase) were performed.

FPA144 was well-tolerated when administered intravenously once per week for 4 weeks at doses up to 150 mg/kg in rats. Corneal epithelium thinning was seen in animals receiving FPA144 at 1.5 mg/kg and higher, and these findings were considered treatment-related. The additional corneal changes were also considered treatment-related, but it is unclear whether they are a direct effect or secondary to the corneal thinning. For the hypertrophic changes in the RPE, it is unclear if the changes are a direct treatment-related effect since changes to the RPE can be caused by a multitude of factors. No pathological findings were detected in the RPE in the 13-week GLP rat toxicity study.

FPA144 was well tolerated when administered by IV once per week for 4 doses up to 150 mg/kg in cynomolgus monkeys. Findings potentially related to FPA144 were corneal epithelium thinning and a unilateral cataract in one high-dose animal.

FPA144 administered to rats once per week for 13 weeks at 1, 5, or 100 mg/kg resulted in treatment-related findings at all dose levels, although most of the effects occurred or were more pronounced in animals given 5 and 100 mg/kg. The most prominent findings were tooth abnormalities (clinical, macroscopic, and microscopic findings) and body weight loss/lack of weight most likely secondary to the tooth findings that necessitated early euthanasia of three animals at 100 mg/kg, ocular findings (ophthalmic and microscopic findings), macroscopic and/or microscopic findings in the Harderian gland and oral mucosa at 5 mg/kg and 100 mg/kg, and macroscopic and/or microscopic findings in the tongue at all dose levels. FPA144-related but non-adverse microscopic findings were also noted in the mammary gland of animals in all dose groups. With the exception of FPA144-related effects on incisors, some degree of recovery was evident for all findings at the end of the recovery phase. Since all findings in the 1 mg/kg dose group were minimal, without clinical consequences, and recoverable, the HNSTD was determined to be 1 mg/kg when given weekly for 13 weeks.

FPA144 given to male and female cynomolgus monkeys by IV infusion once per week for 13 weeks at 1, 5, or 100 mg/kg was well tolerated. FPA144-related effects were limited to microscopic findings of corneal atrophy in animals given 5 and 100 mg/kg and mammary gland atrophy in females from all dose groups. These findings were not associated with clinical sequelae and were not observed at the end of the recovery phase, indicating complete recovery. Therefore, based on the lack of other correlating findings or changes (eg, ophthalmic findings or clinical observations) and the demonstrated reversal, neither FPA144-related microscopic finding was considered adverse. The HNSTD is considered to be above the 100 mg/kg level when given weekly for 13 weeks.

The data from the tissue cross-reactivity study demonstrated that the expression of the target of FPA144 is similar between the species used for toxicology studies and humans, and suggest that the safety findings from the nonclinical toxicology studies are likely to apply to the clinic.

Examinations of the reproductive organs in the toxicological studies demonstrated no evidence of reproductive target toxicity. No specific reproductive toxicity tests have been conducted for FPA144 to date.

FPA144 is an IgG1 monoclonal antibody directed against FGFR2b and is being developed for the treatment of malignancies that overexpress FGFR2b. The toxicology and TK studies with FPA144 were completed in rat and cynomolgus monkey to support the design of the clinical trial.

### *Clinical Background*

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

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

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

FPA144 is a recombinant, afucosylated, humanized immunoglobulin G1 (IgG1) kappa monoclonal antibody directed against FGFR2b. FPA144 is glycoengineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC). Preclinically, FPA144 blocks ligand binding and acts as a targeted immunotherapy that drives NK cells and recruits T cells into targeted tumors. As well as driving NK cells into tumors, in vivo preclinical studies have shown that FPA144 creates an “inflamed” tumor microenvironment consisting of recruited T cells and elevated levels of programmed death-ligand 1 (PD-L1). The three potential mechanisms of action of FPA144 include blocking ligand binding and downstream signaling, decreasing expression of the FGFR2b driver protein, and ADCC.

FPA144 is being developed in combination with chemotherapy for the treatment of patients with unresectable, locally advanced, or metastatic gastric cancer including cancer of the GEJ whose tumors overexpress FGFR2b, as determined by an investigational device(s) being developed as a companion diagnostic test(s). Evaluation of this agent in patients with gastric cancer whose tumors have alterations of FGFR2 is an important strategy to improve the outcome for these patients.

A Phase I study, FPA144-001, entitled “A Phase I Open-Label, Dose-Finding Study Evaluating Safety and Pharmacokinetics of FPA144 in Patients with Advanced Solid Tumors” is ongoing in the U.S., South Korea, and Taiwan. Safety and efficacy data in 74 patients, including preliminary data from an expansion cohort of 24 gastric cancer patients with high FGFR2b overexpression (IHC 3+ intensity in  $\geq 10\%$  of tumor cells as determined in a laboratory developed test), support further clinical investigation of FPA144 in patients with FGFR2b-selected tumors. Based on an August 7, 2017 data cut, treatment with FPA144 resulted in no dose-limiting toxicities (DLTs) reported at doses up to 15 mg/kg administered every two weeks. Of the 74 patients who have received at least one dose of FPA144, 50 patients had gastric cancer, of whom 24 had gastric cancer with high FGFR2b overexpression and were evaluable for response. Of these 24 patients, four, or 16.7% (95% CI 4.7-37.4%), reported a radiographically confirmed partial response (PR) per Response Evaluation Criteria in Solid Tumors (RECIST) criteria (version 1.1). The median duration of response (DoR) in these four patients was 15.4 weeks (95% CI 9.1 to 19.1 weeks). Conversely, no responses were reported in the 25 patients with gastric cancer who either had low or moderate FGFR2b overexpression, were IHC negative, or who had unknown FGFR2b status. One patient with gastric cancer did not have measurable disease and was inevaluable for response.

To address the unmet medical need of patients with unresectable, locally advanced, or metastatic gastric cancers and based on the preliminary Phase I data, Five Prime is proposing FPA144-004 (FIGHT), a double-blind, randomized, controlled, global Phase III study of FPA144 in combination with modified FOLFOX6 (mFOLFOX6) chemotherapy, preceded by a Phase I safety run-in. The Phase I safety run-in will be conducted in the US and will assess safety and tolerability and identify the recommended dose (RD) of FPA144 as an add-on therapy to fluorouracil, leucovorin, and oxaliplatin (mFOLFOX6, a combination that is used globally) for patients with gastrointestinal (GI) tumors. The global Phase III portion of the study will evaluate the efficacy and safety of FPA144 in combination with mFOLFOX6 versus placebo in combination with mFOLFOX6 in patients with unresectable, locally advanced, or metastatic gastric cancers whose tumors have FGFR2b overexpression, as determined by an IHC assay, and/or *FGFR2* amplification, as determined by a circulating tumor DNA (ctDNA) assay. The proposed Phase III study will enroll a majority of Asian patients, from countries including Japan, South Korea, Taiwan, Thailand, and China. The proposed Phase III study will employ 2 diagnostic assays, the Ventana Medical Systems, Inc. FGFR2b IHC assay and the Personal Genome Diagnostics (PGDx) next-generation sequencing (NGS) assay for *FGFR2* testing. The goal is to establish the clinical utility of the IHC and NGS assays for use as companion diagnostic tests. The primary endpoint for the proposed Phase III study will be OS, supported by a principle secondary endpoint of investigator-assessed PFS. Other secondary and exploratory endpoints include overall response rate (ORR), DoR, and physical function, as measured by EQ-5D-5L and EORTC QLQ-C30. Additional development of FPA144 for the treatment of gastric cancer includes FPA144-002, a Phase I pharmacokinetic (PK) safety study in Japan. This dose escalation study is designed to assess the PK and safety of single agent FPA144 and will identify the RD for single agent FPA144 in Japanese patients. The first cohort of three patients treated on FPA144-002 had no DLTs reported at doses of 10 mg/kg administered every two weeks.

#### **ETX2514**

ETX2514 is a novel  $\beta$ -lactamase inhibitor of class A, C, and D beta-lactamases. As such it is active against multiple members of the  $\beta$ -lactamases commonly found in *Acinetobacter baumannii*. In particular, it is a potent inhibitor of several Class D enzymes which confer MDR to many  $\beta$ -lactam antibiotics. In combination with sulbactam, ETX2514 reduces the minimum inhibitory concentration, or MIC, against this organism and restores susceptibility to sulbactam. It is being developed by Entasis as ETX2514SUL, a combination of ETX2514 and sulbactam. The microbiologic efficacy of this combination was demonstrated in large studies of well-characterized MDR *Acinetobacter* isolates from diverse

regions, including Asia. ETX2514SUL was bactericidal and active against penem-resistant Acinetobacter organisms. ETX2514SUL was synergistic with imipenem, further lowering MICs on in-vitro testing. The FDA has granted ETX2514SUL QIDP, Fast Track and Priority Review status.

ETX2514 without sulbactam but in combination with other B-lactams lowered the MICs for E. coli, K. pneumoniae and P. aeruginosa compared to the partner  $\beta$ -lactam antibiotic alone. Entasis has conducted a comprehensive Phase I safety and PK program for ETX2514. Single ascending dose and multiple ascending doses studies showed that ETX2514 alone and in combination with sulbactam or imipenem is well tolerated and safe. There were no noticeable drug-drug interactions.

Entasis plans to develop ETX2514SUL for the treatment of severe A. baumannii infections. Entasis anticipates initiating a Phase II cUTI trial starting in 2018 and a pivotal Phase III trial in MDR Acinetobacter infections in 2019.

#### *Background on Acinetobacters*

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

Severe Acinetobacter infections are associated with mortality rates of 50-60% despite intensive medical care. These infections usually present as blood-stream infections or hospital-acquired pneumonia. However, less severe skin and urinary tract infections are not uncommon. The frequency of Acinetobacter infections is on the rise world-wide. In the United States and EU, the incidence of infection is between 80,000 and 120,000 patients per year in each region. The incidence is higher in Asia-Pacific and especially in China where the organism ranks among the most frequent isolates in intensive care unit patients. In 2015, over 180,000 infections were reported from China alone. In Japan, over 30,000 cases were reported for 2015, which is an increase of approximately 50% since 2012.

#### *Background on Sulbactam*

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

ETX2514 is a non- $\beta$ -lactam BLI of the DBO class. It has structural similarities to avibactam, a BLI recently approved in combination with ceftazidime (Avycaz®). However, ETX2514 has demonstrated greater potency against many  $\beta$ -lactamases, especially the Class D OXA enzymes prevalent in Acinetobacter.

#### **ZL-2301**

ZL-2301 is an oral, small molecule dual TKI which blocks both VEGFR and FGFR. ZL-2301 was studied by our partner Bristol-Myers Squibb mainly for the treatment of HCC, the most common type of liver cancer. To date, ZL-2301 has been tested in 26 trials, including 19 Phase I trials, two Phase II trials and five Phase III trials, with 2,651 oncology patients around the world. In these trials, ZL-2301 has demonstrated anti-tumor activity and a generally well-established safety profile, particularly in HCC patients. In 2012, Bristol-Myers Squibb terminated its development program for ZL-2301 after it missed the primary endpoints in two Phase III trials with advanced HCC patients.

Based on our review of the results from Bristol-Myers Squibb's development program for ZL-2301, our understanding of the etiology of HCC in Chinese patients, standard of care of HCC patients in China and our ongoing research, a number of factors lead us to believe that ZL-2301 has the potential to be an effective treatment option for Chinese HCC patients and merits further clinical trials. These factors include:

- in prior clinical trials, ZL-2301 was observed to have comparable anti-tumor activity in HCC patients to sorafenib, particularly in patients with HCC induced by hepatitis B infection rather than hepatitis C infection. In Chinese patients HCC is typically induced by hepatitis B infection, rather than hepatitis C infection;



- in China, chemotherapy, rather than TKIs, such as sorafenib, remains the primary first-line treatment for HCC and, as a result, a much greater percentage of Chinese patients are TKI-naïve going into second-line treatment, hence more sensitive to TKI treatment;
- limited target therapy treatment options for HCC patients, especially in China; and
- our PD analysis and PK modeling data suggest that there may be a more effective dosing schedule of ZL-2301 compared to the dosing schedule studied in prior clinical trials.

In Bristol-Myers Squibb's BRISK-FL study, which was a Phase III non-inferiority study of ZL-2301 compared to sorafenib in patients without prior systemic treatment, 223 Chinese HCC patients out of 1,155 patients in total participated. Although the study missed the primary end point of OS noninferiority for ZL-2301 versus sorafenib based on the prespecified margin, ZL-2301 demonstrated evidence of anti-tumor activity. Median OS was 9.9 months for sorafenib and 9.5 months for ZL-2301. TTP, ORR, and DCR were similar between sorafenib and ZL-2301. Most frequent grade 3/4 adverse events for sorafenib and ZL-2301 were hand-foot skin reaction (15% and 2%, respectively), hyponatremia (9% and 23%, respectively), AST elevation (17% and 14%, respectively), fatigue (7% and 15%, respectively), and hypertension (5% and 13%, respectively). Discontinuation as a result of adverse events was 33% for sorafenib and 43% for ZL-2301; rates for dose reduction were 50% and 49%, respectively.

Our analysis of Chinese patients in the BRISK-FL study showed that ZL-2301 demonstrated a trend of efficacy and a safety profile comparable to those of sorafenib. In particular, more Chinese HCC patients experienced no dose reduction compared to non-Chinese patients. Our analysis also showed that less Chinese HCC patients experienced one dose or two dose reductions compared to non-Chinese patients. This data suggests that ZL-2301 treatment may be better tolerated by Chinese HCC patients than non-Chinese patients. While the BRISK-FL study was not designed specifically to determine efficacy and safety in a Chinese patient population, we concluded that our analysis of such clinical data was promising and warranted further clinical trials.

It has been debated within the HCC expert community that the biology of Chinese HCC may be different from that of non-Chinese HCC. In China, hepatitis B infections are much more prevalent than that of hepatitis C, and as a result HCC among Chinese patients are usually induced by the hepatitis B virus rather than the hepatitis C virus, which more commonly induces HCC in patients from western countries. We believe that this difference between Chinese HCC patients and non-Chinese HCC patients could potentially explain the difference in outcomes in patients treated with ZL-2301. For example, the subgroup analysis of 512 patients enrolled in the BRISK-FL study whose HCC was induced by hepatitis B infection showed OS of 8.4 months for ZL-2301 treated patients compared to 8.1 months for sorafenib treated patients; the subgroup analysis of 235 patients enrolled in the BRISK-FL study whose HCC was induced by hepatitis C infection showed OS of 10.9 months for ZL-2301 treated patients compared to 12.9 months for sorafenib treated patients. The treatment available to most advanced HCC patients in China is generally limited to traditional chemotherapy, and only a very small portion of Chinese HCC patients have access to sorafenib (Nexavar<sup>®</sup>), a kinase inhibitor co-developed and co-marketed by Bayer Healthcare and Onyx Pharmaceuticals Inc., a subsidiary of Amgen Inc., and used to treat first line HCC in the United States and other jurisdictions. Due to the difference in the standard-of-care in first-line treatment, most Chinese patients are TKI naïve, and they are therefore likely more sensitive and responsive to TKI therapy as compared to western second-line HCC patients who have already been exposed to TKI treatment and in most cases have become TKI resistant.

In addition, our pharmacodynamics analysis and pharmacology modeling data suggest that a 400 mg twice-a-day treatment regime seems to have better coverage for target inhibition as compared to a regime of 800 mg once daily. Therefore, we will explore and optimize the dose and dosing schedule in our further trials.

In 2015, we obtained an exclusive license for the development and commercialization of ZL-2301 in China, Hong Kong and Macau. The SDA has approved our CTA for ZL-2301 as a Category 1 drug, and in the second quarter of 2017, we initiated a Phase II trial of ZL-2301 as a second-line treatment comparing 800mg once daily to 400mg twice daily for advanced HCC patients in China. The recruitment for the Phase II study is ongoing. Preliminary anti-tumor activity has been observed with second line HCC patients treated with ZL-2301. Safety profile to date appears to be tolerable and manageable in general. Pending results of this Phase II study, a Phase III clinical trial in second line HCC patients is anticipated to initiate in the second half of 2018.

In the second quarter of 2017 we initiated a Phase II trial in advanced HCC patients in China to further investigate ZL-2301's optimal treatment schedule and dosage as a second-line treatment. The study is an open label study of ZL-2301 with two treatment arms of 30 patients each. One arm is receiving 800 mg of ZL-2301 once daily and the other arm is receiving 400 mg of ZL-2301 twice daily. The primary endpoints of this Phase II trial are disease control rate at three months post treatment and time to tumor progression. The PK profile of each treatment schedule and dosage level is also being investigated. The recruitment for the Phase II study is ongoing. Preliminary anti-tumor activity has been observed with second line HCC patients treated with ZL-2301. Safety profile to date appears to be tolerable and manageable in general. The data readout for this phase II study is expected in the second half of 2018.

Pending results from the Phase II trial, including the optimal dosage level and schedule, we plan to initiate a Phase III double-blind, randomized, parallel trial to compare ZL-2301 at the selected treatment schedule/dosage with best supportive care versus placebo with best supportive care as a second-line treatment of advanced HCC patients in the second half of 2018. We plan to enroll 348 patients at a 2:1 ratio for the Phase III trial. The primary endpoints will be OS and the secondary endpoints will be time to tumor progression, disease control rate, objective response rate and overall safety. If this Phase III trial yields positive results, we plan to use the results to support an NDA submission of ZL-2301 in China.

#### *Background on Tyrosine Kinase Inhibitors*

Tyrosine kinases are enzymes responsible for the activation of many proteins by signaling transduction cascades, the process by which a foreign DNA is introduced into a cell by a virus or viral vector. The tyrosine kinase inhibitors comprise a relatively new group of anticancer drugs that have been developed as oral formulations. The mechanism of action of tyrosine kinase inhibitors includes modulation of key pathways and mechanisms of angiogenesis, the formation of new blood vessels in human body, and tumorigenesis, the formation of cancers, such as VEGFR. However, tyrosine kinase involvement and activity may vary from tumor to tumor, resulting in differing responses to different TKIs.

VEGF plays a key role in tumor angiogenesis during the development of cancer, tumors at an advanced stage can secrete large amounts of VEGF to stimulate excessive angiogenesis around the tumor in order to provide greater blood flow, oxygen, and nutrients to fuel the rapid growth of the tumor. VEGF and other ligands can bind to three VEGF receptors, VEGFR1, 2 and 3, each of which has been shown to play a role in angiogenesis. Therefore, inhibition of the VEGF/VEGFR signaling pathway can act to stop the growth of the vasculature around the tumor and thereby starve the tumor of the nutrients and oxygen it needs to grow rapidly.

In addition, a growing body of evidence has demonstrated the oncogenic potential of FGFR aberrations in driving tumor growth, promoting angiogenesis, and conferring resistance mechanisms to anti-cancer therapies. There is also evidence that anti-VEGF therapy treatment could increase FGFR pathway activation, leading to drug resistance to anti-VEGF therapies. As a result, simultaneously targeting VEGFR and FGFR is an attractive approach to improve clinical efficacy.

#### *ZL-2301 Mechanism of Action*

By inhibiting VEGFR and FGFR, ZL-2301 affects the human vein endothelium cells, which are responsible for angiogenesis. Since essentially all solid tumors require angiogenesis to progress beyond a few millimeters in diameter, anti-angiogenesis drugs have demonstrated benefits in a wide variety of tumor types.

The exact mechanisms by which ZL-2301 inhibits tumor growth are not entirely understood, but clinical trial results to date suggest that ZL-2301 effectively inhibits tumor growth and such inhibition is associated with the inactivation of VEGFR-2, increased apoptosis, a process of programmed cell death, a reduction in microvessel density, inhibition of cell proliferation and down-regulation of cell cycle regulators.

#### *ZL-2301 Preclinical and Clinical Background*

As discussed below, Bristol-Myers Squibb completed various preclinical studies to evaluate the pharmacodynamics, pharmacokinetics and toxicology profile of ZL-2301.

*Pharmacodynamics.* In preclinical studies, ZL-2301 demonstrated strong in vitro inhibitory effects on human umbilical vein endothelial cells when stimulated with VEGF and basic fibroblast growth factor for VEGFR-2 and basic fibroblast growth factor receptor-1, respectively. Each of ZL-2301 and ZL-2301 alaninate, which becomes the pharmacologically active ZL-2301 after being metabolized, demonstrated, in vivo, a broad spectrum of antitumor activities, with cytostasis, the inhibition of cell growth and multiplication, observed in all human tumor models tested.

In addition, when ZL-2301 was administered in combination with cetuximab, enhanced antitumor activities were observed against mouse xenograft lung tumor tissue samples. Enhanced antitumor activities were also observed when ZL-2301 was administered in combination with ixabepilone and paclitaxel. When tested on a model of human lung carcinoma tissues, ZL-2301 demonstrated more prolonged tumor growth delay than sorafenib. Furthermore, complete tumor stasis was also observed in a staged tumor xenograft derived from HCC patients after ZL-2301 was administered.

Further studies demonstrated that ZL-2301 effected mainly the gastrointestinal, vascular, skeletal and female reproductive systems. The effects of ZL-2301 on these target systems were consistent with the expected pharmacology of ZL-2301. In addition, in repeat-dose studies, reversible increases in serum transaminases were observed in studies conducted on mice, rats and monkeys, total bilirubin and liver weight gains were observed in studies conducted on rats, and microscopic alterations of hepatocellular vacuolation were observed in studies conducted on rats and monkeys, which indicated that ZL-2301 has a significant effect on livers.

*Pharmacokinetics.* ZL-2301 elicited desirable and consistent pharmacokinetic profiles in nonclinical species in vivo. The oral absorption of ZL-2301 alaninate in mice, rats, dogs and monkeys was rapid, with bioavailability ranging from 52% to 97%.

Elimination of ZL-2301 and its metabolites was mainly fecal. ZL-2301 was also found to be highly bound to serum proteins and exhibit a moderate level of extravascular distribution.

*Toxicology.* Comprehensive preclinical toxicology studies were conducted to support the administration of ZL-2301 in patients with cancer. These studies indicated that ZL-2301 alaninate and ZL-2301 inhibited hERG/IKr channels resulting in a high, in the case of ZL-2301 alaninate or moderate, in the case of ZL-2301, risk for QT prolongation. However, neither ZL-2301 alaninate nor ZL-2301 produced substantive effects on rabbit Purkinje fiber action potential duration and no biologically relevant inhibitory effect on any of 53 different receptors, transporters, and ion channels investigated in vitro. ZL-2301 produced no central nervous system-related effects on rats and monkeys, and apart from a slight decrease in heart rates on monkeys, dose-dependent increases in blood pressure, and mild decreases in heart rate in a telemetered rat model, it produced no changes in respiratory function and heart rates or sounds in exploratory or pivotal toxicity studies conducted in dogs or monkeys.

The effects of ZL-2301 alaninate on male and female fertility have not been studied. However, repeat-dose toxicity studies in rats and monkeys indicated that ZL-2301 could potentially impair reproductive function and fertility in females. ZL-2301 alaninate also produced embryo-fetal developmental toxicity in rats and rabbits at doses that did not produce maternal toxicity. As a result, ZL-2301 is considered a selective developmental toxicant in these two species.

With respect to clinical stage studies, Bristol-Myers Squibb conducted three Phase III studies of ZL-2301. The Phase III study called the BRISK-FL study tested the efficacy of ZL-2301 against sorafenib in patients with advanced HCC without prior systemic treatment. The second study, BRISK-PS, tested ZL-2301 against best supportive care in patients that failed or were intolerant to sorafenib. In both studies, ZL-2301 failed to meet its primary endpoint but nonetheless it did demonstrate some anti-tumor activity. Due to these results, a third Phase III trial in which ZL-2301 was used as an adjuvant to TACE was terminated by Bristol-Myers Squibb, prior to its completion in 2012.

## **ZL-3101**

### *Overview*

ZL-3101 is a novel steroid-sparing topical product for the treatment of eczema and psoriasis. We licensed the exclusive worldwide rights to ZL-3101 in 2016 from GSK. The active botanical ingredients in ZL-3101 were originally used in a hospital setting within China to treat patients with eczema and psoriasis. Our management team, who has extensive experience developing botanical products in the clinical setting, acquired ZL-3101 from GSK because it identified ZL-3101 as a potential steroid-sparing treatment for eczema and psoriasis sufferers who have limited natural treatment options. The potential anti-inflammatory benefit of ZL-3101 results from its active botanical formula which incorporates the herbs *Glycyrrhizae Radix et Rhizoma* and *Sophorae Flavescentis*.

We started our Phase II study in patients with mild to moderate subacute eczema in China in the second quarter of 2017.

### *Our Clinical Trial Designs and Strategy*

We have initiated a Phase II proof-of-concept study in patients with mild to moderate subacute eczema in China. This Phase II study is a multi-center, randomized, double-blind, parallel, placebo controlled study to evaluate the efficacy and safety of different ZL-3101 ointment treatment schedule/dose in patients. This study will enroll an estimated 310 patients to ensure at least 250 clinically evaluable patients are available. Enrollment is expected to be completed in the second half of 2018 and top-line results are expected to be reported in the fourth quarter of 2018.

Patients are being recruited and randomized in a ratio of 2:2:1 into groups that receive ZL-3101 twice daily, once daily, or placebo. Randomization is stratified by disease severity. The primary objective is to evaluate efficacy of ZL-3101 using the Eczema Area and Severity Index (EASI score), a tool for the measurement of severity of eczema. It ranges from zero (no eczema) to 72. The primary endpoint is EASI score changes from baseline to day 21 of treatment. The secondary objective is to assess the safety and tolerability of ZL-3101 ointment in subjects with mild to moderate subacute eczema. The safety endpoints include incidence, severity and relationship of adverse events, the proportion of subjects with adverse events leading to discontinuation and local tolerability at various points during the trial.

Pending results of the Phase II study, we plan to initiate a Phase III global, multi-center clinical trial.

### *ZL-3101 Mechanism of Action*

Pharmacologic disease management of eczema and psoriasis is typically aimed at targeting the immune system dysfunction responsible for the inflammatory reaction at the site of the flares, that is, proinflammatory cytokines and other products of T-cell activation. Topical therapies are the mainstay of treatment for most patients with these conditions.

Our preclinical studies demonstrated that the active components of the formulation are not absorbed systemically. Furthermore, GSK-sponsored preclinical studies have demonstrated that ZL-3101 may inhibit cell infiltration and suppress inflammatory cytokines that would otherwise go unchecked and continue to propagate chronic inflammation. Preclinical studies also suggest that ZL-3101 can inhibit overexpression of proinflammatory cytokines such as such as tumor necrosis factor, or TNF- $\alpha$ , and interferon gamma, IFN- $\gamma$ , and ICAM-1, a gene that may be associated with pro-inflammatory pathways.

Therefore, we believe that the anti-inflammatory properties of ZL-3101 may improve lesion clearance. Together with an improved safety profile over currently approved topical therapies, ZL-3101 may offer benefits to eczema patients and significantly improve outcomes for patients globally.

### *ZL-3101 Preclinical Development*

In preclinical development, ZL-3101 demonstrated inhibitory effects in mouse and rat acute inflammation models, with significant inhibition seen in xylene-induced ear swelling, skin capillary permeability and carrageenan-induced paw swelling models. The preclinical studies used 4-dinitrofluorobenzene-, or DNFB-, induced mice which more closely reflect the characteristics of chronic T-cell-dependent inflammation. The degree of swelling in mouse auricles and the inflammatory cell counts were decreased in DNFB-induced delayed type hypersensitivity models of dermatitis and eczema. Significant decreases in IFN- $\gamma$  TNF- $\alpha$  and ICAM-1 levels in auricular tissues were seen following topical application of ZL-3101. Furthermore, histamine-induced itching reactions were reduced in guinea pigs, with significant increases in the itching thresholds following ZL-3101 application. These results suggest that ZL-3101 inhibits the overexpression of inflammation-related cytokines (IFN- $\gamma$ ) and intercellular cell adhesion molecule-1 (ICAM-1), subsequently alleviating the inflammatory, anaphylactic and pruritic characteristics of eczema.

In addition to the anti-inflammatory effects, ZL-3101 demonstrated potent bacteriostatic or bactericidal effects in vitro against *Staphylococcus aureus*, *beta-streptococcus* and hemolytic streptococci *Candida albicans* at a low concentration. *Staphylococcus aureus* is the most common bacteria to infect and colonize the skin in eczema, hence the bactericidal effects of ZL-3101 could be helpful in treating eczema. ZL-3101 showed no significant observable effects in preclinical safety pharmacology studies across the species evaluated.

*Pharmacokinetics.* The systemic exposure of four representative marker compounds from the two herbs used in ZL-3101's formula was assessed following single and repeat dose dermal administration of ZL-3101 (doses up to 5.6 g herb/kg/day) to miniature pigs for up to 28 days. No consistent kinetic profile was observed for any of the marker compounds prohibiting any conclusion to be made on the relationship between dose, dose duration and exposure for these four markers.

*Toxicology.* The results obtained from preclinical toxicology studies of ZL-3101 in miniature pig and rabbit species indicated there were dermal changes at the application site, including erythema, rash, sores and skin scaling, which primarily occurred in the fourth week of the dosing period. When averaged over the entire study per SDA guidelines, the response was classified as "no irritation" at all doses. However, possible adverse events at the application site will be monitored in our clinical trials.

## **Our Preclinical Pipeline**

### **ZL-2302**

ZL-2302 is a multi-targeted TKI with activity on both ALK and crizotinib-resistant ALK mutations developed for the treatment of patients with non-small cell lung cancer who have ALK mutations and have developed crizotinib-resistant mutations and/or brain metastasis. We licensed the exclusive worldwide rights to ZL-2302 from Sanofi in 2015. Our preclinical studies demonstrated that ZL-2302 has a great ability to penetrate the blood-brain barrier, which could make ZL-2302 an effective therapy for the significant portion of the patients who have non-small cell lung cancer with ALK mutations and brain metastasis. Such patients typically have poor prognosis, a low quality of life and limited treatment options.

### *Our Clinical Trial Designs and Strategy*

Our CTA for ZL-2302 has been accepted as a Category 1 drug by the SDA, and we are currently in the process of preparing for Phase I/II multi-center clinical trials in China.

### *Mechanism of action*

ZL-2302 was designed with broad-spectrum activity against resistant ALK mutations and brain penetration as the next-generation ALK inhibitor.

### *ZL-2302 Preclinical Development*

Comprehensive preclinical studies have been done to analyze ZL-2302. The key results are summarized as indicated below. Based on the study data, an IND package has been prepared and filed with the SDA.

*In vitro* pharmacology studies demonstrated that ZL-2302 can inhibit the ALK kinase in both wild-type and active against activated mutant forms (R1275Q, F1174L and F1245V) as well as the resistance gatekeeper mutant (ALK L1196M) and EML4-ALK oncogenic fusion. Such studies have also shown that it inhibits the proliferation of the Ba/F3 expressing wild-type and mutant forms of EML4-ALK and ALK dependent cell lines NCI-H3122, KARPAS-299 and SU-DHL-1. However, it was shown not to inhibit the proliferation of PC3, an ALK independent cell line, at concentrations up to 3  $\mu$ M.

*In vivo* patient-derived xenograft models showed ZL-2302 had antitumor activity in mice bearing the ALK-dependent and Crizotinib-resistant tumors. It also has great brain penetration abilities in mice and can inhibit the intracranial tumor growth in the ALK-dependent xenograft model. The brain-to-plasma ratio of drug exposure is 1.26, which indicated it has good brain penetration.

Preclinical studies have shown that it can be easily absorbed after oral administration with the 15-75% bioavailability in different species. The drug can be widely distributed in the body, but high drug concentration was found in tumor tissues and lung. No drug accumulation was found after repeated dose administration. Safety pharmacology, general toxicology and gene toxicity studies in different species showed ZL-2302 has a good safety profile. No significant toxicity was found. All adverse effects found in the studies are reversible and can be managed and monitored.

## **Internal Discovery Programs**

Our in-house research and development team focuses on the development of immuno-therapies and targeted therapies for the treatment of oncology. Our team members have been directly involved in the discovery, development and commercialization of several successful global drug launches, including fruguintinib and savolitinib while they were at Hutchison Medi-Pharma. We have collaborations with leading academic institutions in China, Tsinghua University and Shanghai Institute of Materia Medica, to support our in-house research projects. We have identified one immune-oncology candidate that is currently under preclinical development

## **Overview of Our License Agreements**

### ***Tesaro***

In September 2016, we entered into a collaboration, development and license agreement with TESARO Inc., or Tesaro, under which we obtained an exclusive sub-license under certain patents and know-how that Tesaro licensed from Merck, Sharp & Dohme Corp. (a subsidiary of Merck & Co. Inc.), or Merck Corp., and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize Tesaro's proprietary PARP inhibitor, niraparib (ZL-2306), in mainland China, Hong Kong and Macau, or licensed territory, in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). We also obtained the right of first negotiation to obtain a license from Tesaro to develop and commercialize certain follow-on compounds of niraparib being developed by Tesaro in our licensed field and licensed territory. Under the agreement, we agreed not to research, develop or commercialize certain competing products and we also granted Tesaro the right of first refusal to license certain immuno-oncology assets developed by us.

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

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

Under the terms of the agreement, we made an upfront payment of \$15.0 million to Tesaro. If we achieve a specified regulatory, development and commercialization milestones, we may be required to pay aggregate milestone payments up to \$39.5 million to Tesaro. In addition, if we successfully develop and commercialize the licensed products, we will pay Tesaro tiered royalties at percentage rates in the mid- to high-teens on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis. In February 2018, we entered into an amendment with Tesaro to eliminate Tesaro's option to co-market niraparib in the licensed territory.

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

### ***Paratek***

In April 2017, we entered into a license and collaboration agreement with Paratek Bermuda, Ltd., a subsidiary of Paratek Pharmaceuticals, Inc., under which we obtained both an exclusive license under certain patents and know-how of Paratek Bermuda Ltd. and an exclusive sub-license under certain intellectual property that Paratek Bermuda Ltd. licensed from Tufts University to develop, manufacture, use, sell, import and commercialize omadacycline (ZL-2401) in mainland China, Hong Kong, Macau and Taiwan, or licensed territory, in the field of all human therapeutic and preventative uses other than biodefense, or the licensed field. Under certain circumstances, our exclusive sub-license to certain intellectual property Paratek Bermuda Ltd. licensed from Tufts University may be converted to a non-exclusive license if Paratek Bermuda Ltd.'s exclusive license from Tufts University is converted to a non-exclusive license under the Tufts Agreement. We also obtained the right of first negotiation to be Paratek Bermuda Ltd.'s partner to develop certain derivatives or modifications of omadacycline in our licensed territory. Paratek Bermuda Ltd. retains the right to manufacture the licensed product in our licensed territory for use outside our licensed territory. We also granted to

Paratek Bermuda Ltd. a non-exclusive license to certain of our intellectual property for Paratek Bermuda Ltd. to develop and commercialize licensed products outside of our licensed territory. Under the agreement, we agreed not to commercialize certain competing products in our licensed territory. We are obligated to use commercially reasonable efforts to develop and commercialize the licensed products in our licensed field and licensed territory, including making certain regulatory filings within a specified period of time.

Under the terms of the agreement, we made an upfront payment to Paratek Bermuda Ltd. of \$7.5 million and we may be required to pay milestone payments up to \$54.5 million to Paratek Bermuda Ltd. for the achievement of certain development and sales milestone events. In addition, we will pay to Paratek Bermuda Ltd. tiered royalties at percentage rates in the range of low- to mid-teens on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

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

#### ***Five Prime***

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

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

Under the terms of the agreement, we made an upfront payment of \$5 million to Five Prime. Additionally, we may be required to pay aggregate developmental and regulatory milestone payments up to \$39 million to Five Prime.

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

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

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

## **Bristol-Myers Squibb**

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

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

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

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

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

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

## **Entasis**

In April 2018, we entered into a collaboration and license agreement with Entasis Therapeutics Holdings, Inc., or Entasis, under which we obtained exclusive rights to develop and commercialize Entasis's proprietary compounds known as ETX2514 and ETX2514SUL, with the possibility of developing and commercializing a combination of such compounds with Imipenem, in mainland China, Hong Kong, Macau, Taiwan, Korea, Vietnam, Thailand, Cambodia, Laos, Malaysia, Indonesia, the Philippines, Singapore, Australia, New Zealand and Japan, or the territory. Our rights to develop and commercialize the licensed products are limited to the lead product (ETX2514SUL) until such product receives FDA approval in the U.S.

Under the terms of the agreement, we are responsible for (i) developing and commercializing the licensed products in the territory under a mutually agreed development plan, and (ii) providing Entasis (or its contract research organization) with clinical and financial support in the territory for the global pivotal Phase III clinical trial of ETX2514SUL as set forth in mutually agreed development plans.

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



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

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

## **GSK**

In October 2016, we entered into a license and transfer agreement with GlaxoSmithKline (China) R&D Co., Ltd, or GSK China, an affiliate of GSK, under which GSK China transferred to us its worldwide, exclusive license under certain patents, know-how, inventory and regulatory materials to develop, manufacture, use and commercialize FUGAN (ZL-3101) and GRAPE, two formulations comprising extracts from traditional Chinese herbs, for the treatment, diagnosis and prevention of any human diseases. In connection with such transfer, GSK China also assigned to us its agreements with Chengdu Bater Pharmaceutical Co., Ltd, or Bater, and Traditional Chinese Medical Hospital, Xinjiang Medical University, or Xinjiang, relating to FUGAN and GRAPE.

We are obligated to use commercially reasonable efforts to develop at least one licensed product, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or an anniversary date in the mid-teens of the first commercial sale of the licensed product, in each case on a product-by-product and country-by-country basis. Under the terms of the agreement, we made an upfront payment to GSK China of RMB 4.5 million. We may be required to make milestone payments to GSK China up to RMB 55.0 million for the achievement of certain development milestone events. In addition, we will pay to GSK China tiered royalties at percentage rates in the low- to mid-single digits on the net sales of FUGAN and GRAPE, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or an anniversary date in the mid-teens of the first commercial sale of the licensed product, in each case on a product-by-product and country-by-country basis. GSK China made a milestone payment to Bater of RMB 4.0 million and we have made a milestone payment to Bater of RMB 2.0 million. We also assumed the obligation to make additional milestone payments up to RMB 4.0 million and RMB 10.0 million under the assigned agreements with Bater and Xinjiang, respectively, for milestones achieved after the assignment of the agreements to us. If we sublicense, sell or otherwise divest the patents and know-how acquired from GSK China to third parties before the completion of certain development phase, we are also required to pay to GSK China half of our income attributed to such sublicense, sale, or divestiture.

The agreement with GSK China will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach. In addition, we have the right to terminate the agreement for convenience upon advance notice to GSK China at any time after completion of a certain stage of development work. GSK China has the right to terminate the agreement if we fail to reach certain development milestones, fail to make payments owed to GSK China, or fail to use commercially reasonable efforts in the development and commercialization of the licensed products and cannot correct such failure in the agreed period. Upon termination of the agreement with GSK China for our uncured breaches, we must, among other actions, assign back to GSK China and/or Bater and Xinjiang the transferred know-how and the license agreements between GSK China and Bater and Xinjiang.

## **Sanofi**

In July 2015, we entered into a license agreement with Sanofi, under which we obtained an exclusive and worldwide license under certain patents and know-how of Sanofi to develop, manufacture, use, sell, import and commercialize Sanofi's ALK inhibitor, or the licensed compound, or ZL-2302 for any oncology indications in humans. Sanofi retains the non-exclusive right to use the licensed compound to conduct internal research and manufacture the licensed compound and licensed product for such research.

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

Under the terms of the agreement, we made upfront payments to Sanofi totaling \$0.5 million. We may be required to make milestone payments to Sanofi up to \$31.0 million for the achievement of certain development and regulatory milestone events. In addition, we will pay Sanofi tiered royalties at percentage rates in the range of high single digits to low double digits on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and country-by-country basis. If we sublicense, transfer or assign (other than through a change of control transaction) the right to the licensed product to third parties, we are also required to pay to Sanofi a share of our sublicensing income.

The agreement with Sanofi will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to Sanofi. Sanofi has the right to terminate the agreement if we challenge any of the licensed patents. Sanofi may also terminate the agreement for our bankruptcy or insolvency. Upon any termination of the agreement, in addition to other obligations, we must grant to Sanofi an exclusive license under certain of our intellectual property to commercialize the licensed product.

## **UCB**

In September 2015, we entered into a license agreement with UCB Biopharma Sprl, under which we obtained an exclusive and worldwide license under certain patents and know-how of UCB Biopharma Sprl to develop, manufacture, use, sell, import and commercialize UCB Biopharma Sprl's proprietary antibody UCB3000, or the licensed compound, or ZL-1101 for the treatment, prevention and diagnosis of any human diseases. UCB Biopharma Sprl retains the non-exclusive right to use the licensed compound for its own research purposes.

We are obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in the U.S. and EU and to file an IND within a certain specified time period. UCB Biopharma Sprl has the right of first negotiation to acquire the rights to the licensed products back from us upon our successful completion of certain clinical development work.

Under the terms of the agreement, we made upfront payments to UCB Biopharma Sprl totaling \$0.8 million. If we successfully develop and commercialize the licensed products, we may be required to make milestone payments to UCB Biopharma Sprl up to an aggregate of \$106.7 million for the achievement of certain development, regulatory and sales milestone events. In addition, we will pay to UCB Biopharma Sprl royalties at percentage rates in the range of mid-single digits to low-double digits on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and country-by-country basis. If we sublicense the right to the licensed product to third parties, we are also required to pay to UCB Biopharma Sprl a low-double digit percentage share of our sublicensing income.

The agreement with UCB Biopharma Sprl will remain in effect until the expiration of the royalty term and may be earlier terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. In addition, we have the right to terminate the agreement for convenience at any time upon advance notice to UCB Biopharma Sprl. Each party also has the right to terminate the agreement if the other party challenges its patents. Upon our termination of the agreement for convenience or UCB Biopharma Sprl's termination for our material breach, bankruptcy or patent challenges, among other obligations, we must grant UCB Biopharma Sprl an exclusive license under certain of our intellectual property to develop and commercialize ZL-1101.

## **Competition**

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

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

## Patents and Other Intellectual Property

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

### Patents

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

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

### ZL-2306

As of December 31, 2017, we exclusively licensed two issued patents in the PRC directed to ZL-2306’s free base compound, and salts thereof, and analogues of ZL-2306. These issued patents are projected to expire between 2027 and 2028. We also exclusively licensed one pending patent application in the PRC directed to a salt that covers 4-methylbenzenesulfonate monohydrate, the active pharmaceutical ingredient, or API, of ZL-2306. If this patent application issues as a patent, such patent will be projected to expire in 2029. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC.

### ZL-2401

As of December 31, 2017, we exclusively licensed four issued patents in the PRC directed to ZL-2401’s compound, formulations and crystal form and one pending patent application in the PRC directed to other crystalline forms of ZL-2401. The issued composition of matter patent covering ZL-2401 is projected to expire in 2021 and the other two issued patents are projected to expire in 2029. If the two patent applications are issued, they are expected to expire in 2029. We have also exclusively licensed two issued patents in Hong Kong and Taiwan, respectively that cover a crystalline salt form of ZL-2401, which expire in 2029. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC, Hong Kong and Taiwan.

#### *FPA144*

As of December 31, 2017, we exclusively licensed one issued patent in the PRC and one issued patent in Hong Kong. These issued patents are directed to certain anti-FGFR2b antibodies, and are projected to expire in 2029. We have also exclusively licensed one pending patent application in the PRC, two pending patent applications in Taiwan, one pending patent application in Hong Kong. If issued, claims of these patent applications are projected to expire between 2034 and 2036. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC, Hong Kong and Taiwan.

#### *ZL-2301*

As of December 31, 2017, we exclusively licensed four issued patents in the PRC, one issued patent in Taiwan and one issued patent in Hong Kong that relate to ZL-2301. Of these issued patents, one patent in the PRC is a composition-of-matter patent that covers the ZL-2301 compound and its analogues. One patent in the PRC covers the medical use of ZL-2301. These patents are projected to expire in 2023. Our exclusively licensed patents also include a patent in the PRC that covers a manufacturing process for intermediates useful in the synthesis of ZL-2301's API. This patent is projected to expire in 2027. In addition, one patent we exclusively licensed in the PRC covers a crystal form of brivanib alaninate and is projected to expire in 2026. The issued patent in Hong Kong that we exclusively licensed is projected to expire in 2023. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions other than the PRC and Hong Kong.

#### *ETX2514*

As of the effective date of the Entasis Agreement, we exclusively licensed one issued patent in the PRC, one issued patent in Japan, and a corresponding issued patent or pending patent application in each of several additional jurisdictions in the territory of the Entasis Agreement, including Australia, Hong Kong, Taiwan and Korea. These issued patents or pending applications are directed to certain beta-lactamase inhibitor compounds, including ETX2514, and are projected to expire in 2033. We have also exclusively licensed a second family of patent applications having one pending patent application in each of the PRC, Japan, Australia, Taiwan, Korea, and four other jurisdictions in the territory. If issued, claims of these patent applications are projected to expire in 2035. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the territory of the Entasis Agreement.

#### *ZL-3101*

As of December 31, 2017, we own one issued patent in the PRC directed to the pharmaceutical composition and therapeutic uses of ZL-3101. Our issued patent in the PRC is projected to expire in 2029. We do not own or have an exclusive license to any patents or patent applications in any jurisdictions outside of the PRC.

#### *ZL-2302*

As of December 31, 2017, we exclusively licensed one issued patent application in the PRC. We also exclusively licensed two issued U.S. patents, one pending U.S. patent application, and 15 issued patents and 28 pending patent applications in other jurisdictions, including Australia, Canada, Europe, Japan, South Korea and Taiwan. The issued patents in this portfolio are directed to the pharmaceutical composition and therapeutic uses of ZL-2302, and are projected to expire between 2032 and 2033, excluding any additional term for patent term adjustments or patent term extensions in jurisdictions where such adjustments and extensions are available.

#### *ZL-1101*

As of December 31, 2017, we exclusively licensed one issued patent and one pending patent application in the PRC. We also exclusively licensed three issued U.S. patents, two pending U.S. patent applications and approximately 26 issued patents and 44 pending patent applications in other jurisdictions, including Australia, Canada, Europe, Hong Kong, Japan, South Korea, South Africa and Taiwan. The issued patents and pending patent applications in this portfolio cover antibody sequences and therapeutic uses of ZL-1101. The issued patents in this portfolio are projected to expire between 2030 and 2032.

### *Patent Term*

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

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

### *Trade Secrets*

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

### *Trademarks and domain names*

We conduct our business using trademarks with various forms of the “ZAI LAB” and “再鼎医药” brands, as well as domain names incorporating some or all of these trademarks.

### **Employees**

As of December 31, 2017, we employed a total of 88 full-time employees, including a total of 25 employees with M.D. or Ph.D. degrees. Of our workforce, 72 employees are engaged in research and development. None of our employees is represented by labor unions or covered by collective bargaining agreements.

### **Raw Materials and Supplies**

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

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

## Quality Control and Assurance

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

## Regulation

### Government Regulation of Pharmaceutical Product Development and Approval

#### *PRC regulation of pharmaceutical product development and approval*

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

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

To implement the regulatory reform introduced by Innovation Opinion, the SDA is currently revising the fundamental law, regulations and rules regulating pharmaceutical products and the industry, which includes the framework law known as the PRC Drug Administration Law. However, as of April 15, 2018, the implementing regulations for many of the reforms in the Innovation Opinion had not been promulgated, and therefore, the details in the implementation of the regulatory changes remained uncertain in some respects.

#### *Regulatory authorities*

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

- monitoring and supervising the administration of pharmaceutical products, medical appliances and equipment as well as cosmetics in the PRC;
- formulating administrative rules and policies concerning the supervision and administration of the pharmaceutical, medical device, and cosmetics industry;
- evaluating, registering and approving of new drugs, generic drugs, imported drugs and traditional Chinese medicine, or TCM;
- approving and issuing permits for the manufacture and export/import of pharmaceutical products and medical appliances and equipment and approving the establishment of enterprises to be engaged in the manufacture and distribution of pharmaceutical products; and
- examining and evaluating the safety of pharmaceutical products, medical devices, and cosmetics and handling significant accidents involving these products.

The National Health and Family Planning Commission, or NHFPC, is rebranded as the National Health Commission (or NHC). The NHC is an authority at the ministerial level under the State Council and is primarily responsible for national public health. The NHC combines the former NHFPC, the Leading Group Overseeing Medical and Healthcare Reform under the State Council, the China National Working Commission on Aging, partial responsibilities of the Ministry of Industry and Information Technology in relation to tobacco control, and partial responsibilities from the State Administration of Work Safety in relation to occupational safety. The predecessor of NHFPC is the Ministry of Health, or MOH. Following the establishment of the former State Food and Drug Administration (SFDA) in 2003, the MOH was put in charge of the overall administration of the national health in the PRC excluding the pharmaceutical industry. The MOH performs a variety of tasks in relation to the health industry such as establishing medical institutes and producing professional codes of ethics for public medical personnel. The MOH is also responsible for overseas affairs, such as dealings with overseas companies and governments.

As of April 15, 2018, the details in the implementation of the changes of the regulatory authorities are still under development and remained uncertain in some respects. The central government expects to complete the restructuring at the state level by the end of 2018. The provincial governments must submit proposal for organizational changes or final appointments by September 2018, with the goal to complete restructuring by the end of 2018. Municipal and county level authorities must complete the restructure by first quarter of 2019.

#### *Healthcare System Reform*

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

- One of the main objectives of the reform was to establish a basic healthcare system to cover both urban and rural residents and provide the Chinese people with safe, effective, convenient and affordable healthcare services. As of 2017, basic medical insurance coverage has reached more than 95% of the country's population. By 2020, a basic healthcare system covering both urban and rural residents should be established.
- Another main objective of reform was to improve the healthcare system, through the reform and development of a graded diagnosis and treatment system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision.
- The reforms aimed to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education were to be provided to urban and rural residents. In the meantime, the reforms also encouraged innovations by pharmaceutical companies to eliminate pharmaceutical products that fail to prove definite efficacy and positive risk-benefit ratio.
- The key tasks of the reform in 2016 were as follows: (1) to deepen the reform of public hospitals, (2) to accelerate the development of a graded diagnosis and treatment system, (3) to consolidate and improve the universal medical insurance system, (4) to guarantee drug supply, (5) to establish and improve a comprehensive supervision system, (6) to cultivate talented health-care practitioners, (7) to stabilize and perfect the basic public health service equalization system, (8) to advance the construction of health information technology, (9) to accelerate the development of the health services industry generally, and (10) to strengthen organization and implementation.

#### *Drug Administration Laws and Regulations*

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

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

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

In October 2017, the former CFDA released an amendment to the Drug Administration Law (Draft for Public Comments). This draft amendment reflects the former CFDA's recent reform initiatives on the market authorization holder system, clinical trial practices, drug review and approval practices and GMP and GSP certification. This amendment is expected to be promulgated in early 2018.

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

#### *Good Laboratories Practice Certification for Nonclinical Research*

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

#### *Animal Testing Permits*

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

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



## *Administrative measures for drug registration*

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

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

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

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

## *Regulations on the Clinical Trials and Registration of Drugs*

### **Four Phases of Clinical Trials**

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

### **Approval Authority for Clinical Trial Applications**

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

### **Special Examination and Approval for Domestic Category 1 Drugs**

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

In March 2016, the former CFDA issued the Reform Plan for Registration Category of Chemical Medicine, or the Reform Plan, which outlined the reclassifications of drug applications under the Administrative Measures for Drug Registration. Under the Reform Plan, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have

equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the Domestic New Drug Application and the Imported Drug Application procedures under the Administrative Measures for Drug Registration, respectively.

According to the Special Examination and Approval Provisions, the former CFDA conducts special examination and approval for new drug registration applications when:

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

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

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

### **Drug Clinical Practice Reform and Compliance with GCP**

In October 2017, the Chinese government announced an administrative reform of clinical trial institutions. Certification of clinical trial institutions by the former CFDA and the former National Health and Family Planning Commission of the PRC is no longer required. Under this reform, a clinical trial institution can be engaged by a drug marketing authorization applicant (i.e., a sponsor) to conduct a drug clinical study after it has been duly recorded with the online platform designated by the former CFDA. In October 2017, the former CFDA released the Rules for Administration of Drug Clinical Trial Institutions (Draft for Public Comments). This draft specifies requirements for clinical trial institutions and recordal procedures. Pursuant to this draft, a clinical trial institution should comply with the GCP requirements and be capable of undertaking pharmaceutical clinical trials. It should evaluate or engage a third party to evaluate its clinical trial proficiency, facilities and expertise. A drug marketing authorization applicant should only engage a duly recorded clinical trial institution to carry out a drug clinical trial.

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

### **Pilot Plan for the Marketing Authorization Holder System**

Under the authorization of the Standing Committee of the National People's Congress, the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder Mechanism on May 26, 2016, which provides a detailed pilot plan for the marketing authorization holder system, or the MAH System, for drugs in 10 provinces in China. Under the MAH System, domestic drug research and development institutions and individuals in the piloted regions are eligible to be holders of drug registrations without having to become drug manufacturers. The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and GMP-

certified, and are also located within the piloted regions. Drugs qualified for the MAH System are: (1) new drugs (including Category 1 and 2 drugs under the Reform Plan) approved after the implementation of the MAH System; (2) generic drugs approved as Category 3 or 4 drugs under the Reform Plan; (3) previously approved generics that have passed the equivalence assessments against originator drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the piloted regions, but have been moved out of the piloted regions due to corporate mergers or other reasons.

The above mentioned draft amendment to the Drug Administration Law (dated October 2017) proposes to roll out this MAH System nationwide. Uncertainties exist as to how this MAH System will be implemented universally to substitute the Pilot Plan.

### **Administrative Protection and Monitoring Periods for New Drugs**

According to the Administrative Measures for Drug Registration, the Implementing Regulations of the Drug Administration Law and the Reform Plan, the SDA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for Category 1 new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs.

During the monitoring period of a new drug, the SDA will not accept other applications for new drugs containing the same active ingredient. This renders an actual five-year exclusivity protection for Category 1 new drugs. The only exception is that the SDA will continue to handle any application if, prior to the commencement of the monitoring period, the SDA has already approved the applicant's clinical trial for a similar new drug. If such application conforms to the relevant provisions, the SDA may approve such applicant to manufacture or import the similar new drug during the remainder of the monitoring period.

### **Non-Inferiority Standard**

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

### **New Drug Application**

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

### *International Multi-Center Clinical Trials Regulations*

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

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;
- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the drug under clinical trial, and satisfy the statistical and relevant legal requirements; and

- The onshore and offshore international multi-center clinical trial research centers shall be subject to on-site inspections by competent PRC governmental agencies.

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

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

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

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

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

#### *Drug Technology Transfer Regulations*

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

#### **Conditions for the Application for New Drug Technology Transfer**

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

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

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

### **Conditions for the Application of Drug Production Technology Transfer**

Applications for drug production technology transfer may be submitted if:

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

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

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

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

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

### *Permits and Licenses for Manufacturing of Drugs*

#### **Pharmaceutical Manufacturing Permit**

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

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

#### **Business Licenses**

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

## **GMP Certificates**

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

A GMP certification certifies that a manufacturer's factory and quality management system have met certain criteria for engaging in the planning and manufacturing of drug products, which address institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, maintenance of sales records and manner of handling customer complaints and adverse reaction reports. In January 2011, the MOH issued an updated set of GMP standards, also known as the new GMP, to replace the previous version issued in 1998. There are also five annexes to the new GMP issued by the former SFDA in February 2011, with detailed requirements for the manufacture of sterile drugs, drug/substances/APIs, biologics, blood products and traditional Chinese medicines. Two additional annexes were published in May 2015, with detailed requirements for IT systems and validation.

The GMP certificate is valid for a term of five years and an application for renewal must be submitted six months prior to its expiration date. The SDA and its provincial branches are authorized to monitor the continued compliance of pharmaceutical manufacturers, for example, by a follow-up inspection of implementation of the GMP requirements. Failure to continuously comply with the statutory requirements may lead to rectification orders imposed on the manufacturers. Penalties for breach of GMP compliance can vary depending on the degree of seriousness. Administrative sanctions range from a rectification notice to monetary fines, suspension of production and business operation, and revocation of the pharmaceutical manufacturing permit and the Pharmaceutical GMP Certificate.

### ***U.S. Regulation of Pharmaceutical Product Development and Approval***

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

Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's GLP regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable good clinical practices, or GCPs and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review and review by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced to assess compliance with the FDA's cGMP;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA; and
- payment of user fees and FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

### *Preclinical Studies*

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, or NCEs, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the pre-clinical tests must comply with federal regulations, including GLPs and the U.S. Department of Agriculture's Animal Welfare Act. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

### *Clinical Studies*

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

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

- Phase I: The drug is initially introduced into a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients with the target diseases.

- Phase II: The drug is administered to a limited patient population to determine dose tolerance and optimal dosage required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy.
- Phase III: The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a drug during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA. A pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the drug. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need. Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may mandate the performance of Phase IV clinical trials.

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

#### *NDA Submission and FDA Review Process*

Following trial completion, trial results and data are analyzed to assess safety and efficacy. The results of product development, pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling for the drug, information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application may include negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product to the satisfaction of the FDA. Under federal law, the submission of most NDAs is subject to the payment of an application user fees; a waiver of such fees may be obtained under certain limited circumstances. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.



Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2017, the user fee for an application requiring clinical data, such as an NDA, is \$2,038,100. PDUFA also imposes an annual product fee for human drugs (\$97,750) and an annual establishment fee (\$512,200) on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA conducts a preliminary review of an NDA within 60 days of receipt and informs the sponsor by the 74<sup>th</sup> day after FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for a "priority review" NDA. The FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

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

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

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

minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

### **Section 505(b)(2) NDAs**

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

#### *Special FDA Expedited Review and Approval Programs*

The FDA has various programs, including Fast Track Designation, accelerated approval, priority review and Breakthrough Therapy Designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

### **Fast Track Designation**

To be eligible for a Fast Track Designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast track designation determination within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with FDA, FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

### **Priority Review**

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a priority review.

## **Breakthrough Therapy Designation**

Under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted by Congress in 2012, a sponsor can request designation of a drug candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA may take certain actions, such as holding timely meetings with the sponsor through the development process and providing timely advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

## **Accelerated Approval**

FDASIA also codified and expanded on FDA’s accelerated approval regulations, under which FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit over existing treatments based on a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. This determination takes into account the severity, rarity or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform Phase IV or post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track Designation, priority review, accelerated approval and Breakthrough Therapy Designation, do not change the standards for approval, do not receive either more or less favorable review from FDA based on this designation, and may not ultimately expedite the development or approval process.

## *Pediatric Trials*

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

## *Orphan Drug Designation and Exclusivity*

Under the Orphan Drug Act, FDA may designate a drug product as an “orphan drug” if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but the product will be entitled to orphan product exclusivity, meaning that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is typically one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent that covers the approved drug (and to only those patent claims covering the approved drug, a method for using it, or a method for manufacturing it) is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a NCE. A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Specifically, the applicant must certify with respect to each relevant patent that: the required patent information has not been filed; the listed patent has expired; the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

#### *Post-Marketing Requirements*

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on

promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that drugs be manufactured in specific approved facilities and in accordance with cGMP. Applicants may also rely on third parties for the production of clinical and commercial quantities of drugs, and these third parties must operate in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using third party contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed or tested by them. Such enforcement actions include issuance of warning letters, injunctions, suspension of manufacturing operations, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase IV testing, risk minimization action plans and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

#### *Other U.S. Regulatory Matters*

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Health Care Reform Law, as amended by the Health Care and Education Affordability Reconciliation Act, or ACA. If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

#### *Rest of the World Regulation of Pharmaceutical Product Development and Approval*

For other countries outside of China and the United States, such as countries in Europe, Latin America or other parts of Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and ethical principles.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### **Coverage and Reimbursement**

#### ***PRC Coverage and Reimbursement***

Historically, most Chinese healthcare costs have been borne by patients out-of-pocket, which has limited the growth of more expensive pharmaceutical products. However, in recent years the number of people covered by government and private insurance has increased. According to the PRC National Bureau of Statistics, as of December 31, 2015, 666 million urban employees and residents in China were enrolled in the national medical insurance program, representing an increase of 11.44% from December 31, 2014. The PRC government has announced a plan to give every person in China access to basic healthcare by year 2020.

#### *Reimbursement under the National Medical Insurance Program*

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. The State Council expects the pilot Urban Resident Basic Medical Insurance to cover the whole nation by 2010.

Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the Medical Insurance Catalogue. The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee, jointly issued by several authorities including the Ministry of Labor and Social Security and the MOF, among others, on May 12, 1999, provides that a pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements:

- it is set forth in the Pharmacopoeia of the PRC;
- it meets the standards promulgated by the SDA; and
- if imported, it is approved by the SDA for import.

Factors that affect the inclusion of a pharmaceutical product in the Medical Insurance Catalogue include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public.

The PRC Ministry of Human Resources and Social Security, together with other government authorities, has the power to determine the medicines included in the NRDL. In February 2017, the PRC Ministry of Human Resources and Social Security released the 2017 NRDL. The 2017 NRDL expands its scope and covers 2,535 drugs in total, including 339 drugs that are newly added. The 2017 NRDL reflects an emphasis on innovative drugs and drugs that treat cancer and other serious diseases. For instance, most of the innovative chemical drugs and biological products approved in China between 2008 and the first half of 2016 have been included in the 2017 NRDL or its candidate list.

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

Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price. The percentage of reimbursement for Part B medicines differs from region to region in the PRC.

The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the national medical insurance program in a calendar year is capped at the amounts in such participant's individual account under such program. The amount in a participant's account varies, depending on the amount of contributions from the participant and his or her employer.

#### *National List of Essential Drugs*

On August 18, 2009, MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Drugs and the Guidelines on the Implementation of the National List of Essential Drugs System, which aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National List of Essential Drugs. MOH promulgated the National List of Essential Drugs (Catalog for the Basic Healthcare Institutions) on August 18, 2009, and promulgated the revised National List of Essential Drugs on March 13, 2013. According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in National List of Essential Drugs. The drugs listed in National List of Essential Drugs shall be purchased by centralized tender process and shall be subject to the price control by NDRC. Remedial drugs in the National List of Essential Drugs are all listed in the Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

#### *Commercial Insurance*

On October 25, 2016, the State Council and the Communist Party of China jointly issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

#### *Price Controls*

Instead of direct price controls which were historically used in China but abolished in June 2016, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices as discussed below.

The Guiding Opinions concerning the Urban Medical and Health System Reform, promulgated on February 21, 2000, aims to regulate the purchasing process of pharmaceutical products by medical institution. The MOH and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions promulgated on July 7, 2000 and the Notice on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions promulgated on August 8, 2001, medical institutions established by county or higher level government or state-owned enterprises (including state-controlled enterprises) are required to implement centralised tender procurement of drugs.

The MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation), or there Centralised Procurement Regulations, on March 13, 2002, and promulgated Sample Document for Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation), or the Centralised Tender Sample Document in November 2001, to implement the tender process requirements and ensure the requirements are followed uniformly throughout the country. The Centralised Tender Regulations and the Centralised Tender Sample Document provide rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On January 17, 2009, the MOH, the SDA and other four national departments jointly promulgated the Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions. According to the notice, public medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralised procurement. Each provincial government shall formulate its catalogue of drugs subject to centralised procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by public medical institutions shall be covered by the catalogue of drugs subject to centralised procurement. On July 7, 2010, the MOH and six other ministries and commissions jointly promulgated the Notice on Printing and Distributing the Working Regulations of Medical Institutions for Centralised Procurement of Drugs to further regulate the centralised procurement of drugs and clarify the code of conduct of the parties in centralised drug procurement.

The centralized tender process takes the form of public tender operated and organised by provincial or municipal government agencies. The centralised tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralised tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.

#### *Insurance Reform*

The Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents issued by the State Council on January 3, 2016, call for the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangement who participate in the basic medical insurance for urban employees.

According to the Main Tasks of Healthcare System Reform in 2016 issued by the General Office of the State Council on April 21, 2016, the key tasks of the medical insurance reform are: (1) to advance the establishment of the mechanisms of stable and sustainable financing and security level adjustment, (2) to advance the integration of the basic medical insurance systems for urban and rural residents, (3) to consolidate and improve the system for serious illness insurance for urban and rural residents, (4) to reform medical insurance payment methods, and (5) to advance the development of commercial health insurance.



The Human Resources and Social Security Departments issued the Guiding Opinions on Actively Promoting the Coordinated Healthcare, Medical Insurance and Pharmaceutical Reforms on June 29, 2016, which state that reform will focus on exploring and leveraging the fundamental role of medical insurance through further integration of medical insurance systems in all aspects, deepening the reform of the payment methods for medical insurance and promoting innovation in the medical insurance management system.

According to the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System issued by the State Council on December 27, 2016, one of the guiding principles is to insist on the reform of the coordinated development among healthcare, medical insurance and pharmaceutical systems. The reform intends to establish a complete policy structure in healthcare by 2017, including by perfecting the graded diagnosis and treatment system, establishing and improving the comprehensive supervision and modern hospital management systems, improving the universal medical insurance system, perfecting drug production and distribution policies and strengthening public health service, medical service, medical insurance, drug supply, supervision and management systems throughout the healthcare industry.

### ***U.S. Coverage and Reimbursement***

Successful sales of our products or drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new product acceptance. These third-party payors are increasingly reducing reimbursements for medical drugs and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Medicare payment for some of the costs of prescription drugs may increase demand for drugs for which we receive marketing approval. However, any negotiated prices for our drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, if third-party payors do not consider a drug to be cost-effective compared to other available therapies, they may not cover such drugs as a benefit under their plans or, if they do, the level of payment may not be sufficient.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, enacted in March 2010, has had a significant impact on the health care industry. The ACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate

Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013, and, due to subsequent legislative amendments, will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

### ***Rest of the World Coverage and Reimbursement***

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal drugs for which their national health insurance systems provide reimbursement and to control the prices of medicinal drugs for human use. A member state may approve a specific price for the medicinal drug or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the medicinal drug on the market. Historically, drugs launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

### **Other Healthcare Laws**

#### ***Other PRC Healthcare Laws***

##### ***Advertising of Pharmaceutical Products***

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

##### ***Insert Sheet and Labels of Pharmaceutical Products***

According to the Measures for the Administration of the Insert Sheets and Labels of Drugs effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the SDA. A drug insert sheet should include the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage and adverse reaction.

##### ***Packaging of Pharmaceutical Products***

According to the Measures for The Administration of Pharmaceutical Packaging effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards. If no national or professional standards are available, the enterprise can formulate its own standards and put into implementation after obtaining the approval of the food and drug administration or bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its own packaging standard. Drugs that have not developed and received approval for packing standards must not be sold or traded in PRC (except for drugs for the military).

## **Other U.S. Healthcare Laws**

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

### *Anti-Kickback Statute*

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for, or to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines and possible exclusion from Medicare, Medicaid, and other federal health care programs. Exclusion would mean that our products were no longer eligible for reimbursement under federal healthcare programs.

### *False Claims*

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Analogous state law equivalents may apply and may be broader in scope than the federal requirements. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

### *Payments to Physicians*

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports to the government by March 31, 2014 and June 30, 2014, and the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

#### **Other Significant PRC Regulation Affecting Our Business Activities in China**

##### ***PRC Regulation of Foreign Investment***

Investment activities in China by foreign investors are principally governed by the Guidance Catalogue of Industries for Foreign Investment, or the Catalogue, which was promulgated and is amended from time to time by the MOFCOM and the National Development and Reform Commission. Pursuant to the latest Catalogue, amended and issued on June 28, 2017 and effective on July 28, 2017, or the 2017 Catalogue, industries listed therein are divided into two categories: encouraged industries and the industries within the catalogue of special management measures, or the Negative List. The Negative List is further divided into two sub-categories: restricted industries and prohibited industries. Establishment of wholly foreign-owned enterprises is generally allowed in industries outside of the Negative List. For the restricted industries within the Negative List, some are limited to equity or contractual joint ventures, while in some cases Chinese partners are required to hold the majority interests in such joint ventures. In addition, restricted category projects are subject to government approvals and certain special requirements. Foreign investors are not allowed to invest in industries in the prohibited category. Industries not listed in the Catalogue are generally open to foreign investment unless specifically restricted by other PRC regulations. Pursuant to the 2017 Catalogue, the manufacture of pharmaceutical products falls in the encouraged industries for foreign investments.

Under PRC law, the establishment of a wholly foreign-owned enterprise is subject to the approval of, or the requirement for record filing with, the MOFCOM or its local counterparts and the wholly foreign owned enterprise must register with the competent administrative bureau of industry and commerce. We have duly obtained the approvals from the MOFCOM or its local counterparts for our interest in our wholly-owned PRC subsidiaries and completed the registration of these PRC subsidiaries with the competent administrative bureau of industry and commerce.

The Interim Measures for Record-filing Administration of the Establishment and Change of Foreign-invested Enterprises, or FIE Record-filing Interim Measures, was issued by MOFCOM in October 2016 and revised in July 2017. Pursuant to FIE Record-filing Interim Measures, the establishment and change of foreign-invested enterprises are subject to record-filing procedures, instead of prior approval requirements, provided that the establishment or change does not involve special entry administrative measures. If the establishment or change of FIE matters involve the special entry administrative measures, the approval of the MOFCOM or its local counterparts is still required. Pursuant to the Announcement 2016 No. 22 of the National Development and Reform Commission and the MOFCOM dated October 8, 2016, the special entry administrative measures for foreign investment apply to restricted and prohibited categories specified in the Catalogue, and the encouraged categories are subject to certain requirements relating to equity ownership and senior management under the special entry administrative measures.

##### ***PRC Regulation of Commercial Bribery***

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third party promoters for the implementation of, or acting in

conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of failure to monitor their operating activities.

#### *PRC Regulation of Product Liability*

In addition to the strict new drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the PRC, or the PRC Civil Law, promulgated on April 12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

On February 22, 1993, the Product Quality Law of the PRC, or the Product Quality Law, was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised by the Ninth National People's Congress on July 8, 2000 and by the Eleventh National People's Congress on August 27, 2009. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep it confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

#### *PRC Tort Law*

Under the Tort Law of the PRC which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as issuance of a warning, recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages.

#### *PRC Regulation of Intellectual Property Rights*

China has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names.

#### **Patents**

Pursuant to the PRC Patent Law, most recently amended in December 2008, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten years from the date of application. The PRC Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention

or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the State Intellectual Property Office, or SIPO. Normally, the SIPO publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the SIPO for a substantive examination within three years from the date of application.

Article 20 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China.

### **Patent Enforcement**

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offences such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, and if the loss suffered by the patent holder arising from the infringement cannot be determined, the damages for infringement shall be calculated as the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

### **Medical Patent Compulsory License**

According to the PRC Patent Law, for the purpose of public health, the SIPO may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded.

### **Exemptions for Unlicensed Manufacture, Use, Sale or Import of Patented Products**

The PRC Patent Law provides five exceptions for unauthorized manufacture, use, sale or import of patented products. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope;

- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;
- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or
- Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, uses or imports patented drugs or patented medical equipment for the abovementioned person.

However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in PRC Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

### **Trade Secrets**

According to the PRC Anti-Unfair Competition Law, the term “trade secrets” refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders.

Under the PRC Anti-Unfair Competition Law which was promulgated on September 2, 1993 and was amended on November 4, 2017, business persons are prohibited from infringing others’ trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, intimidation, solicitation or coercion; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; or (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence. If a third party knows or should have known of the fact that an employee or former employee of the right owner of trade secrets or any other entity or individual conducts any of the illegal acts above mentioned, but still accepts, publishes, uses or allows any other to use such secrets, such practice shall be deemed as infringement of trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB100,000 to RMB500,000, where the circumstance is serious, the fine shall be between RMB500,000 to RMB3,000,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a Chinese court for loss and damages incurred due to the misappropriation.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

### **Trademarks and Domain Names**

**Trademark.** The PRC Trademark Law and its implementation rules protect registered trademarks. The PRC Trademark Office of State Administration of Industry and Commerce is responsible for the registration and administration of trademarks throughout the PRC. The Trademark Law has adopted a “first-to-file” principle with respect to trademark registration. As of June 30, 2017, we had two registered trademarks in China and four trademark applications pending outside China.

**Domain Name.** Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names. We have registered zaibio.com, zaibiotech.com, zailaboratory.com, zailab.com.cn, zaimedicine.com and zaipharma.com.

### *PRC Regulation of Labor Protection*

Under the Labor Law of the PRC, effective on January 1, 1995 and subsequently amended on August 27, 2009, the PRC Employment Contract Law, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, employers must

establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the PRC.

Pursuant to the Law of Manufacturing Safety of the PRC effective on November 1, 2002 and amended on August 27, 2009 and August 31, 2014, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable PRC laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011, the Interim Regulations on the Collection and Payment of Social Security Funds which became effective on January 22, 1999, Interim Measures concerning the Maternity Insurance of Employees which become effective on December 14, 1994, and the Regulations on Work-related Injury Insurance which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

#### ***Regulations Relating to Foreign Exchange Registration of Offshore Investment by PRC Residents***

In July 2014, SAFE issued the SAFE Circular 37, and its implementation guidelines, which abolished and superseded the SAFE Circular 75. Pursuant to SAFE Circular 37 and its implementation guidelines, PRC residents (including PRC institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle, or SPV, directly established or indirectly controlled by PRC residents for the purposes of offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such PRC residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a PRC resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the PRC individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or PRC residents to penalties under PRC foreign exchange administration regulations.

#### ***Regulations Relating to Employee Stock Incentive Plan***

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules, which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies issued by SAFE on March 28, 2007. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these



circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

#### *Regulations Relating to Dividend Distribution*

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

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

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

#### *Regulations Relating to Foreign Exchange*

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, or SAFE Circular No. 142, regulating the conversion by a foreign-invested enterprise of foreign currency-registered capital into RMB by restricting how the converted RMB may be used. SAFE Circular No. 142 provides that the RMB capital converted from foreign currency registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within China. SAFE also strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign-invested enterprises. The use of such RMB capital may not be changed without SAFE's approval, and such RMB capital may not in any case be used to repay RMB loans if the proceeds of such loans have not been used. In March 2015, SAFE issued SAFE Circular No. 19, which took effective and replaced SAFE Circular No. 142 on June 1, 2015. Although SAFE Circular No. 19 allows for the use of RMB converted from the foreign currency-denominated capital for equity investments in China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted RMB for purposes beyond the business scope, for entrusted loans or for inter-company RMB loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to nonassociated enterprises. Violations of SAFE Circular 19 or Circular 16 could result in administrative penalties.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e.g., pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e.g. profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of foreign exchange as a result of capital

reduction, liquidation, early repatriation or share transfer in a foreign-invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment, or SAFE Circular No. 13, which took effect on June 1, 2015. SAFE Circular No. 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment.

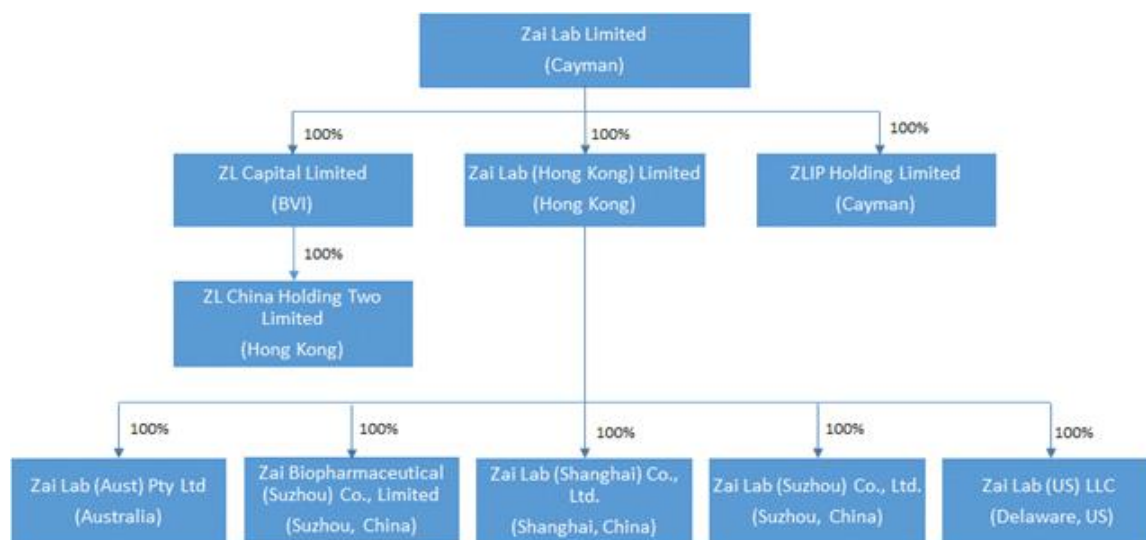
*Other PRC National- and Provincial-Level Laws and Regulations*

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients’ medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control. We believe that we are currently in compliance with these laws and regulations; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

**C. Organizational Structure**

The following diagram illustrates our corporate structure, including our principal subsidiaries, as of the date of this Annual Report on Form 20-F:



## **D. Property, Plant and Equipment**

We are headquartered in Shanghai where we have our main administrative and laboratory offices, which is 3,632 square meters in size. The lease for this facility expires in 2020. We also have a 98 square meter office in Beijing, the lease for which expires in 2020. In early 2017, we built a small molecule drug product facility in Suzhou, China capable of supporting clinical and commercial production and have begun construction of a large molecule facility in Suzhou, China using GE Healthcare FlexFactory platform technology capable of supporting clinical production of our drug candidates. The cost to complete the small molecule facility was approximately \$6.7 million and was paid with cash on hand. The construction of the large molecule facility is expected to be completed in the first half of 2018, which we expect to cost approximately \$13.0 million and has been, and we expect will continue to be, financed with cash. We believe our current facilities are sufficient to meet our near-term needs.

## **ITEM 4A. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*You should read the following discussion and analysis of our financial condition and results of operations together with “Item 3.A. Selected Financial Data” and our consolidated financial statements appearing elsewhere in this Annual Report on Form F-20. This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words “expect,” “anticipate,” “intend,” “believe,” or similar language. All forward-looking statements included in this annual report are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. In evaluating our business, you should carefully consider the information provided under “Item 3.D. Risk Factors.” Actual results could differ materially from those projected in the forward-looking statements. The terms “Company”, “Zai Lab”, “we”, “our” or “us” as used herein refer to Zai Lab Limited and its consolidated subsidiaries unless otherwise stated or indicated by context.*

### **A. Operating Results.**

#### **Overview**

We are an innovative biopharmaceutical company based in Shanghai focusing on discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical need in the China market, including in the fields of oncology, autoimmune and infectious diseases therapies. Our mission is to transform patients’ lives in China and eventually leverage our capabilities to impact human health worldwide.

Since our founding in 2014, we have assembled a pipeline consisting of seven drug candidates through partnerships with global biopharmaceutical companies. These include five late-stage assets targeting fast growing segments of China’s pharmaceutical market and two assets addressing global unmet medical needs. We believe that management’s decades-long global drug development expertise, combined with our demonstrated understanding of the pharmaceutical industry, clinical resources and regulatory system in China, has provided us, and will continue to provide us, opportunities to partner with global companies aiming to bring innovative products to market in China efficiently and effectively.

Our consolidated net loss attributable to ordinary shareholders for the year ended December 31, 2015, 2016 and 2017 was \$18.0 million, \$37.5 million and \$50.4 million, respectively.

#### **Basis of Presentation**

Our consolidated statement of operations data for the years ended December 31, 2015, 2016 and 2017 and our consolidated statement of financial position data as of December 31, 2016 and 2017 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. Our consolidated financial statements appearing elsewhere in this Annual Report on Form 20-F have been prepared in accordance with U.S. GAAP.

## Factors Affecting our Results of Operations

### *Innovation Platform*

#### Research and Development Expenses

We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been steadily advancing and expanding, with six clinical-stage drug candidates being investigated. For more information on the nature of the efforts and steps necessary to develop our drug candidates, see “Business” and “Regulation.”

To date, we have financed our activities primarily through private placements and our initial public offering. Through December 31, 2017, we have raised approximately \$164.6 million in equity financing and approximately \$157.7 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was \$11.5 million, \$32.2 million and \$32.4 million for the years ended December 31, 2015, 2016 and 2017, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our six clinical-stage drug candidates and continue research and development of our preclinical-stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. These expenditures include:

- expenses incurred for payments to CROs, investigators and clinical trial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits and equity compensation expense;
- expenses for licensors;
- the cost of acquiring, developing, and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include office leases and other overhead expenses;
- costs associated with pre-clinical activities and regulatory operations;
- expenses associated with the construction and maintenance of our manufacturing facilities; and
- costs associated with operating as a public company.

For more information on the research and development expenses incurred for the development of our drug candidates, see “Key Components of Results of Operations—Research and Development Expenses.”

#### General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel compensation and related costs, including share-based compensation for administrative personnel. Other general and administrative expenses include 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 general and administrative activities. We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as we prepare to manufacture and commercialize our products. These increases will likely include increased headcount, increased share compensation charges, expanded infrastructure and increased costs for insurance. We also incur increased legal, compliance, accounting and investor and public relations expenses associated with being a public company.

#### Our Ability to Commercialize Our Drug Candidates

All of our drug candidates are still in development. Six of our drug candidates are in clinical development and various others are in pre-clinical development. Our ability to generate revenue from our drug candidates is dependent on their receipt of regulatory approval for and successful commercialization of such products, which may never occur.

Certain of our drug candidates may require additional pre-clinical and/or clinical development, regulatory approval in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

## Our License Arrangements

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant drug product under these agreements as well as tiered royalties based on the net sales of the licensed products. These expenses are recorded in research and development expense in our consolidated financial statements and totalled \$6.2 million, \$17.1 million and \$8.0 million for the years ended December 31, 2015, 2016 and 2017, respectively.

## Key Components of Results of Operations

### Taxation

#### Cayman Islands

Zai Lab Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands. For more information, see “Taxation—Material Cayman Islands Taxation.”

#### People’s Republic of China

Our subsidiaries incorporated in the PRC are governed by the EIT Law and regulations. Under the EIT Law, the standard Enterprise Income Tax, or EIT, rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years. For more information, see “Taxation—Material People’s Republic of China Taxation.”

## Results of Operations

The following table sets forth a summary of our consolidated results of operations for the periods indicated. This information should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 20-F. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

(in thousands, except share and per share data)	Year ended December 31,		
	2017	2016	2015
<b>Comprehensive Loss Data:</b>			
Operating expenses:			
Research and development	\$ (39,342)	\$ (32,149)	\$ (13,587)
General and administrative	(12,049)	(6,380)	(2,762)
Loss from operations	(51,391)	(38,529)	(16,349)
Interest income	527	403	5
Changes in fair value of warrants	200	(1,920)	(1,980)
Other income	933	2,534	341
Other expense	(403)	—	(39)
Loss before income tax and share of loss from equity method investment	(50,134)	(37,512)	(18,022)
Income tax expense	—	—	—
Share of loss from equity method investment	(250)	—	—
Net loss attributable to ordinary shareholders	\$ (50,384)	\$ (37,512)	\$ (18,022)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	21,752,757	9,439,028	8,693,655
Net loss per share, basic and diluted	\$ (2.32)	\$ (3.97)	\$ (2.07)

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

**Research and Development Expenses**

The following table sets forth the components of our research and development expenses for the years indicated.

(in thousands)	Year ended December 31,			
	2017	%	2016	%
<b>Research and development expenses:</b>				
Personnel compensation and related costs	\$ 9,370	23.8	\$ 6,095	19.0
Licensing fees	7,948	20.2	17,108	53.2
Payment to CROs/CMOs	14,993	38.1	6,759	21.0
Other costs	7,031	17.9	2,187	6.8
<b>Total</b>	<b>\$ 39,342</b>	<b>100.0</b>	<b>\$ 32,149</b>	<b>100.0</b>

Research and development expense increased by \$7.2 million to \$39.3 million for year ended December 31, 2017 from \$32.1 million for year ended December 31, 2016. The increase in research and development expense included the following:

- \$3.3 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the year ended December 31, 2017 and the grants of new share options and vesting of restricted shares to certain employees; and
- \$8.2 million for increased payment to CROs/CMOs in fiscal year 2017 as we advanced our drug candidate pipeline; and
- \$4.8 million for increased rental fee, lab consumables and legal expenses.

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

The following table summarizes our research and development expense by program for the years ended December 31, 2017 and December 31, 2016, respectively:

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

During the year ended December 31, 2017, 32.1% and 37.5% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. During the year ended December 31, 2016, 62.6% and 15.1% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. ZL-2306 represented approximately 43% and 63% of our external research and development expense, which includes payments to CROs, CMOs and investigators, for the year ended December 31, 2017 and 2016, respectively. ZL-2401 represented approximately 45% of our external research and development expense, which includes licensing fees and payment to CROs and CMOs, for the year ended December 31, 2017. No other programs represented a significant amount of research and development expense for the years ended December 31, 2017 or December 31, 2016. Though we manage our external research and development expenses by program we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.

## General and Administrative Expenses

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

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

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

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

## Interest Income

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

## Changes in Fair Value of Warrants

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

## Share of loss from equity method investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. We account for our \$1.9 million investment using the equity method of accounting because we do not control the investee but have the ability to exercise significant influence over the operating and financial policies of the investee. An investment loss of \$249,652 related to this investment was recorded for the year ended December 31, 2017.

## Other Income

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

## Net Loss Attributable to Ordinary Shareholders

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

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the years indicated.

(in thousands)	Year ended December 31,			
	2016	%	2015	%
<b>Research and development expenses:</b>				
Personnel compensation and related costs	\$ 6,095	19.0	\$ 3,172	23.3
Licensing fees	17,108	53.2	6,203	45.7
Payment to CROs/CMOs	6,759	21.0	3,180	23.4
Other costs	2,187	6.8	1,032	7.6
<b>Total</b>	<b>\$ 32,149</b>	<b>100.0</b>	<b>\$ 13,587</b>	<b>100.0</b>

Research and development expense increased by \$18.6 million to \$32.1 million for year ended December 31, 2016 from \$13.6 million for year ended December 31, 2015. The increase in research and development expense included the following:

- \$2.9 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during year ended December 31, 2016 and the grants of new share options to certain employees;
- \$10.9 million for increased licensing fees in connection with the upfront fee paid for licensing agreement with Tesaro for ZL-2306 in fiscal year 2016 (see “Business—Our Clinical Pipeline—ZL-2306” for further information); and
- \$3.6 million for increased payment to CROs/CMOs in fiscal year 2016 as we advanced our drug candidate pipeline.

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

(in thousands)	Year ended December 31,			
	2016	%	2015	%
<b>Research and development expenses:</b>				
Clinical programs	\$ 20,129	62.6	\$ 6,020	44.3
Preclinical programs	4,839	15.1	3,821	28.1
Unallocated research and development expenses	7,181	22.3	3,746	27.6
<b>Total</b>	<b>\$ 32,149</b>	<b>100.0</b>	<b>\$ 13,587</b>	<b>100.0</b>

During the year ended December 31, 2016, 62.6% and 15.1% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. During the year ended December 31, 2015, 44.3% and 28.1% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. ZL-2306 represented approximately 63% of our external research and development expense, which includes licensing fees and payments to CROs and CMOs, for the year ended December 31, 2016. ZL-2303 represented approximately 10% and 61% of our external research and development expense for the years ended December 31, 2016 and December 31, 2015, respectively. No other programs represented a significant amount of research and development expense for the years ended December 31, 2016 or December 31, 2015. Though we manage our external research and development expenses by program we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.



## General and Administrative Expenses

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

(in thousands)	Year ended December 31,			
	2016	%	2015	%
<b>General and Administrative Expenses:</b>				
Personnel compensation and related costs	\$ 3,120	48.9	\$ 1,811	65.6
Professional service fee	2,691	42.2	340	12.3
Other costs	569	8.9	611	22.1
<b>Total</b>	<b>\$ 6,380</b>	<b>100.0</b>	<b>\$ 2,762</b>	<b>100.0</b>

General and administrative expenses increased by \$3.6 million to \$6.4 million for year ended December 31, 2016 from \$2.8 million for year ended December 31, 2015. The increase in general and administrative expenses included the following:

- \$1.3 million for increased personnel compensation and related costs which was primarily attributable to increased administrative personnel compensation costs, due to hiring of more personnel during year ended December 31, 2016 and the grants of new share options to certain employees; and
- \$2.4 million for increased professional service fee due to the increase of legal due diligence expenses in fiscal year 2016.

## Interest Income

Interest income increased by \$0.4 million for year ended December 31, 2016 due to higher cash on hand in 2016.

## Changes in Fair Value of Warrants

On December 31, 2015, we entered into a warrant agreement with an investor to purchase up to 461,808 of our Series A2 preferred shares at \$2.1651 per share. The fair value of the warrants of \$2.0 million was expensed on the date of issuance and an additional \$1.9 million change in fair value was expensed in 2016 on the re-measurement date.

## Other Income

Other income increased by \$2.2 million for year ended December 31, 2016 primarily as a result of an increase in governmental subsidies.

## Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of \$37.5 million for the year ended December 31, 2016 compared to net loss attributable to ordinary shareholders of \$18.0 million for the year ended December 31, 2015.

## Critical Accounting Policies and Significant Judgments and Estimates

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

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

## **Share-Based Compensation**

### *Awards Granted to Employees*

We grant share options to eligible employees, management and directors and account for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation*, or ASC 718.

Share-based awards are measured at the grant date fair value and recognized as an expense (i) immediately at grant date if no vesting conditions are required or (ii) using a graded vesting method over the requisite service period, which is the vesting period. See Note 11 to the consolidated financial statements included elsewhere in this Annual Report on Form 20-F for further details on the assumptions used to estimate the fair value of share-based awards granted in prior periods.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

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

We, with the assistance of an independent third party valuation firm, determined the fair value of the stock options granted to employees. The binomial option pricing model was applied in determining the estimated fair value of the options granted to employees.

### *Awards Granted to Non-Employees*

We have accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 505, *Equity-Based Payments to Non-Employees*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if we had paid cash for the services provided by the non-employees.

## **Fair Value Measurements**

We apply ASC Topic 820, *Fair Value Measurements and Disclosures*, of ASC 820, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Include other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches, for example, to measuring the fair value of assets and liabilities: (1) market approach, (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of our company primarily include cash and cash equivalents, prepayments and other current assets, accounts payable, warrant liabilities and other payables. As of each reporting date, the carrying values of cash and cash equivalents, prepayments and other current assets, accounts payable and other payables approximated their fair values due to the short-term maturity of these instruments. The warrant liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at each reporting date. We determined the fair values of the warrant liabilities with the assistance of an independent third party valuation firm, and we have measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of each reporting date.

### ***Fair Value of Our Ordinary Shares***

Prior to our initial public offering in September 2017, we were a private company with no quoted market prices for our ordinary shares. We have therefore needed to make estimates of the fair value of our ordinary shares at various dates for the following purposes:

- determining the fair value of our ordinary shares at the date of issuance and the dates of subsequent measurement of convertible instruments as one of the inputs in determining the intrinsic value of the beneficial conversion feature, if any; and
- determining the fair value of our ordinary shares at the date of the grant of a share-based compensation award to our employees and non-employees as one of the inputs in determining the grant date fair value of the award.

In determining the fair value of our ordinary shares as of various valuation dates, we first applied an income approach, specifically a discounted cash flow, or DCF, analysis based on our projected cash flows using management's best estimates as of the valuation date and the market approach by referring to transaction prices of our private equity financing transactions with independent third parties to conclude on the equity value. We then applied the option-pricing method to allocate the equity value between preferred shares and ordinary shares. The determination of the equity value requires complex and subjective judgments to be made regarding prospects of the industry and the products at the respective valuation dates, our projected financial and operating results, our unique business risks and the liquidity of our shares.

The income approach involves applying appropriate discount rates to estimated cash flows that are based on earnings forecasts. However, these fair values are inherently uncertain and highly subjective. The major assumptions utilized in DCF analysis include:

*Financial projection.* The projected cash flows include among other things, an analysis of projected revenue growth, gross margins, effective tax rates, capital expenditures, working capital requirements and depreciation and amortization. The assumptions used in deriving the fair values are consistent with our business plan. These assumptions include no material changes in the existing political, legal and economic conditions in China; our ability to retain competent management and key personnel to support our ongoing operations; and no material deviation in historical industry trends and market conditions from current forecasts. These assumptions are inherently uncertain.

*Discount Rates.* The discount rates were based on the weighted average cost of capital and ranged from 16%-25% where the cost of equity was determined based on a Capital Asset Pricing Model, which includes a consideration of the factors including risk-free rate, comparative industry risk, equity risk premium, company size and non-systemic risk factors.

*Discount for Lack of Marketability, or DLOM.* DLOM reflects the fact that our shares were privately-held shares. DLOM was quantified by various valuation techniques, such as the Black-Scholes option pricing model. Under this method, the cost of the put option, which could be used to hedge the price change before the privately held shares can be sold, was considered as a basis to determine the DLOM. This option pricing method is one of the methods commonly used in estimating DLOM. The key assumptions of such model include risk-free rates, timing of a liquidity event, and estimated volatility of our shares. The farther the valuation date is from an expected liquidity event, the higher the put option value and thus the higher the implied DLOM. The lower DLOM is used for the valuation, the higher is the determined fair value of the ordinary shares.

The equity value of our company determined at the respective valuation dates based on the income approach under the above assumptions and the market approach referring to transaction price of our private equity financing transactions with independent third parties was allocated between the preferred shares and ordinary shares. The option-

pricing method was used to allocate equity value, taking into account the guidance prescribed by the AICPA Audit and Accounting Practice Aid, “*Valuation of Privately-Held Company Equity Securities Issued as Compensation*.” The method treats common stock and preferred stock as call options on the enterprise’s value, with exercise prices based on the liquidation preference of the preferred stock.

The option-pricing method involves making estimates of the anticipated timing and probability of a potential liquidity event, such as a sale of our company, an initial public offering, a redemption event (for Series C preferred shares issued in June 2017) and estimates of risk free rate and the volatility of our equity securities. The anticipated timing and probability were based on the plans of our board of directors and management. The risk free rate is adopted based on the United States Treasury bond yield with a maturity commensurate with the expected time to liquidity, adjusted by country risk premium between China and the United States. Estimating the volatility of the share price of a privately held company is complex because there is no readily available market for the shares. We estimated the volatility of our shares to be 70% based on the historical volatilities of comparable publicly traded companies engaged in similar lines of business. Had we used different estimates of volatility, the allocations between preferred and ordinary shares would have been different.

After our initial public offering in September 2017, the closing market price of the underlying shares on the applicable grant date is used to determine the fair value of our ordinary shares.

### **Income Taxes**

Current income taxes are provided on the basis of net income for financial reporting purposes, adjusted for income and expense items which are not assessable or deductible for income tax purposes, in accordance with the regulations of the relevant tax jurisdictions. We follow the liability method of accounting for income taxes.

Under this method, deferred tax assets and liabilities are determined based on the temporary differences between the financial statements carrying amounts and tax bases of assets and liabilities by applying enacted statutory tax rates that will be in effect in the period in which the temporary differences are expected to reverse. We record a valuation allowance to offset deferred tax assets if based on the weight of available evidence, it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. The effect on deferred taxes of a change in tax rate is recognized in our consolidated financial statements in the period of change.

In accordance with the provisions of ASC 740, *Income Taxes*, we recognize in our financial statements the benefit of a tax position if the tax position is “more likely than not” to prevail based on the facts and technical merits of the position. Tax positions that meet the “more likely than not” recognition threshold are measured at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. We estimate our liability for unrecognized tax benefits which are periodically assessed and may be affected by changing interpretations of laws, rulings by tax authorities, changes and/or developments with respect to tax audits, and expiration of the statute of limitations. The ultimate outcome for a particular tax position may not be determined with certainty prior to the conclusion of a tax audit and, in some cases, appeal or litigation process.

We consider positive and negative evidence when determining whether some portion or all of our deferred tax assets will not be realized. This assessment considers, among other matters, the nature, frequency and severity of current and cumulative losses, forecasts of future profitability, the duration of statutory carry-forward periods, our historical results of operations, and our tax planning strategies. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based upon the level of our historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe it is more likely than not that we will not realize the deferred tax assets resulted from the tax loss carried forward in the future periods.

The actual benefits ultimately realized may differ from our estimates. As each audit is concluded, adjustments, if any, are recorded in our financial statements in the period in which the audit is concluded. Additionally, in future periods, changes in facts, circumstances and new information may require us to adjust the recognition and measurement estimates with regard to individual tax positions. Changes in recognition and measurement estimates are recognized in the period in which the changes occur. As of December 31, 2016 and 2017, we did not have any significant unrecognized uncertain tax positions.

## B. Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. We incurred net losses of \$50.4 million, \$37.5 million and \$18.0 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of \$110.6 million. Our primary use of cash is to fund research and development costs. Our operating activities used \$32.4 million, \$32.2 million and \$11.5 million of cash flows during the years ended December 31, 2017, 2016 and 2015, respectively. Historically, we have financed our operations principally through proceeds from private placements of preferred shares and warrants of \$164.6 million as well as proceeds from our initial public offering. At December 31, 2017, we had cash and cash equivalents of \$229.7 million. We believe that our current level of cash and cash equivalents will be sufficient to meet our anticipated cash needs for the foreseeable future.

Our ability to pay dividends may depend on receiving distributions of funds from our PRC subsidiaries. Relevant PRC statutory laws and regulations permit payments of dividends by our PRC subsidiaries only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of our PRC subsidiaries. In accordance with the relevant applicable PRC laws and regulations, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the board of directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. Our PRC subsidiaries were established as domestic enterprises and therefore are subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2017, 2016 and 2015, no appropriation to statutory reserves was made because our PRC subsidiaries had substantial losses during such periods. As a result of relevant applicable PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as a general reserve fund, our PRC subsidiaries are restricted in their ability to transfer a portion of its net assets. Foreign exchange and other regulations in the PRC may further restrict our PRC subsidiaries from transferring funds to us in the form of dividends, loans and advances. As of December 31, 2017, amounts restricted are the paid-in capital of our PRC subsidiaries, which amounted to \$81.0 million.

The following table provides information regarding our cash flows for the years ended December 31, 2017, 2016 and 2015:

(in thousands)	Year ended December 31,		
	2017	2016	2015
Net cash (used in) operating activities	\$ (32,367)	\$ (32,158)	\$ (11,465)
Net cash (used in) investing activities	(10,434)	(2,730)	(738)
Net cash provided by financing activities	187,860	106,200	18,278
Effect of foreign exchange rate changes	652	(524)	(67)
Net increases in cash and cash equivalents	\$ 145,711	\$ 70,788	\$ 6,008

### *Net cash used in operating activities*

During the year ended December 31, 2017, our operating activities used \$32.4 million of cash, which resulted principally from our net loss of \$50.4 million, adjusted for non-cash charges of \$10.5 million, and by cash provided in our operating assets and liabilities of \$7.5 million. Our net non-cash charges during the year ended December 31, 2017 primarily consisted of \$0.5 million of depreciation expense, \$9.9 million of share-based compensation expense, \$0.2 million loss from equity investees and a \$0.2 million gain from changes in fair value of warrants.

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

During the year ended December 31, 2015, our operating activities used \$11.5 million of cash, which resulted principally from our net loss of \$18.0 million, adjusted for non-cash charges of \$4.8 million, and by cash provided by our operating assets and liabilities of \$1.7 million. Our net non-cash charges during the year ended December 31, 2015 primarily consisted of \$0.1 million of depreciation expense, \$2.7 million of share-based compensation expense and a \$2.0 million loss from changes in fair value of warrants.

**Net cash used in investing activities**

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

Net cash used in investing activities was \$2.7 million for the year ended December 31, 2016 compared to \$0.7 million for the year ended December 31, 2015. The increase in cash used in investing activities was due to the construction of our small molecule commercial facility and other investments in 2016.

**Net cash provided by financing activities**

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

Net cash provided by financing activities was \$106.2 million for the year ended December 31, 2016 compared to \$18.3 million for the year ended December 31, 2015. The increase was due to the issuance of \$106.2 million Series B preferred shares and warrants.

**C. Research and Development, Patents and Licenses, etc.**

Full details of our research and development activities and expenditures are given in the “Business” and “Operating and Financial Review and Prospects” sections of this annual report above.

**D. Trend Information.**

Other than as described elsewhere in this Annual Report on Form 20-F, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

**E. Off-balance Sheet Arrangements.**

We currently do not engage in trading activities involving non-exchange traded contracts or interest rate swap transactions or foreign currency forward contracts. In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

**F. Tabular Disclosure of Contractual Obligations.**

The following table sets forth our contractual obligations as of December 31, 2017. Amounts we pay in future periods may vary from those reflected in the table.

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
	(in thousands)				
Operating Lease Obligations	\$ 3,026	\$ 1,311	\$ 1,303	\$ 358	\$ 54
Purchase Obligations	4,926	4,926	—	—	—
Investment Obligations	2,017	—	—	—	2,017
Total	<u>\$ 9,969</u>	<u>\$ 6,237</u>	<u>\$ 1,303</u>	<u>\$ 358</u>	<u>\$ 2,071</u>

We also have obligations to make future payments to third party licensors that become due and payable on the achievement of certain development, regulatory and commercial milestones as well as tiered royalties on net sales. We have not included these commitments on our balance sheet or in the table above because the commitments are cancellable if the milestones are not complete and achievement and timing of these obligations are not fixed or determinable.

### **Recently Issued Accounting Standards**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Updates, or ASU, 2014-09, *Revenue from Contracts with Customers (Topic 606)*, to clarify the principles of recognizing revenue and create common revenue recognition guidance between U.S. GAAP and International Financial Reporting Standards, or IFRS. An entity has the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application. ASU 2014-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2016, and early adoption is not permitted. In August 2015, the FASB updated this standard to ASU 2015-14, the amendments in this update defer the effective date of Update 2014-09, that the update should be applied to annual reporting periods beginning after December 15, 2017 and earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.

In May 2016, FASB issued ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*. The amendments in this update do not change the core principle of the guidance in Topic 606. Rather, the amendments in this update affect only the narrow aspects of Topic 606. The areas improved include: (1) Assessing the Collectability Criterion in Paragraph 606-10-25-1(e) and Accounting for Contracts That Do Not Meet the Criteria for Step 1; (2) Presentation of Sales Taxes and Other Similar Taxes Collected from Customers; (3) Noncash Consideration; (4) Contract Modifications at Transition; (5) Completed Contracts at Transition; and (6) Technical Correction. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements for Topic 606 (and any other topic amended by update 2014-09).

We are in a development stage, with no revenues to date.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on the balance sheet. This ASU requires lessees to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Lessees are permitted to make an accounting policy election to not recognize the asset and liability for leases with a term of twelve months or less. The ASU does not significantly change the lessees' recognition, measurement and presentation of expenses and cash flows from the previous accounting standard. Lessors' accounting under the ASC is largely unchanged from the previous accounting standard. In addition, the ASU expands the disclosure requirements of lease arrangements. Lessees and lessors will use a modified retrospective transition approach, which includes a number of practical expedients. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. We are currently evaluating this ASU to determine the full impact on our consolidated financial statements, as well as the impact of adoption on policies, practices and systems. As of December 31, 2017, we have \$3.0 million of future minimum operating lease commitments that are not currently recognized on our consolidated balance sheets. Therefore, we would expect changes to our consolidated balance sheets for the recognition of these and any additional leases entered into in the future upon adoption.

In May 2017, FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*. The guidance provides clarity and reduces diversity in practice and cost and complexity when accounting for a change to the terms or conditions of a share-based payment award. The amendments in this update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. We do not expect the requirements of ASU 2017-09 will have a material impact on our consolidated financial statements.

### **JOBS Act Exemptions and Foreign Private Issuer Status**

We qualify as an "emerging growth company" as defined in the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act. We may take advantage of this exemption for up to five

years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than \$1.07 billion in annual revenue, have more than \$700.0 million in market value of our ordinary shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

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

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



## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

### A. Directors and Senior Management

#### Our Executive Officers and Directors

Below is a list of the names and ages of our directors and officers as of March 31, 2018, and a brief account of the business experience of each of them. The business address for our directors and officers is c/o Zai Lab Limited, 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210.

Name	Age	Position(s)
<b>Executive Officers</b>		
Ying (Samantha) Du	53	Director, Chairman and Chief Executive Officer
Harald Reinhart	66	Chief Medical Officer, Autoimmune and Infectious Diseases
Qi Liu	52	Chief Medical Officer, Oncology
Billy Cho	40	Chief Financial Officer
Ning Xu	53	Executive Vice President, Clinical Operations and Regulatory Affairs
James Yan	54	Executive Vice President, Head of Early Development and Drug Safety
<b>Non-Management Directors</b>		
Nisa Leung	47	Director
Peter Wirth	67	Director; Senior Advisor
Marietta Wu	49	Director
Jianming Yu	46	Director
John Diekman	75	Director
Tao Fu	46	Director
<b>Other Key Employees</b>		
Minghui Chen	50	Vice President, Government and Regulatory Affairs
Xiaopeng (Tom) Feng	45	Vice President, Finance
Jonathan Wang	36	Senior Vice President, Head of Business Development
Bo Zhang	45	Senior Vice President, Chemistry, Manufacturing and Controls
<b>Scientific Advisors</b>		
Richard A. Flavell	72	Scientific Advisor
Gwen Fyfe	66	Scientific Advisor
Neal Rosen	67	Scientific Advisor

#### Executive Officers

Ying (Samantha) Du, Ph.D., co-founded our company and has been our director, chairman and chief executive officer since our inception. Prior to founding our company, Dr. Du spent two years as managing director of healthcare investments at Sequoia Capital China, where she led four investments. From 2001 to 2011, Dr. Du was founder and chief executive officer of Hutchison Medi-Pharma and the co-founder and chief scientific officer of Hutchison China MediTech Limited, a Nasdaq-listed biopharmaceutical company, where she pioneered China-based global biopharmaceutical innovation by bringing five internally-discovered innovative drug candidates into clinical trials,

including two global Phase III ready drug candidates. Dr. Du began her career with Pfizer in the United States in 1994, where she was involved in the development and launch of two global drugs. While at Pfizer, she was responsible for Pfizer's global metabolic licensing program on the scientific side. She received a Ph.D. in biochemistry from the University of Cincinnati. Dr. Du has also been involved with and chaired several Chinese regulatory and government related committees.

*Harald Reinhart, M.D.*, has been our chief medical officer, autoimmune and infectious diseases since 2017. He is currently adjunct clinical professor of infectious diseases at the Yale School of Medicine. Prior to joining our company, in 2012, Dr. Reinhart joined Shionogi US as head of Clinical Development and Medical Affairs, where he directed a broad portfolio of antibiotics, diabetes, allergy and pain medications, as well as guided a pharmaceutical product through NDA submission and approval. Between 2003 and 2011, Dr. Reinhart held senior roles at Novartis, where he oversaw successful filings of NDAs and NDAs for Coartem, Famvir, Sebivo, and Cubicin, managed clinical development groups for transplantation, renal disease and immunity, and supervised the transitioning of projects from research into clinics. Dr. Reinhart received a medical degree from the University of Würzburg in Germany. He completed his medical specialty training in the United States with board-certifications in internal medicine and infectious diseases.

*Qi Liu, M.D., Ph.D.* has been our chief medical officer, oncology since 2015. Prior to joining our company, Dr. Liu was the clinical head of the BioVenture group at AstraZeneca and the executive medical director of AstraZeneca Oncology, where she played an important role in establishing AstraZeneca's biologics joint ventures and was responsible for its joint venture global clinical development programs and regulatory strategy and submissions. She also played a key role in the TKI development program. Prior to joining AstraZeneca, Dr. Liu was an assistant professor at the MD Anderson Cancer Center. Dr. Liu received a medical degree from Shanghai Medical University (currently known as Shanghai Medical College of Fudan University) and a Ph.D. in molecular genetics from the University of Georgia. She completed a post-doctoral fellowship at Memorial Sloan Kettering Cancer Center and a medical oncology and hematology fellowship at the MD Anderson Cancer Center with board certifications in internal medicine, medical oncology and hematology.

*Billy Cho, M.B.A., M.A.*, has been our chief financial officer since March 2018. Prior to joining our company, Mr. Cho served as Managing Director and Head of Asia Healthcare Investment Banking at Citigroup. Based in Hong Kong since 2011, Mr. Cho was responsible for healthcare client coverage at Citigroup across the Asia Pacific region and led many biopharma transactions in China including Zai Lab's US IPO. Prior to this, he was based in New York in healthcare M&A investment banking and also spent time in corporate development for a pharmaceutical services company. Mr. Cho started his career at Ernst & Young performing financial audits of US-based healthcare companies. Mr. Cho earned his M.B.A. from the Wharton School of the University of Pennsylvania and M.A. in Accounting from University of Virginia.

*Ning Xu, M.D.*, has been our executive vice president, clinical operations and regulatory affairs since 2014. Prior to joining our company, he served as vice president, head of clinical development service at Covance China. Before joining Covance, Dr. Xu served as a senior medical and regulatory affairs executive at Johnson & Johnson and GlaxoSmithKline. Dr. Xu received a medical degree from Peking Union Medical College and a master of business administration from the University of Illinois at Chicago. Dr. Xu also completed a postdoctoral fellowship at the Medical School, University of Illinois at Chicago. Between 2011 and 2015, he was the chairman of the Advisory Council of DIA China and a director of DIA Global.

*James Yan, Ph.D.*, has been our executive vice president and head of pre-clinical development and drug safety since 2015. Prior to joining our company, Dr. Yan was the head of the Covance early development Shanghai site, where he was responsible for all aspects of the business. Between 2009 and 2011, Dr. Yan served as the head of drug safety evaluation and program management of Hutchison Medi-Pharma. Prior to Hutchison Medi-Pharma, Dr. Yan had significant experience at Pfizer in the United States. Over the course of his career, Dr. Yan was been involved in many IND and NDA filings for multiple drug candidates and gained substantial experience working with regulatory agencies in several countries. Dr. Yan received a Ph.D. from Peking Union Medical University and completed post-doctoral training at the University of Chicago's Ben-May Institute for Cancer Research. He is a diplomat of the American Board of Toxicology, a council member of the China Society of Toxicology and a member of the Drug Toxicity and Drug Safety Evaluation Committee.

## **Non-Management Directors**

*Nisa Leung* has been our independent director since 2014. Ms. Leung is a Managing Partner at Qiming Venture Partners, where she leads its health care investments. In addition to serving on our board of directors, Ms. Leung is also a member of the board of directors of Berry Genomics, a biotechnology company that provides prenatal genetic testing; CanSino Biotechnology, a vaccine developer; dMed, a Shanghai-based CRO consulting startup; Gan & Lee Pharmaceuticals, a developer of insulin analog; Nurotron Biotechnology, a developer of neurostimulation systems; and Venus Medtech, a developer of interventional artificial cardiac valve systems. Ms. Leung received a master of business administration from the Stanford Graduate School of Business.

*Peter Wirth* has been our director since 2017 and has been our senior advisor since 2015. He is chairman of FORMA Therapeutics Holdings LLC, a small molecule drug discovery company; executive chairman of ZappRx, a digital health care company; chair of the board of directors at Syros Pharmaceuticals, a Nasdaq-listed biopharmaceutical company; and director of Aura Biosciences, Inc., a biopharmaceutical company. From 2011 to 2014, Mr. Wirth served as president and director of Lysosomal Therapeutics, Inc., a biopharmaceutical company focused on small molecule research. From 1996 to 2011, Mr. Wirth served as a senior executive at Genzyme, which is now part of Sanofi, and most recently as its executive vice president of legal and corporate development, chief risk officer and corporate secretary. During the last five years, Mr. Wirth also served as a director of Synageva BioPharma Corp., a biopharmaceutical company which is now owned by Nasdaq-listed Alexion Pharmaceuticals. Mr. Wirth received a law degree from Harvard Law School.

*Marietta Wu, M.D., Ph.D.*, co-founded our company, has been our director since 2014 and served as our chief operating officer from 2014 to 2017. She also serves as a director of JING Medicine Technology (Shanghai) Ltd., Qiagen (Suzhou) Translational Medicine Co., Ltd. and Kira Pharmaceuticals (Hong Kong) Limited. Prior to founding our company, Dr. Wu served as general manager of greater China and later managing director of Burrill & Company, or Burrill, where she led Burrill's operation in greater China and focused on venture capital investing in China and Taiwan related to life science opportunities. Prior to joining Burrill, Dr. Wu was director of strategy at Edwards Lifesciences. From 2009 to 2010, Dr. Wu also served as acting chief operating officer of Waterstone Pharmaceuticals, a specialty pharmaceutical company with key operations in China. She also held various financial and business development positions at Eli Lilly & Company. Dr. Wu received her medical degree from Shanghai Jiaotong University School of Medicine, a Ph.D. in Medical Sciences from Medical College of Ohio and a master of business administration from the University of Michigan Ross School of Business. Dr. Wu is a founding member of the China Healthcare Investment Conference.

*Jianming Yu, Ph.D.*, has been our director since 2016. Dr. Yu is a co-founder of New Horizon Capital and has been its managing partner and chief executive officer since its inception in 2005. Dr. Yu also founded Advantech Capital, a growth fund specializing in innovative technologies and healthcare, and has served as its managing partner since 2015. In addition, Dr. Yu is founder and managing partner of Redview Capital, a private equity fund with focus on consumer products and services, advanced manufacturing, and new energy sectors. Dr. Yu received a master of business administration from Kellogg School of Management, Northwestern University, and a Ph.D. in biology from Harvard University.

*John D. Diekman, Ph.D.*, has been our independent director since 2017. Dr. Diekman is founding partner of 5AM Ventures, where he has served since 2002. He is chairman of the board of directors of IDEAYA Biosciences, Inc., an oncology-focused biotechnology company; director of Igenica Biotherapeutics, Inc., a developer of antibody-based oncology treatments; director of Wildcat Discovery Technologies, Inc., a technology company that discovers materials for energy storage applications; charter trustee of Princeton University; chairman of the board of directors of The Scripps Research Institute; and a member of the advisory board of the Schaeffer Center for Health Policy and Economics at the University of Southern California. During the last five years, Dr. Diekman also served as director of Calibrum LLC, a biopharmaceutical research company focused on diabetes and other metabolic diseases; Cellular Research, Inc., a single-cell genomics startup; and PhaseRx Inc., a biopharmaceutical company developing mRNA treatments for life-threatening inherited liver diseases in children. Dr. Diekman holds an A.B. in Organic Chemistry from Princeton University and a Ph.D. in Chemistry from Stanford University.

*Tao Fu* has been our independent director since 2017. He is currently executive vice president, chief commercial and business officer of Portola Pharmaceuticals, Inc., a publicly traded biotechnology company specializing in cardiovascular disease, hematological disorders and cancer. In this role, Mr. Fu leads Portola's commercial operations, marketing, sales and business development functions. Prior to joining Portola in June 2015, Mr. Fu was vice president,

business development, head of M&A and alliance management at BMS. Mr. Fu led all M&A, divestiture, strategic transaction and venture investment opportunities as well as alliance management for BMS. Between 2003 and 2015, Mr. Fu worked at Johnson & Johnson in a number of roles, most recently as vice president, business development, where he was responsible for global M&A activities in the pharmaceutical sector. Prior to joining Johnson & Johnson, Mr. Fu held managerial positions with Scios Inc., a biotechnology company in California; McKinsey & Company, a global management consulting firm; and Becton Dickinson, a leading medical device company. Mr. Fu received a master of science in cell biology from the University of Rochester, and a master of business administration in finance and marketing from Vanderbilt University. Mr. Fu did his undergraduate studies in biology at Tsinghua University and is a Chartered Financial Analyst (CFA).

#### **Other Key Employees and Advisors**

*Minghui Chen* has been our vice president, government and regulatory affairs since 2017. Prior to joining our company, he was senior director at a subsidiary of Wuxi Apptec. From 2012 to 2013, he was vice president at Cenova Ventures. From 2008 to 2011, he was head of regulatory affairs at Hutchison Medi-Pharma, where he maintained a highly successful track record of leading new drug submissions and obtaining fast approvals through the green channel. Mr. Chen also had significant experience working in the regulatory affairs department at AstraZeneca in China prior to joining Hutchison Medi-Pharma. Mr. Chen received a bachelor of science in pharmacology from Fudan University Medical School.

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

*Jonathan Wang* has been our senior vice president, head of business development since 2014. Prior to joining our company, Mr. Wang was an investment professional at OrbiMed, where he was responsible for China healthcare investment and portfolio management. From 2005 to 2011, Mr. Wang worked as a consultant at the Boston Consulting Group in China, where he specialized in pharmaceutical and healthcare engagements, assisting multinational and local companies with their China strategy. Previously, Mr. Wang also gained financial transactional experience at Goldman Sachs Investment Banking. Mr. Wang received a master of business administration in healthcare management from Wharton Business School.

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

*Richard A. Flavell*, Ph.D., FRS, has served on our scientific advisory board since 2017. Since 2002, Dr. Flavell has been the Sterling Professor of Immunobiology at Yale University School of Medicine. Prior to joining the Yale faculty in 1988, Dr. Flavell was the President and Chief Scientific Officer of Biogen Research Corporation. Dr. Flavell received a Ph.D. in biochemistry from the University of Hull, England, and performed postdoctoral work in Amsterdam and Zurich. He is an Investigator of the Howard Hughes Medical Institute, a fellow of the Royal Society, a member of the National Academy of Sciences, and a member of the Institute of Medicine of the National Academies. He has published over 800 papers and has received many awards, including the Invitrogen Meritorious Career Award from the American Association of Immunologists.

*Gwen Fyfe*, M.D., has served on our scientific advisory board since 2016. Since 2009, Dr. Fyfe has been a consultant for venture capital firms and for a variety of biotechnology companies. From 1997 to 2009, Dr. Fyfe held various positions with Genentech Inc. (now a member of the Roche Group), including Vice President, Oncology Development and Vice President, Avastin Franchise Team, as well as the honorary title of Senior Staff Scientist. Dr. Fyfe played an important role in the development of Genentech's approved oncology agents including Rituxan®, Herceptin®, Avastin® and Tarceva®. From 1990 to 1997, Dr. Fyfe was Medical Director at Chiron Therapeutics. Dr. Fyfe currently serves as a director of Array Biopharma, Inc., Cascadian Therapeutics and Molecular Partners AG and

previously served as a director of Infinity Pharmaceuticals, Inc. Dr. Fyfe received a medical degree from Washington University and is a board-certified pediatric oncologist. She has been an invited member of Institute of Medicine panels, National Cancer Institute working groups and grant committees and American Society of Clinical Oncologists oversight committees.

*Neal Rosen, M.D., Ph.D.* has served on our scientific advisory board since 2016. Dr. Rosen is a Member of the Department of Medicine and a Member of the Molecular Pharmacology and Chemistry Program at Memorial Sloan Kettering Cancer Center, where he serves as Head of Developmental Therapeutics. He is also a Professor of Pharmacology, Cell Biology and Medicine at Cornell University Medical School. He has played an important role in the development of tyrosine kinase-mediated signaling inhibitors and has pioneered the concept that cancer cells are dependent on cellular machinery for protein folding. Dr. Rosen received a medical degree and a Ph.D. in Molecular Biology from the Albert Einstein College of Medicine. He completed a residency in Internal Medicine at the Brigham and Women's Hospital and post-doctoral training and a fellowship in Medical Oncology at the National Cancer Institute, where he served on the senior staff prior to joining the faculty of Memorial Sloan Kettering Cancer Center. He was the recipient of the NIH/NCI Outstanding Investigator Award in 2016.

## **B. Compensation**

### **Employment Arrangements with Our Executive Officers**

We have entered into employment agreements with each of our executive officers and our directors (other than our non-employee directors) (together, the "executive officers"). All of our executive officers (other than Drs. Du and Reinhard and Mr. Cho) are employed by both of our Hong Kong subsidiary, Zai Lab (Hong Kong) Limited, and our Shanghai subsidiary, Zai Lab (Shanghai) Co., Ltd. Dr. Du is employed by Zai Lab Limited pursuant to an employment agreement that became effective November 10, 2017 and Dr. Du also is party to an employment agreement with Zai Lab (Shanghai) Co., Ltd. (In addition, Dr. Du has entered into an agreement with our U.S. subsidiary, Zai Lab (US) LLC, pursuant to which a portion of her base salary will be paid by Zai Lab (US) LLC based on the level of services that she provides this entity). Dr. Reinhard and Mr. Cho are employed by Zai Lab (Hong Kong) Limited.

### ***Employment Agreements with Executive Officers at Zai Lab (Hong Kong) Limited and Zai Lab Limited***

Under the terms of the Zai Lab (Hong Kong) Limited employment agreements with our executive officers, other than Dr. Du, or the terms of the Zai Lab Limited employment agreement with Dr. Du, we may terminate an executive officer's employment at any time, with or without "cause," by giving such executive officer a notice of termination. In the event of a voluntary termination other than for "good reason" or termination by the company for cause, the executive officer will receive the unpaid portion of his or her base salary, computed pro rata to the date of termination, plus reimbursement for unpaid business expenses ("accrued compensation"). In the event of a termination without "cause," as applicable, or a resignation of the executive officer for "good reason," the executive officer, other than Dr. Du, will receive the accrued compensation, plus a separation benefit consisting of either one or three months' base pay and fringe benefits depending on service (the "severance period"), plus any additional compensation that may be required by applicable law. In the event that Dr. Du's employment is terminated without "cause" or she resigns for "good reason" (each, a "qualifying termination") Dr. Du will receive the following amounts: (i) the accrued compensation, (ii) a separation benefit consisting of eighteen months' base pay and the Company's portion of monthly premiums for health, dental and vision insurance coverage, to be paid in the form of salary continuation over the eighteen-month period following the effective date of her termination of employment and (iii) accelerated vesting of any unvested stock options, restricted stock or other equity awards granted to Dr. Du prior to the occurrence of a qualifying termination (such equity acceleration, the "Equity Acceleration" and together with the benefits described in subsections (i) and (ii), the "Severance Benefits"). In the event of a qualifying termination of Dr. Du's employment within twelve months following a change in control of the Company (as defined in her employment agreement), in addition to the Severance Benefits, Dr. Du is entitled to receive an additional lump-sum payment equal to the sum of (x) six (6) months' base salary, (y) two times her target bonus and (z) six months of the Company's portion of monthly premiums for health, dental, and vision insurance coverage.

For purposes of the employment agreements described above, "cause" means (1) the executive officer's repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the executive officer's obligations and duties in the company, (2) the conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws, (3) the executive officer's gross mismanagement of the business and affairs of the company or of its subsidiaries that directly results in a material loss to the company and for which the company has

reasonable proof was committed by the executive officer, (4) material violation of any terms of the employment agreement or the restrictive covenants agreement between the executive officer and the company, or (5) a conclusive finding by an independent fact finder appointed by the board of directors for any willful misconduct, dishonesty or acts of moral turpitude by the executive, which is materially detrimental to the interests and well-being of the Company, including, without limitation harm to its business or reputation. In addition, for this purpose, “good reason” means (1) any material diminution of the executive officer’s duties or responsibilities (except in connection with a termination for cause, or by reason of death or “disability”) or an assignment of duties or responsibilities that are materially inconsistent with the executive officer’s position, (2) any material breach of the employment agreement by the company which is not cured within ten (10) business days after written notice is given to the company, or (3) except in the case of Dr. Reinhart, relocation of the executive officer’s original employment location (for Dr. Du, relocation from the place of assignment by the company), without consent, to a location more than thirty (30) kilometers from the original employment location, other than temporary relocations of no longer than six (6) calendar months.

In the event of termination of employment by reason of death or disability, the executive officer, other than Dr. Du, is entitled to receive the accrued compensation, a payment equal to one month’s base salary and fringe benefits, plus any other additional compensation required by law. For purposes of the employment agreement, “disability” means the executive officer is incapacitated or disabled by accident, sickness or otherwise, so as to render him or her mentally or physically incapable of performing the services under the employment agreement for a period of ninety (90) or more consecutive days, or for ninety (90) days during any six (6) month period. In the event of termination of Dr. Du’s employment by reason of death or disability (as defined above), she will receive the accrued compensation, plus a separation benefit consisting of one month base pay and the Company’s portion of monthly premiums for health, dental and vision insurance coverage, as well as the Equity Acceleration.

As a condition to receiving payments during an applicable severance period, the executive officer must execute a release of claims that is satisfactory to the Company.

Each executive officer has generally agreed to assign to us or our designee all rights and titles to any inventions created while he or she is performing services within the scope of employment with us or utilizing our facilities. Each executive officer has also agreed, during his or her employment with us and thereafter, not to use, disclose or transfer any confidential information of our company other than as authorized by us within the scope of his or her duties. Moreover, each of our executive officers has agreed to execute the company’s compliance agreement regarding confidentiality, trade secrets, intellectual property and competitive activities, which subjects the executive to certain restrictive covenant obligations, including an agreement by the executive, for the term of his or her employment with Zai Lab (Hong Kong) Limited (or, in the case of Dr. Du, employment with Zai Lab Limited) and for a period of one to two years thereafter, not to (i) directly or indirectly, compete with our business within any country where we conduct or, at the time of his or her employment, are actively engaged in planning to conduct, our business or (ii) solicit for any employees of our company or orders from any person, firm or company which was at any time during the 12 months prior to termination of such employment a customer or supplier of our company, or to modify its business relationship with our company in a manner adverse thereto.

Subsequent to the end of the Company’s fiscal year the Company entered into an employment agreement with Mr. Cho pursuant to which he will serve as the Company’s Chief Financial Officer. The terms and conditions of the agreement are substantially similar to those described above for our other executive officers, except that in the event of a termination of Mr. Cho’s employment without “cause,” or his resignation for “good reason,” Mr. Cho will receive his accrued compensation, plus a separation benefit consisting of either six (6) or twelve (12) months’ base pay and fringe benefits depending on his length of service with the Company, as well as any additional compensation that may be required by applicable law. The agreement also provides that Mr. Cho will receive certain equity awards in connection with his hiring, which are set forth in the table under “Outstanding Awards” below, as well as a sign-on bonus.

#### ***Employment Agreements with Executive Officers at Zai Lab (Shanghai) Co., Ltd.***

Executive officers working for Zai Lab (Shanghai) Co., Ltd., except for Dr. Reinhart and Mr. Cho, are party to a service agreement with Zai Lab (Shanghai) Co., Ltd. The employment agreements with Zai Lab (Shanghai) Co., Ltd. provide that we engage each executive officer on a fixed term (Dr. Du’s agreement with Zai Lab (Shanghai) Co. Ltd. is a permanent agreement). We provide labor protection and work conditions that comply with the safety and sanitation requirements stipulated by the relevant PRC laws. Relevant executive officers (except non-PRC nationals) and the company contribute to statutory social insurance and other benefits.

During any probation period, we may immediately terminate an executive's employment agreement without payment of severance or other liability if the executive fails to meet the company's recruiting requirements. Outside any probation period, we may terminate an executive officer's employment with Zai Lab (Shanghai) Co., Ltd. by providing the executive with thirty (30) days' notice or one month's base salary in lieu of such notice and a severance benefit in accordance with local law if (i) the executive is ill or suffers any injury that is not work-related, and fails to perform the original work after the prescribed treatment period or fails to perform other work arranged by the company;, (ii) the executive is not qualified for the job, and still fails to be qualified for the job after training is given or the position is adjusted, (iii) there is a significant change to the objective circumstances on which this contract is based, resulting in the failure to perform this contract, and after the consultations by both parties, no agreement can be reached in respect of the modification of the content of this contract, (iv) the company needs to terminate employees during any reorganization to avoid bankruptcy, or because it experiences serious difficulties in production or operation, and (v) other circumstances prescribed by PRC laws or regulation. In addition, we may terminate the executive's employment without notice or payment if (i) the executive seriously or continuously violates, or violates several times the employment rules and policies of the company, (ii) the executive commits serious dereliction in the performance of his or her duties, or practices graft, or engages in malpractice to seek private benefit, as applicable, in either case causing severe damage to the interests of the company, (iii) the executive commits fraud or uses coercive measures or takes advantage of the company's vulnerability to make it enter into this contract or to make amendments thereto against the company's will, (iv) the executive is prosecuted for criminal liability, or in the case of Dr. Liu and Dr. Yan, is subject to re-education through labor in accordance with law; or (v) under other circumstances as permitted by PRC laws and regulations. The executive officers may voluntarily terminate his or her contract without cause with thirty (30) days' prior notice to us. Each of Dr. Liu and Dr. Yan may also terminate employment immediately without notice if the company engages in certain actions, including, among other things, directing the executive to perform tasks that are unsafe.

Each executive officer has agreed to comply with our rules and policies regarding confidentiality and, during his or her employment with us and thereafter, has agreed not to use or disclose any confidential information of our company other than as authorized by us within the scope of his or her duties. Moreover, each of our executive officers has agreed that for a certain period of time after his or her employment with us at Zai Lab (Shanghai) Co., Ltd., he or she will not (i) work for another company or individual that is in competition with us or (ii) manufacture any product or operate any business which is in competition with us. Each of Dr. Du and Dr. Xu are entitled to receive monthly compensation during their 24-month non-compete period in an amount equal to 30% of their respective average monthly salaries received during the 12 months immediately preceding the termination of their employment. In addition, each of Dr. Du and Dr. Xu have agreed that, during employment and within one year after the termination thereof, certain "works for hire," as defined in the agreements, shall belong to the company.

In addition, we have been advised by our PRC counsel, Zhong Lun Law Firm, that notwithstanding any provision to the contrary in our employment agreements at Zai Lab (Shanghai) Co., Ltd., we may still be required to make severance payments upon termination without Cause to comply with the PRC labor laws and other relevant PRC regulations, which entitle employees to severance payments in case of early termination.

#### **Compensation of Directors and Executive Officers**

In the year ended December 31, 2017, we paid aggregate salaries, bonuses and benefits (excluding equity-based grants) of approximately \$2.333 million to our executive officers. Executive officers are eligible to receive an annual incentive bonus, as determined by our board of directors, based on achievement of pre-established individual, departmental and company performance goals. We do not separately set aside any amounts for pensions, retirement or other benefits for our executive officers, other than pursuant to relevant statutory requirements, and, in the case of executives who are not PRC citizens, health and life insurance. In the year ended December 31, 2017, we paid aggregate cash retainers (excluding equity-based grants and consulting fees) of approximately \$54,709 to our non-employee directors pursuant to our non-employee director compensation policy, described below. For information regarding equity-based grants to our executive officers and directors, see "—2017 Equity Incentive Plan."

#### **2017 Equity Incentive Plan**

The following summary describes the material terms of the Zai Lab Limited 2017 Equity Incentive Plan (the "2017 Equity Plan"), which is the only equity plan under which the Company currently grants equity awards. This summary is not a complete description of all provisions of our 2017 Equity Plan and is qualified in its entirety by reference to our 2017 Equity Plan, which has been previously filed as an exhibit to our registration statement on Form F-1.

**Purposes.** The purposes of our 2017 Equity Plan are to attract, retain and reward key employees and directors of, and consultants and advisors to, the Company and its subsidiaries, to incentivize them to generate shareholder value, to enable them to participate in the growth of the Company and to align their interests with the interests of our shareholders.

**Administration.** Our 2017 Equity Plan is administered by our compensation committee, which has the discretionary authority to interpret our 2017 Equity Plan, determine eligibility for and grant awards, determine, modify and waive the terms and conditions of any award, determine the form of settlement of awards, designate whether an award will be over, or with respect to, ordinary shares or ADSs, prescribe forms, rules and procedures relating to our 2017 Equity Plan and awards and otherwise do all things necessary or desirable to carry out the purposes of our 2017 Equity Plan. Our compensation committee may delegate such of its duties, powers and responsibilities as it may determine to one or more of its members, members of our board of directors and, to the extent permitted by law, officers of the Company, and may delegate to employees and other persons such ministerial tasks as it deems appropriate. As used in this summary, the term “Administrator” refers to our compensation committee and its authorized delegates, as applicable.

**Eligibility.** Key employees, directors, consultants and advisors of the Company and its subsidiaries are eligible to participate in our 2017 Equity Plan. Eligibility for stock options intended to be incentive stock options, or ISOs, is limited to employees of the Company or certain affiliates. Eligibility for stock options, other than ISOs, and stock appreciation rights, or SARs, is limited to individuals who are providing direct services on the date of grant of the award to the Company or certain affiliates.

**Authorized shares.** Subject to adjustment as described below, the maximum number of shares that may be delivered in satisfaction of awards under our 2017 Equity Plan is 1,924,327 shares, plus an annual increase, to be added as of January 1st of each year from January 1, 2018 to January 1, 2027, equal to the lesser of (i) four percent (4%) of the number of shares outstanding as of the close of business on the immediately preceding December 31st; and (ii) the number of shares determined by our board of directors on or prior to such date for such year. For purposes of our 2017 Equity Plan, “share” means a share of our common stock (an “ordinary share”), unless there are ADSs representing ordinary shares available, in which case “share” means the number of ADSs equal to an ordinary share. If the ratio of ADSs to ordinary shares is not 1:1, then (a) the maximum number of shares that may be delivered under our 2017 Equity Plan, (b) all award adjustments made pursuant to our 2017 Equity Plan; and (c) all awards designated as awards over ordinary shares will automatically be adjusted to reflect the ratio of the ADSs to ordinary shares, as reasonably determined by the Administrator. Up to the total number of shares available for awards under the plan may be delivered in satisfaction of ISOs.

Subject to applicable laws, shares delivered under our 2017 Equity Plan may be newly issued ordinary shares, previously issued ordinary shares acquired by us or ADSs. Any shares underlying awards that are settled or that expire, become unexercisable, terminate or are forfeited or repurchased by us, in each case without the delivery of shares, will again be available for issuance under our 2017 Equity Plan. In addition, the number of shares delivered in satisfaction of awards will be determined net of shares withheld by us in payment of the exercise price or purchase price of an award or in satisfaction of tax withholding requirements with respect to an award.

**Individual limits.** The maximum number of shares subject to share options that may be granted to any participant in our 2017 Equity Plan in any calendar year is 577,298 shares and the maximum number of shares subject to SARs that may be granted to any participant in any calendar year is 288,649 shares. The maximum number of shares subject to awards other than share options and SARs that may be granted to any participant in any calendar year is 288,649 shares.

**Director limits.** In addition to the individual limits described above, the maximum grant date fair value of awards granted under our 2017 Equity Plan to any non-employee director of the Company in respect of his or her service as a director with respect to any calendar year may not exceed \$500,000, assuming maximum payout.

**Types of awards.** Our 2017 Equity Plan provides for the grant of share options, SARs, restricted and unrestricted shares and share units, performance awards, and other awards that are convertible into or otherwise based on our shares. Dividend equivalents may also be provided in connection with awards under our 2017 Equity Plan.

- 1. Stock options and SARs.** The Administrator may grant share options, including ISOs, and SARs. A share option is a right entitling the holder to acquire shares upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price of each share option, and the base value of each SAR,



granted under our 2017 Equity Plan shall be no less than 100% of the fair market value of a share on the date of grant (110% in the case of certain ISOs). Other than in connection with certain corporate transactions or changes to our capital structure, share options and SARs granted under our 2017 Equity Plan may not be repriced or substituted for with new share options or SARs having a lower exercise price or base value, nor may any consideration be paid upon the cancellation of any share options or SARs that have a per share exercise or base price greater than the fair market value of a share on the date of such cancellation, in each case, without shareholder approval. Each share option and SAR will have a maximum term of not more than ten years from the date of grant (or five years, in the case of certain ISOs).

2. *Restricted and unrestricted shares and share units.* The Administrator may grant awards of shares, share units, restricted shares and restricted share units. A share unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted share unit is a share unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted shares are shares that are subject to restrictions requiring that they be redelivered or offered for sale to the Company if specified conditions are not satisfied.

3. *Performance awards.* The Administrator may grant performance awards, which are awards subject to performance criteria. The Administrator may grant performance awards that are intended to qualify as exempt performance-based compensation under Section 162(m), to the extent applicable, and awards that are not intended to so qualify.

4. *Other stock-based awards.* The Administrator may grant other awards that are convertible into or otherwise based on shares, subject to such terms and conditions as it determines.

5. *Substitute awards.* The Administrator may grant substitute awards, which may have terms and conditions that are inconsistent with the terms and conditions of our 2017 Equity Plan.

**Vesting; terms of awards.** The Administrator determines the terms of all awards granted under our 2017 Equity Plan, including the time or times an award vests or becomes exercisable, the terms on which an award remains exercisable, and the effect of termination of a participant's employment or service on an award. The Administrator may at any time accelerate the vesting or exercisability of an award.

**Transferability of awards.** Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

**Performance criteria.** Our 2017 Equity Plan provides for grants of performance awards subject to "performance criteria." Performance criteria with respect to those awards that are intended to qualify as "performance-based compensation" for purposes of Section 162(m) are limited to objectively determinable measures of performance relating to any, or any combination of, the following (measured either absolutely or comparatively (including, without limitation, by reference to an index or indices or the performance of one or more companies) and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof and subject to such adjustments, if any, as the Administrator specifies, consistent with the requirements of Section 162(m) of the Code, to the extent applicable): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; share or ADS price; shareholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or strategic business criteria, consisting of one or more objectives including meeting specified market penetration or value added, product development or introduction (including, without limitation any clinical trial accomplishments, regulatory or other filings or approvals, or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, patent application or issuance goals. To the extent consistent with the requirements of the performance-based compensation exception under Section 162(m) of the Code, the Administrator may provide in the case of any award intended to qualify for such exception that one or more of the performance criteria applicable to such award will be adjusted in an objectively

determinable manner to reflect events (for example, but without limitation, acquisitions or dispositions) occurring during the performance period that affect the applicable performance criteria. During a transition period following the completion of our initial public offering, the Administrator may grant awards under our 2017 Equity Plan that are exempt from Section 162(m) of the Code and its requirements under a special transition rule.

**Effect of certain transactions.** In the event of certain covered transactions (including the consummation of a merger, consolidation, or the sale of substantially all of the Company's assets or shares, a change in ownership of the Company's shares, or the dissolution or liquidation of the Company), the Administrator may, with respect to outstanding awards, provide for (in each case, on such terms and subject to such conditions as it deems appropriate):

1. The assumption, substitution or continuation of some or all awards (or any portion thereof) by the acquirer or surviving entity;
2. The acceleration of exercisability or delivery of shares in respect of any award, in full or in part; and/or
3. The cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the Administrator may otherwise determine, each award will automatically terminate immediately upon the consummation of the covered transaction, other than awards that are substituted for or assumed.

**Adjustment provisions.** In the event of certain corporate transactions, including an extraordinary cash dividend, share dividend, share split or combination of shares (including a reverse share split), recapitalization or other change in our capital structure, the Administrator shall make appropriate adjustments to the maximum number of shares that may be issued under our 2017 Equity Plan, the individual award limits, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of, outstanding awards, and any other provisions affected by such event.

**Clawback.** The Administrator may provide that any outstanding award or the proceeds of any award or shares acquired thereunder will be subject to forfeiture and disgorgement to the Company if the participant to whom the award was granted violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

**Amendments and termination.** The Administrator may at any time amend our 2017 Equity Plan or any outstanding award and may at any time terminate our 2017 Equity Plan as to future grants. However, except as expressly provided in our 2017 Equity Plan, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent (unless the Administrator expressly reserved the right to do so at the time the award was granted). Any amendments to our 2017 Equity Plan will be conditioned on shareholder approval to the extent required by law or applicable stock exchange requirements.

**Outstanding awards.** The following table summarizes the outstanding share options and restricted shares held by our directors and executive officers, as well as by their affiliates, as of March 31, 2018.

Name	Ordinary shares* underlying outstanding awards, which represent options unless otherwise indicated	Purchase price (\$/share)	Exercise price (\$/share)	Date of grant(1)
Samantha Du	216,666	N/A US\$	0.60	March 5, 2015
	1,739,166	N/A US\$	0.60	October 22, 2015
	604,376	N/A US\$	1.20	March 9, 2016
	922,184	N/A US\$	1.74	August 25, 2016
	350,000	N/A US\$	20.90	March 28, 2018
Harald Reinhart	66,666	N/A US\$	3.00	May 12, 2017
	100,000	N/A US\$	18.00	September 20, 2017
	100,000	N/A US\$	20.90	March 28, 2018
Qi Liu	333,333	N/A US\$	0.60	October 22, 2015
	33,333	N/A US\$	1.74	August 25, 2016
Billy Cho	400,000	N/A US\$	21.84	March 2, 2018
	100,000 (2)	N/A	N/A	March 2, 2018
Ning Xu	211,666	N/A US\$	0.60	March 5, 2015
	450,000	N/A US\$	0.60	October 22, 2015
James Yan	333,333	N/A US\$	0.60	October 22, 2015
	83,333	N/A US\$	1.74	August 25, 2016
Marietta Wu	48,611	N/A US\$	0.60	March 5, 2015 (3)
	60,000	N/A US\$	0.60	October 22, 2015 (3)
	25,000	N/A US\$	1.20	March 9, 2016 (3)
Peter Wirth	12,500 (2)	N/A	N/A	January 1, 2018
Tao Fu	25,000 (2)	N/A	N/A	September 20, 2017
	12,500 (2)	N/A	N/A	January 1, 2018
John Diekman	25,000 (2)	N/A	N/A	September 20, 2017
	12,500 (2)	N/A	N/A	January 1, 2018

(1) Options expire on or before the 10-year anniversary of the grant date.

(2) Represents restricted shares.

(3) Options expire on or before April 5, 2019.

### Other Compensation Programs

#### 2017 Cash Bonus Plan

Our board of directors has adopted and our shareholders have approved the Zai Lab Limited 2017 Cash Bonus Plan (our “Cash Plan”). Starting in calendar year 2018, annual award opportunities for executive officers and key employees of the Company and its subsidiaries will be granted under our Cash Plan. The following summary describes the material terms of our Cash Plan. This summary is not a complete description of all provisions of our Cash Plan and is qualified in its entirety by reference to our Cash Plan, which is filed as an exhibit to this Annual Report on Form 20-F.

**Administration.** Our Cash Plan will be administered by our compensation committee and its delegates. As used in this summary, the term “Administrator” refers to our compensation committee and its authorized delegates, as applicable. The Administrator will have the discretionary authority to interpret our Cash Plan, determine eligibility for and grant awards, determine, modify or waive the terms and conditions of any award, prescribe forms, rules and procedures relating to our Cash Plan and awards, and otherwise do all things necessary or appropriate to carry out the purposes of our Cash Plan.

**Eligibility and participation.** Executive officers and key employees of the Company and its subsidiaries will be eligible to participate in our Cash Plan and will be selected from time to time by the Administrator to participate in the plan.

**Awards.** For each award granted under our Cash Plan, the Administrator will establish the performance criteria applicable to the award, the amount or amounts payable if the performance criteria are achieved and such other terms and conditions as the Administrator deems appropriate. Our Cash Plan permits the grant of awards that are intended to satisfy the requirements of the performance-based compensation exception under Section 162(m) of the Code, to the extent applicable, or Section 162(m) Awards, and awards that are not intended to satisfy such requirements. For Section 162(m) Awards, the terms of the award will be established within the time periods required under Section 162(m) of the Code.

**Performance criteria.** Awards under our Cash Plan will be made based on, and subject to achieving, specified criteria established by the Administrator. Performance criteria for Section 162(m) Awards are limited to objectively determinable measures of performance relating to any, or any combination of, the following (measured either absolutely or comparatively (including, without limitation, by reference to an index or indices or the performance of one or more companies) and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof and subject to such adjustments, if any, as the Administrator specifies, consistent with the requirements of Section 162(m) of the Code, to the extent applicable): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; share or ADS price; shareholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or strategic business criteria, consisting of one or more objectives based on: meeting specified market penetration or value added, product development or introduction (including, without limitation any clinical trial accomplishments, regulatory or other filings or approvals, or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, patent application or issuance goals.

To the extent consistent with the requirements of the performance-based compensation exception under Section 162(m) of the Code, the Administrator may provide in the case of any award intended to qualify for such exception that one or more of the performance criteria applicable to such award will be adjusted in an objectively determinable manner to reflect events (for example, but without limitation, acquisitions or dispositions) occurring during the performance period that affect the applicable performance criteria. During a transition period following the completion of our initial public offering, the Administrator may grant awards under our Cash Plan that are exempt from Section 162(m) of the Code and its requirements under a special transition rule.

**Payments under an award; individual limits.** A participant will be entitled to payment under an award only if all conditions to payment have been satisfied in accordance with our Cash Plan and the terms of the award. Following the end of a performance period, the Administrator will determine (and, to the extent required by Section 162(m) of the Code, take such steps to certify) whether and to what extent the applicable performance criteria have been satisfied and will determine the amount payable under each award. The Administrator has the discretionary authority to increase or decrease the amount actually paid under any award, provided that the actual payment of Section 162(m) Awards may not be more than the amount indicated by the certified level of achievement. The maximum amount payable to any participant in any calendar year under Section 162(m) Awards will be \$5,000,000.

**Recovery of compensation.** Payments in respect of an award will be subject to forfeiture and disgorgement to the Company if the participant to whom the award was granted violates a non-competition, non-solicitation, confidentiality or other restrictive covenant or to the extent provided in any applicable Company policy that provides for forfeiture or disgorgement, or as otherwise required by law or applicable stock exchange listing standards.

**Amendment and termination.** The Administrator may amend or terminate our Cash Plan at any time, except that any amendment or termination that would materially and adversely affect a participant's rights under an award will require the consent of the affected participant, unless the Administrator expressly reserved the right to so amend the award at the time of grant, and any amendment will be approved by our stockholders if required by Section 162(m) of the Code.

## ***Non-Employee Director Compensation Policy***

Our board of directors has adopted a non-employee director compensation policy under which each member of our board of directors who is not an employee of the Company or one of our affiliates (each a “non-employee director”) will be eligible to receive an annual cash retainer payment of \$50,000. In addition, each non-employee director who was appointed to our board of directors following the adoption of this policy and whose appointment was effective prior to our IPO received an award of 25,000 restricted shares under our 2017 Equity Plan, which vests ratably on each of the first three anniversaries of the date of grant, subject to continued service as a member of our board of directors through such date. Further, commencing in calendar year 2018, non-employee directors will be eligible to receive an annual grant of 12,500 restricted shares under our 2017 Equity Plan, which will vest in full on the first anniversary of the date of grant, subject to continued service as a member of our board of directors through such date.

In addition, the non-employee director compensation policy provides for the following additional annual cash retainer payments for the members and chairpersons of our board committees: audit committee chair, \$20,000; audit committee member, \$10,000; compensation committee chair, \$15,000; compensation committee member, \$7,500; nominating committee chair, \$10,000; and nominating committee member, \$5,000.

### **C. Board Practices**

#### ***Composition of Our Board***

Our board of directors consists of seven directors, of whom two qualify as independent directors under the rules and regulations of the SEC and Nasdaq Stock Market. Our directors hold office until they are removed from office by special resolution at an annual general meeting of the shareholders or by a vote of the board of directors. In addition, a director will cease to be a director if the director (i) dies, becomes bankrupt or makes any arrangement or composition with his or her creditors, (ii) is found to be or becomes of unsound mind or (iii) resigns his office by notice in writing to the Company. For information regarding the period during which our officers and directors have served in their respective positions, please see “Item 6.A. Directors and Senior Management.”

#### ***Duties of Directors***

Under Cayman Islands law, all of our directors owe us fiduciary duties, including a duty of loyalty, a duty to act honestly and a duty to act in good faith and in a manner they believe to be in our best interests. Our directors also have a duty to exercise the skill they actually possess and such care and diligence that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our amended articles of association, as amended and restated from time to time. We have the right to seek damages if a duty owed by any of our directors is breached.

#### ***Board Committees***

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

##### *Audit Committee*

Our audit committee consists of Tao Fu, John Diekman and Marietta Wu, with Mr. Fu serving as chairman of the committee. We have determined that Mr. Fu qualifies as a financial expert as set forth under the applicable rules of the SEC and that Mr. Fu and Dr. Diekman each satisfies the independence requirements under the rules of the Nasdaq Stock Market and under Rule 10A-3 of the Exchange Act.

The audit committee oversees our accounting and financial reporting processes and the audits of our financial statements. Our audit committee is responsible for, among other things:

- selecting, and evaluating the qualifications, performance and independence of, the independent auditor;
- approving or, as permitted, pre-approving auditing and non-auditing services permitted to be performed by the independent auditor;
- considering the adequacy of our internal accounting controls and audit procedures;

- reviewing with the independent auditor any audit problems or difficulties and management’s response;
- reviewing and approving related party transactions;
- reviewing and discussing the annual audited financial statements with management and the independent auditor;
- establishing procedures for the receipt, retention and treatment of complaints received from our employees regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- meeting separately, periodically, with management, internal auditors and the independent auditor; and
- reporting regularly to the full board of directors.

#### *Compensation Committee*

Our compensation committee consists of Peter Wirth, Jianming Yu and Nisa Leung, with Mr. Wirth serving as chairman of the committee.

Our compensation committee is responsible for, among other things:

- reviewing, evaluating and, if necessary, revising our overall compensation policies;
- reviewing and evaluating the performance of our directors and executive officers and determining the compensation of our executive officers;
- reviewing and approving our executive officers’ employment agreements with us;
- determining performance targets for our executive officers with respect to our incentive compensation plan and equity-based compensation plans;
- administering our equity-based compensation plans in accordance with the terms thereof; and
- carrying out such other matters that are specifically delegated to the compensation committee.

#### *Nominating and Corporate Governance Committee*

Our nominating and corporate governance committee consists of Samantha Du, Jianming Yu and Nisa Leung, with Ms. Du serving as chairman of the committee.

Our nominating and corporate governance committee is responsible for, among other things:

- selecting the board nominees for election by the shareholders or appointment by the board;
- periodically reviewing with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and
- advising the board periodically with regards to significant developments in corporate governance law and practices as well as our compliance with applicable laws and regulations, and making recommendations to the board on corporate governance matters.

## Code of Ethics

Our board of directors has adopted a code of ethics to set standards for our directors, officers and employees as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the reports and documents that we file or submit to the applicable stock exchanges, and in any other public communications; (iii) compliance with applicable governmental and regulatory laws, rules, codes and regulations; (iv) prompt internal reporting of any violations of the code of ethics; and (v) accountability for adherence to the code of ethics.

## Complaints Procedures

Our board of directors has adopted procedures for the confidential receipt, retention, and treatment of complaints from, or concerns raised by, employees regarding accounting, internal accounting controls and auditing matters as well as illegal or unethical matters. The complaint procedures are reviewed by the audit committee from time to time as warranted to ensure their continuing compliance with applicable laws and listing standards as well as their effectiveness.

### D. Employees

As of December 31, 2017, 2016 and 2015, we had 88, 50 and 24 full-time employees, respectively. None of our employees are represented by labor unions or covered by collective bargaining agreements. The number of employees by function as of the end of the period for our fiscal years ended December 31, 2017, 2016 and 2015 was as follows:

By Function	2017	2016	2015
Discovery	17	16	8
Development	55	24	8
General and Administrative	16	10	8
Total	88	50	24

### E. Share Ownership.

We had 50,555,903 ordinary shares outstanding as of March 31, 2018. The following table and accompanying footnotes set forth information relating to the beneficial ownership of our ordinary shares as of March 31, 2018 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our directors;
- each of our executive officers; and
- all of our executive officers and directors as a group.

Our major shareholders do not have voting rights that are different from our shareholders in general. Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

Name of beneficial owner†	Ordinary Shares Beneficially Owned	
	Number	Percent
<b>Executive Officers and Directors:</b>		
Samantha Du(1)	9,072,796	17.4%
Harold Reinhart	—	—
Qi Liu(2)	178,887	*
Billy Cho	—	—
Ning Xu(3)	366,554	*
James Yan(4)	188,887	*
Marietta Wu(5)	133,611	*
Peter Wirth	300,000	*
John Diekman	—	—
Tao Fu	—	—
Nisa Leung	—	—
Jianming Yu	—	—
<b>All Executive Officers and Directors as a Group</b>	<b>10,240,735</b>	<b>19.4%</b>
<b>Beneficial Owners of 5% or More of our Ordinary Shares:</b>		
QM 11 Limited(6)	10,470,933	20.7%
Investment funds affiliated with Advantech Capital(7)	7,167,397	14.2%
The Z Trust(8)	4,289,930	8.5%
FMR, LLC(9)	4,278,583	8.5%
Investment funds affiliated with Sequoia Capital(10)	3,884,152	7.7%
KPCB China Fund II, L.P.(11)	3,787,311	7.5%

\* The person beneficially owns less than 1% of our outstanding ordinary shares.

† The business address of all directors and officers is 4560 Jinke Road, Bldg. 1, 4F, Pudong, Shanghai, China 201210.

- (1) Includes 1,461,975 ordinary shares issuable to Dr. Du upon exercise of vested options and options exercisable within 60 days of March 31, 2018. Includes 6,267,488 ordinary shares held by certain holders of ordinary shares, including Zai management and their affiliates. Although Dr. Du does not have any pecuniary interest in these ordinary shares, these shareholders have granted Dr. Du the right to vote their shares and, therefore, she may be deemed to be the beneficial owner of the ordinary shares held by these shareholders.
- (2) Includes 178,887 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2018.
- (3) Includes 366,554 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2018.
- (4) Includes 188,887 ordinary shares issuable upon exercise of vested options and options exercisable within 60 days of March 31, 2018.
- (5) Includes 133,611 ordinary shares issuable upon exercise of vested options.
- (6) Based on a Schedule 13G filed on February 14, 2018. The address for QM 11 Limited is Unit 1904 Gloucester Tower, The Landmark, Central, Hong Kong.
- (7) Based on a Schedule 13G filed on February 13, 2018. Consists of (i) 6,734,064 ordinary shares held by Maxway Investment Limited and (ii) 433,333 ordinary shares held by Harbor Front Investment Limited. The address for Maxway Investment Limited and Harbor Front Investment Limited is c/o DMS House, 20 Genesis Close, George Town, Grand Cayman, KY1-1103, Cayman Islands.
- (8) The address for The Z Trust is 16015 Huebner BLF, San Antonio, Texas 78248-1469.



- (9) Based upon the information provided by FMR LLC in a Schedule 13G filed on February 13, 2018. Abigail P. Johnson is a Director, the and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02110
- (10) Based on a Schedule 13G filed on February 14, 2018. Consists of (i) 2,986,278 ordinary shares held by Sequoia Capital CV IV Holdco, Ltd. and (ii) 897,874 ordinary shares held by SCC Growth I Holdco A, Ltd. The address for Sequoia Capital CV IV Holdco, Ltd. and SCC Growth I Holdco A, Ltd. is Conyers Trust Company (Cayman) Limited, P.O. Box 2681, Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman, KY1-1111, Cayman Islands.
- (11) Based on a Schedule 13G filed on February 14, 2018. The address for KPCB China Fund II, L.P. is c/o Campbells Corporate Services Limited, Floor 4, Willow House, Cricket Square, PO Box 268 Grand Cayman KY1-1104, Cayman Islands.

As of December 31, 2017, based on public filings with the SEC, there are no major shareholders owning 5% or more of our ordinary shares or ADSs representing ordinary shares, except as described above. As of December 31, 2017, we had 11 holders of record with addresses in the United States, including Citibank, N.A., depository of our ADS program, which held 15,031,735 ordinary shares as of that date.

To our knowledge, except as disclosed above, we are not owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any other natural or legal person or persons, severally or jointly. To our knowledge, there are no arrangements the operation of which may at a subsequent date result in us undergoing a change in control. Our major shareholders do not have different voting rights than any of our other shareholders.

## **ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

### **A. Major Shareholders.**

Please refer to "Item 6.E. Directors, Senior Management and Employees—Share Ownership."

### **B. Related Party Transactions**

The following is a description of related party transactions we have entered into since January 1, 2017 with any members of our board of directors or executive officers and beneficial holders of more than 5% of our ordinary shares:

#### **Agreements and Transactions with Shareholders**

##### ***Registration Rights Agreement***

We have entered into a shareholders agreement in January 2016, or the Registration Rights Agreement, with certain of our shareholders, in which we granted certain demand registration rights, piggyback registration rights and F-3 registration rights to holders of our registrable securities.

### **Shareholder Private Placements**

On June 26, 2017, we closed a private placement transaction pursuant to which we sold an aggregate of 1,998,958 of Series C preferred shares for an aggregate consideration of \$30,000,000. The following table sets forth the number of shares of our Series C preferred shares we issued to our 5% stockholders and their affiliates in this transaction:

<u>Investor</u>	<u>Shares of Series C preferred shares</u>	<u>Purchase price (\$)</u>
The Z Trust	133,264	2,000,000
QM 11 Limited	66,632	1,000,000

### **Other Relationships**

#### **Voting Proxy**

Certain holders of our ordinary shares, which hold 6,267,488 ordinary shares, have granted Dr. Du the right to vote their ordinary shares.

#### **Quan Venture Partners I, L.L.C.**

Quan Venture Fund I, L.P., or Quan Fund, is a Cayman Islands exempted limited partnership organized in April 2017 to make capital investments in global public and private companies with a particular focus on the healthcare industry. Quan Fund's general partner, which is responsible for investment and divestment decisions related to the Quan Fund, is Quan Venture Partners I, L.L.C., or Quan GP, a Cayman Islands limited liability company. Each of Dr. Du and Marietta Wu are managers of Quan GP. In the first half of 2017, Zai sold its interest in three entities to the Quan Fund, for a total consideration of approximately \$500,000.

### **Agreements with Our Directors and Executive Officers**

#### **Compensation of Directors and Executive Officers**

See "Item 6.B. Directors, Senior Management and Employees—Compensation—Compensation of Directors and Executive Officers" for a discussion of our compensation of directors and executive officers.

#### **Employment Agreements**

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see "Item 6.B. Directors, Senior Management and Employees—Compensation—Employment Arrangements with Our Executive Officers."

#### **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and executive officers. We also maintain a general liability insurance policy which covers certain liabilities of our directors and executive officers arising out of claims based on acts or omissions in their capabilities as directors or officers.

### **C. Interests of Experts and Counsel**

Not applicable.

## ITEM 8. FINANCIAL INFORMATION

### A. Consolidated Financial Statements and Other Financial Information

See “Item 18 Financial Statements.”

### A.7 Legal Proceedings

We are, from time to time, subject to claims and suits arising in the ordinary course of business. Although the outcome of these and other claims cannot be predicted with certainty, management does not believe that the ultimate resolution of these matters will have a material adverse effect on our financial position or on our results of operations. We are not currently a party to, nor is our property the subject of, any material legal proceedings.

### A.8 Dividend Policy

We have never declared or paid dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not have any present plan to pay any dividends. The declaration and payment of any dividends in the future will be determined by our board of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions.

### B. Significant Changes

We have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

## ITEM 9. THE OFFER AND LISTING

### A. Offering and Listing Details

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Global Market in U.S. dollars.

	Price Per ADS	
	High	Low
<b>Annual:</b>		
2017 (since September 20, 2017)	\$ 35.74	\$ 20.67
2018 (through April 27, 2018)	\$ 27.34	\$ 17.86
<b>Quarterly:</b>		
Third Quarter 2017 (since September 20, 2017)	\$ 32.64	\$ 23.80
Fourth Quarter 2017	\$ 35.74	\$ 20.67
First Quarter 2018	\$ 27.34	\$ 19.80
Second Quarter 2018 (through April 27, 2018)	\$ 22.88	\$ 17.86
<b>Most Recent Six Months:</b>		
November 2017	\$ 30.16	\$ 24.40
December 2017	\$ 27.20	\$ 20.67
January 2018	\$ 26.97	\$ 20.91
February 2018	\$ 27.34	\$ 19.80
March 2018	\$ 23.48	\$ 21.89
April 2018 (through April 27, 2018)	\$ 22.88	\$ 17.86

### B. Plan of Distribution

Not applicable.

### C. Markets

Our ADSs have been listed on the Nasdaq Global Market since September 20, 2017 under the symbol “ZLAB.”

**D. Selling Shareholders**

Not applicable.

**E. Dilution**

Not applicable.

**F. Expenses of the Issue**

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

**A. Share Capital**

Not applicable.

**B. Memorandum and Articles of Association**

We are a Cayman Islands company and our affairs are governed by our fourth memorandum and articles of association and the Companies Law.

The following are summaries of material provisions of our fourth amended and restated memorandum and articles of association that became effective immediately prior to the completion of our initial public offering in September 2017, insofar as they relate to the material terms of our ordinary shares.

**Registered Office and Objects**

Our registered office in the Cayman Islands is located at Harbour Place 2nd Floor, 103 South Church Street, P.O. Box 472, George Town, Grand Cayman KY1-1106, Cayman Islands, or at such other location within the Cayman Islands as our board of directors may from time to time decide. The objects for which our company is established are unrestricted and we have full power and authority to carry out any object not prohibited by the Companies Law, as amended from time to time, or any other law of the Cayman Islands.

**Board of Directors**

See “Item 6.C. Directors, Senior Management and Employees—Board Practices.”

**Ordinary Shares**

**General.** Our authorized share capital consists of \$5,000.00 divided into 83,333,333 ordinary shares, with a par value of \$0.00006 each. Our ordinary shares are issued in registered form, and are issued when registered in our register of members. Certificates representing the ordinary shares are issued in registered form. Our shareholders who are non-residents of the Cayman Islands may freely hold and transfer their ordinary shares.

**Dividends.** The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. Our fourth amended and restated articles of association provide that dividends may be declared and paid out of our profits, realized or unrealized, or from any reserve set aside from profits which our board of directors determine is no longer needed. Dividends may also be declared and paid out of share premium account or any other fund or account which can be authorized for this purpose in accordance with the Companies Law. Holders of ordinary shares will be entitled to the same amount of dividends, if declared.

**Voting rights.** In respect of all matters subject to a shareholders’ vote, each ordinary share is entitled to one vote. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one or more shareholders present in person or by proxy and who together hold not less than 10% of the nominal value of the total issued voting shares of our company. Each holder of our ordinary shares is entitled to have one vote for each ordinary share registered in his or her name on our register of members.

A quorum required for a meeting of shareholders consists of one or more shareholders who hold at least one-third of all voting power of our share capital in issue at the date of the meeting present in person or by proxy or, if a corporation or other non-natural person, by its duly authorized representative. Shareholders' meetings may be held annually. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Extraordinary general meetings may be called by a majority of our board of directors or our chairman or upon a requisition of shareholders holding at the date of deposit of the requisition not less than one-third of the aggregate voting power of our company. Advance notice of at least seven days is required for the convening of our annual general meeting and other general meetings unless such notice is waived in accordance with our articles of association.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to all issued and outstanding shares cast at a meeting, while a special resolution also requires the affirmative vote of no less than two-thirds of the votes cast attaching to the issued and outstanding shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our fourth amended and restated memorandum and articles of association.

**Transfer of ordinary shares.** Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four;
- the shares are free from any lien in favor of the Company; and
- a fee of such maximum sum as the Nasdaq Stock Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on 14 days' notice being given by advertisement in one or more newspapers or by electronic means, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year.

**Liquidation.** On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of ordinary shares), assets available for distribution among the holders of ordinary shares shall be distributed by a liquidator who may divide our assets for distribution among our shareholders in his discretion. The liquidator also may vest all or part of our assets in trust. None of our shareholders may be compelled to accept any shares subject to liability.

**Calls on ordinary shares and forfeiture of ordinary shares.** Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their ordinary shares in a notice served to such shareholders at least 14 clear days prior to the specified time of payment. The ordinary shares that have been called upon and remain unpaid are subject to forfeiture.

**Redemption of ordinary shares.** The Companies Law and fourth amended and restated articles of association permit us to purchase our own shares. In accordance with our fourth amended and restated articles of association and provided the necessary shareholders or board approval have been obtained, we may issue shares on terms that are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner, including out of capital, as may be determined by our board of directors.

**Variations of rights of shares.** All or any of the special rights attached to any class of shares may, subject to the provisions of the Companies Law, be varied with the written consent of the holders of a majority of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with such existing class of shares.

**Inspection of books and records.** Holders of our ordinary shares have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we will provide our shareholders with annual audited financial statements.

**Issuance of additional shares.** Our fourth amended and restated memorandum of association authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our fourth amended and restated memorandum of association also authorizes our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights and voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

**Anti-Takeover provisions.** Some provisions of our fourth amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders.

**Exempted company.** We are an exempted company with limited liability under the Companies Law. The Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);

- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.

### **C. Material Contracts**

We have not entered into any material contracts other than in the ordinary course of business and other than those described in “Item 4. Information on the Company” or elsewhere in this Annual Report on Form 20-F.

### **D. Exchange Controls**

See “Item 4.B. Information on the Company—Business—Regulation—Regulations Relating to Foreign Exchange Registration of Offshore Investment by PRC Residents.”

### **E. Taxation**

The following is a discussion of the material Cayman Islands, People’s Republic of China and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decisions to acquire ADSs.

#### **Material Cayman Islands Taxation**

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

#### **Material People’s Republic of China Taxation**

We are a holding company incorporated in the Cayman Islands.

Under the EIT Law and its implementation rules, an enterprise established outside of China with a “de facto management body” within China is considered a “resident enterprise,” and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term “de facto management body” as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State Administration of Taxation issued SAT Circular 82, which provides certain specific criteria for determining whether the “de facto management body” of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation’s general position on how the “de facto management body” text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, all offshore enterprises controlled by a PRC enterprise or a PRC enterprise will be regarded as a PRC tax resident by virtue of having its “de facto management body” in China only if all of the following conditions are met:

- (i) the primary location of the day-to-day operational management is in the PRC;
- (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC;
- (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and

(iv) at least 50% of voting board members or senior executives habitually reside in China.

We believe that none of Zai Lab Limited and its subsidiaries outside of China is a PRC resident enterprise for PRC tax purposes. Zai Lab Limited is not controlled by a PRC enterprise or PRC enterprise group, and we do not believe that Zai Lab Limited meets all of the conditions above. Zai Lab Limited is a company incorporated outside China. As a holding company, some of its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside China. For the same reasons, we believe our other subsidiaries outside of China are also not PRC resident enterprises. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term “de facto management body.”

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

See “Item 3.D. Risk Factors—Risks Related to Doing Business in China—If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders.”

Pursuant to the EIT Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in China, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) it must have directly owned such percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. Furthermore, the Administrative Measures for Non-Resident Enterprises to Enjoy Treatments under Tax Treaties (For Trial Implementation), which became effective in October 2009, require that non-resident enterprises must obtain approval from the relevant tax authority in order to enjoy the reduced tax rate. There are also other conditions for enjoying the reduced tax rate according to other relevant tax rules and regulations. Accordingly, our subsidiary Zai Lab (Hong Kong) Limited may be able to enjoy the 5% tax rate for the dividends it receives from its PRC incorporated subsidiaries if they satisfy the conditions prescribed under SAT Circular 81 and other relevant tax rules and regulations and obtain the approvals as required. However, according to SAT Circular 81, if the relevant tax authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

If our Cayman Islands holding company, Zai Lab Limited, is not deemed to be a PRC resident enterprise, holders of our ADSs and ordinary shares who are not PRC residents will not be subject to PRC income tax on dividends distributed by us or gains realized from the sale or other disposition of our shares or ADSs.

#### **Material United States Federal Income Tax Considerations**

The following discussion, subject to the limitations set forth below, describes the material U.S. federal income tax consequences for a U.S. Holder (as defined below) of the acquisition, ownership and disposition of ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person’s decision to acquire our



ADSs. This discussion is limited to U.S. Holders who hold such ADSs as capital assets (generally, property held for investment). This discussion is based on Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the PRC and the United States, or the U.S.-PRC Tax Treaty, each as available and in effect on the date hereof, all of which are subject to change or differing interpretations, possibly with retroactive effect, which could affect the tax consequences described herein. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

For purposes of this summary, a “U.S. Holder” is a beneficial owner of an ADS that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States or any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) it has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court can exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

Except as explicitly set forth below, this summary does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders subject to special rules, including:

- banks or other financial institutions;
- insurance companies;
- real estate investment trusts;
- regulated investment companies
- grantor trusts;
- tax-exempt organizations;
- persons holding ADSs through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- dealers or traders in securities, commodities or currencies;
- persons whose functional currency is not the U.S. dollar;
- certain former citizens and former long-term residents of the United States;
- persons holding ADSs as part of a position in a straddle or as part of a hedging, conversion or integrated transaction for U.S. federal income tax purposes; or
- direct, indirect or constructive owners of 10% or more of our total combined voting power or value.

In addition, this summary does not address the 3.8% Medicare contribution tax imposed on certain net investment income, the U.S. federal estate and gift tax or the alternative minimum tax consequences of the acquisition, ownership, and disposition of ADSs. We have not received nor do we expect to seek a ruling from the U.S. Internal Revenue Service, or the IRS, regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Moreover, on December 22, 2017, President Trump signed into law new legislation that significantly revises the Code. The overall impact of the new federal tax law is uncertain and the impact of this tax reform on holders of our ADSs is also uncertain and could be adverse. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of ADSs.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership should consult its own tax advisors as to the U.S. federal income tax consequences of acquiring, owning and disposing of ADSs.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEIR SITUATIONS AS WELL AS THE APPLICATION OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S. OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.

## **ADSs**

A U.S. Holder of ADSs will generally be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that such ADSs represent. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depository or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of non-U.S. withholding taxes (if any), and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

## **Taxation of Dividends**

As described in “Item 8. Financial Information—A.8 Dividend Policy,” we do not currently anticipate paying any distributions on our ADSs in the foreseeable future. However, subject to the discussion below in “—Passive Foreign Investment Company Considerations,” to the extent there are any distributions made with respect to our ADSs, the gross amount of any distribution on the ADSs (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder’s adjusted tax basis in the ADSs and thereafter as capital gain. However, because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax accounting principles, U.S. Holders should expect to treat distributions paid with respect to the ADSs as dividends. Dividends paid to corporate U.S. Holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. This discussion assumes that distributions on the ADSs, if any, will be paid in U.S. dollars.

Dividends paid to a non-corporate U.S. Holder by a “qualified foreign corporation” may be subject to reduced rates of U.S. federal income taxation if certain holding period and other requirements are met. A qualified foreign corporation generally includes a foreign corporation (other than a PFIC) if (1) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (2) it is eligible for benefits under a comprehensive U.S. income tax treaty that includes an exchange of information program and which the U.S. Treasury Department has determined is satisfactory for these purposes.

Our ADSs are listed on the Nasdaq Global Market, which is an established securities market in the United States. IRS guidance indicates that the ADSs will be readily tradable for these purposes.

The United States does not have a comprehensive income tax treaty with the Cayman Islands. However, in the event that we were deemed to be a PRC resident enterprise under the EIT Law (see “—Material People’s Republic of China Taxation” above), although no assurance can be given, we might be considered eligible for the benefits of the U.S.-PRC Tax Treaty, and if we were eligible for such benefits, dividends paid on the ADSs, regardless of whether the ADSs are readily tradable on an established securities market in the United States, would be eligible for the reduced rates of U.S. federal income taxation, subject to applicable limitations. U.S. Holders should consult their own tax advisors regarding the availability of the reduced tax rates on dividends in light of their particular circumstances.

Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

In the event that we were deemed to be a PRC resident enterprise under the EIT Law (see “—People’s Republic of China Taxation” above), ADS holders might be subject to PRC withholding taxes on dividends paid with respect to ADSs. In that case, subject to certain conditions and limitations, such PRC withholding tax may be treated as a foreign tax eligible for credit against a U.S. Holder’s U.S. federal income tax liability under the U.S. foreign tax credit rules. For purposes of calculating the U.S. foreign tax credit, dividends paid on the ADSs will be treated as income from sources outside the United States and will generally constitute passive category income. If a U.S. Holder is eligible for U.S.-PRC Tax Treaty benefits, any PRC taxes on dividends will not be creditable against such U.S. Holder’s U.S. federal income tax liability to the extent such tax is withheld at a rate exceeding the applicable U.S.-PRC Tax Treaty rate. An eligible U.S. Holder who does not elect to claim a foreign tax credit for PRC tax withheld may instead be eligible to claim a deduction, for U.S. federal income tax purposes, in respect of such withholding but only for the year in which such U.S. Holder elects to do so for all creditable foreign income taxes. The U.S. foreign tax credit rules are complex. U.S. Holders should consult their own tax advisors regarding the foreign tax credit or deduction rules in light of their particular circumstances.

### ***Taxation of Capital Gains***

Subject to the discussion below in “—Passive Foreign Investment Company Considerations” below, upon the sale, exchange, or other taxable disposition of ADSs, a U.S. Holder generally will recognize gain or loss on the taxable sale or exchange in an amount equal to the difference between the amount realized on such sale or exchange and the U.S. Holder’s adjusted tax basis in the ADSs. The initial tax basis of ADSs to a U.S. Holder will generally be the U.S. Holder’s U.S. dollar purchase price for the ADS.

Subject to the discussion below in “—Passive Foreign Investment Company Considerations” below, such gain or loss will be capital gain or loss. Under current law, capital gains of non-corporate U.S. Holders derived with respect to capital assets held for more than one year are generally eligible for reduced rates of taxation. The deductibility of capital losses is subject to limitations. Capital gain or loss, if any, recognized by a U.S. Holder generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders are encouraged to consult their own tax advisors regarding the availability of the U.S. foreign tax credit in consideration of their particular circumstances.

If we were treated as a PRC resident enterprise for EIT Law purposes and PRC tax were imposed on any gain (see “—Material People’s Republic of China Taxation” above), and if a U.S. Holder is eligible for the benefits of the U.S.-PRC Tax Treaty, the holder may be able to treat such gain as PRC source gain under the treaty for U.S. foreign tax credit purposes. A U.S. Holder will be eligible for U.S.-PRC Tax Treaty benefits if (for purposes of the treaty) such holder is a resident of the United States and satisfies the other requirements specified in the U.S.-PRC Tax Treaty. Because the determination of treaty benefit eligibility is fact-intensive and depends upon a holder’s particular circumstances, U.S. Holders should consult their tax advisors regarding U.S.-PRC Tax Treaty benefit eligibility. U.S. Holders are also encouraged to consult their own tax advisors regarding the tax consequences in the event PRC tax were to be imposed on a disposition of ADSs, including the availability of the U.S. foreign tax credit and the ability and whether to treat any gain as PRC source gain for the purposes of the U.S. foreign tax credit in consideration of their particular circumstances.

### ***Passive Foreign Investment Company Considerations***

#### ***Status as a PFIC***

The rules governing PFICs can have adverse tax effects on U.S. Holders. We generally will be classified as a PFIC for U.S. federal income tax purposes if, for any taxable year, either: (1) 75% or more of our gross income consists of certain types of passive income (the Income Test), or (2) the average value (determined on a quarterly basis), of our assets that produce, or are held for the production of, passive income (including cash) is 50% or more of the value of all of our assets (the Asset Test).

Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation’s income.

Whether we are a PFIC for any taxable year is a factual determination that can be made only after the end of each taxable year and which depends on the composition of our income and the composition and value of our assets for the relevant taxable year. The fair market value of our assets for purposes of the PFIC rules (including goodwill) may be determined in large part by reference to the quarterly market price of our ADSs, which is likely to fluctuate significantly. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash in our business, including any cash that is raised in a financing transaction.

We believe that our Hong Kong subsidiary, Zai Lab (Hong Kong) Limited, was a PFIC for its taxable year ended December 31, 2017 and we do not expect that the Company and its subsidiaries will be treated as PFICs for the current taxable year. However, because we hold a substantial amount of passive assets, including cash, and because the value of our assets (including goodwill) may be determined by reference to the market value of our ADSs, which may be especially volatile due to the early stage of our drug candidates, we cannot give any assurance that we will not be a PFIC status for the current or any future taxable year.

If we are a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless we cease to be a PFIC and (i) the U.S. Holder makes the “deemed sale election” described below, (ii) the U.S. Holder has a valid mark-to-market election in effect as described below, or a PFIC during such U.S. Holder’s holding period in which we are a PFIC or makes a purging election to cause a deemed sale of the PFIC shares at their fair market value in connection with a QEF election (as discussed below). If a U.S. Holder makes a deemed sale election, such U.S. Holder will be deemed to have sold the shares held by such U.S. Holder at their fair market value, and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, a U.S. Holder’s ADSs subject to such election will not be treated as shares in a PFIC, and the rules described below with respect to any “excess distributions” or any gain from an actual sale or other disposition of the ADSs will not apply. Prospective investors should consult their own tax advisors regarding our PFIC status for the current or any future taxable years.

#### *U.S. Federal Income Tax Treatment of a Shareholder of a PFIC*

If we are a PFIC for any taxable year during which a U.S. Holder owns ADSs, the U.S. Holder, absent the elections listed above, generally will be subject to adverse rules (regardless of whether we continue to be a PFIC) with respect to (1) any “excess distributions” (generally, any distributions received by the U.S. Holder on its ADSs in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder’s holding period for its ADSs) and (2) any gain realized on the sale or other disposition, including in certain circumstances a pledge, of its ADSs.

Under these adverse rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder’s holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income and (c) the amount allocated to each other taxable year during the U.S. Holder’s holding period in which we were a PFIC (i) will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and (ii) will be subject to an interest charge at a statutory rate with respect to the resulting tax attributable to each such other taxable year. Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we were a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

If we are a PFIC, a U.S. Holder will generally be treated as owning a proportionate amount (by value) of stock or shares owned by us in any direct or indirect subsidiaries that are also PFICs, or Lower-tier PFICs, and will be subject to similar adverse rules with respect to any distributions we receive from, and dispositions we make of, the stock or shares of such subsidiaries. U.S. Holders are urged to consult their tax advisors about the application of the PFIC rules to any of our subsidiaries.

#### *PFIC “Mark-to-Market” Election*

In certain circumstances if we are a PFIC for any taxable year, a U.S. Holder can be subject to rules different from those described above by making a mark-to-market election with respect to its ADSs, provided that the ADSs are “marketable.” ADSs will be marketable if they are “regularly traded” on a “qualified exchange” or other market within the meaning of applicable U.S. Treasury Regulations. ADSs will be treated as “regularly traded” in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter. A “qualified exchange” includes a national securities exchange that is registered with the SEC.

Under current law, the mark-to-market election may be available to U.S. Holders of ADSs if the ADSs are listed on the Nasdaq Global Market (which constitutes a qualified exchange) and such ADSs are “regularly traded” for purposes of the mark-to-market election (for which no assurance can be given).

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the U.S. Holder’s ADSs at the close of the taxable year over the U.S. Holder’s adjusted tax basis in its ADSs. Accordingly, such mark-to-market election may accelerate the recognition of income without a corresponding receipt of cash. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder’s adjusted tax basis in its ADSs over the fair market value of its ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income. The adjusted tax basis of a U.S. Holder’s ADSs will be adjusted to reflect amounts included in gross income or allowed as a deduction because of such mark-to-market election. If a U.S. Holder makes an effective mark-to-market election, gains from an actual sale or other disposition of ADSs in a year in which we are a PFIC will be treated as ordinary income, and any losses incurred on a sale or other disposition of ADSs will be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If we are a PFIC for any taxable year in which a U.S. Holder owns ADSs but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

A mark-to-market election is not permitted for the shares of any of our subsidiaries that are also classified as PFICs (unless the shares of such subsidiaries are themselves marketable). Prospective investors should consult their own tax advisors regarding the availability of, and the procedure for making, a mark-to-market election, and whether making the election would be advisable, including in light of their particular circumstances.

#### *PFIC “QEF” Election*

Alternatively, if we provide the necessary information, a U.S. Holder can be subject to rules different from those described above by electing to treat us (and each Lower-tier PFIC, if any) as a QEF under Section 1295 of the Code in the first taxable year that we (and each Lower-tier PFIC) are treated as a PFIC with respect to the U.S. Holder. A U.S. Holder must make the QEF election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder’s timely filed U.S. federal income tax return.

In any year in which we determine that we are a PFIC, we will provide the information necessary for a U.S. Holder to make a QEF election with respect to us upon the request of a U.S. Holder and will endeavor to cause each Lower-tier PFIC that we control to provide such information with respect to such Lower-tier PFIC. However, there can be no assurance that we will be able to cause any Lower-tier PFIC we do not control to provide such information. We may elect to provide the information necessary to make such QEF elections on our website.

If you make a QEF election with respect to a PFIC, you will be taxed currently on your pro rata share of the PFIC’s ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC, even if no distributions were received. If a U.S. Holder makes a QEF election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder’s income under the QEF election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its ADSs by an amount equal to any income included under the QEF election and will decrease its tax basis by any amount distributed on the ADSs that is not included in the U.S. Holder’s income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of ADSs in an amount equal to the difference between the amount realized and the U.S. Holder’s adjusted tax basis in the ADSs, as determined in U.S. dollars. Once made, a QEF election remains in effect unless invalidated or terminated by the IRS or revoked by the U.S. Holder. A QEF election can be revoked only with the consent of the IRS. A U.S. Holder will not be currently taxed on the ordinary income and net capital gain of a PFIC with respect to which a QEF election was made for any taxable year of the non-U.S. corporation for which such corporation does not satisfy the PFIC Income Test or Asset Test.

U.S. Holders should note that if they make QEF elections with respect to us and any Lower-tier PFIC, they may be required to pay U.S. federal income tax with respect to their ADSs for any taxable year significantly in excess of any cash distributions received on the ADSs for such taxable year. U.S. Holders should consult their tax advisers regarding the advisability of, and procedure for, making QEF elections in their particular circumstances.

#### *PFIC Information Reporting Requirements*

If we are a PFIC in any year with respect to a U.S. Holder, such U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ADSs, and certain U.S. Holders will be required to file an annual information return (also on IRS Form 8621) relating to their ownership of our ADSs.

THE U.S. FEDERAL INCOME TAX RULES RELATING TO PFICS ARE COMPLEX. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

#### ***U.S. Backup Withholding and Information Reporting***

Backup withholding and information reporting requirements may apply to distributions on, and proceeds from the sale or disposition of, ADSs that are held by U.S. Holders. The payor may be required to withhold U.S. backup withholding tax on payments made with respect to the ADSs to a U.S. Holder, other than an exempt recipient, if the U.S. Holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding requirements. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability (if any) or refunded provided the required information is furnished to the IRS in a timely manner.

Certain U.S. Holders of specified foreign financial assets with an aggregate value in excess of the applicable dollar threshold are required to report information relating to their holding of ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by certain financial institutions) with their tax return for each year in which they hold ADSs. U.S. Holders should consult their own tax advisers regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of ADSs.

THE ABOVE DISCUSSION DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. PROSPECTIVE INVESTORS ARE STRONGLY URGED TO CONSULT THEIR OWN TAX ADVISORS ABOUT THE TAX CONSEQUENCES OF AN INVESTMENT IN THE ADSs.

#### **F. Dividends and Payment Agents**

Not applicable.

#### **G. Statement by experts**

Not applicable.

#### **H. Documents on display**

We are subject to the informational requirements of the Exchange Act and are required to file reports and other information with the SEC. Shareholders may read and copy any of our reports and other information at, and obtain copies upon payment of prescribed fees from, the public reference room maintained by the SEC at 100 F Street N.E., Washington, D.C. 20549. The public may obtain information on the operation of the public reference room by calling the U.S. Securities and Exchange Commission at 1-800-SEC-0330. The SEC also maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system.

We are a “foreign private issuer” as such term is defined in Rule 405 under the Securities Act, and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, we do not file the same reports that a U.S. domestic issuer would file with the SEC.

We also make available on our website’s investor relations page, free of charge, our annual report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. The address for our investor relations page is “ir.zailaboratory.com” The information contained on our website is not incorporated by reference in this annual report.

**I. Subsidiary information**

Not applicable.

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

***Foreign Exchange Risk***

Renminbi (“RMB”) is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People’s Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of our company included aggregated amounts of RMB25.7 million and RMB44.2 million, which were denominated in RMB, as of December 31, 2017 and 2016, respectively, representing 2% and 8% of the cash and cash equivalents as of December 31, 2017 and 2016, respectively.

Our business mainly operates in the PRC with most of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the RMB because the value of our business is effectively denominated in RMB, while the ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. On July 21, 2005, the PRC government changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that the PRC government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the RMB by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day’s value, respectively.

To the extent that we need to convert U.S. dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amounts available to us.

## Credit Risk

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents. The carrying amounts of cash and cash equivalents represent the maximum amount of loss due to credit risk. As of December 31, 2017 and 2016, all of our cash and cash equivalents were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions.

## Inflation

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. According to the National Bureau of Statistics of China, the Consumer Price Index in China increased by 1.6%, 2.0% and 1.4% in 2017, 2016 and 2015, respectively. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

## ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

### A. Debt Securities

Not applicable.

### B. Warrants and Rights

Not applicable.

### C. Other Securities

Not applicable

### D. American Depositary Shares

#### Fees and Charges our ADS Holders May Have to Pay

An ADS holder will be required to pay the following service fees to Citibank, N.A., the depository of our ADS program, and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of the ADSs):

<u>Service</u>	<u>Fees</u>
• Issuance of ADSs (e.g., an issuance of ADS upon a deposit of ordinary shares, upon a change in the ADS(s)-to-share ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to U.S.\$0.05 per ADS issued
• Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS(s)-to-share ratio, or for any other reason)	Up to U.S. \$0.05 per ADS cancelled
• Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to U.S. \$0.05 per ADS held
• Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to U.S. \$0.05 per ADS held
• Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to U.S. \$0.05 per ADS held
• ADS Services	Up to U.S. \$0.05 per ADS held on the applicable record date(s) established by the depository bank



As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the expenses and charges incurred by the depositary bank in the conversion of foreign currency;
- the fees and expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the servicing or delivery of deposited property.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to the ADS holder. Certain of the depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

The depositary has agreed to pay certain amounts to us in exchange for its appointment as depositary. We may use these funds towards our expenses relating to the establishment and maintenance of the ADR program, including investor relations expenses, or otherwise as we see fit. The depositary has reimbursed us for expenses related to the administration and maintenance of the facility in the amount of \$1.6 million, after deduction of applicable U.S. taxes, for the year ended December 31, 2017.

## PART II

### ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

### ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

#### Material Modifications to the Rights of Security Holders

None.

#### Use of Proceeds

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File No. 333-219980), in relation to our initial public offering, which was declared effective by the SEC on September 20, 2017. In September 2017, we completed our initial public offering in which we issued and sold an aggregate of 9,583,333 ADSs (reflecting the full exercise of the over-allotment option by the underwriters to purchase an additional 1,250,000 ADSs), resulting in net proceeds to us of approximately \$157.7 million. J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Leerink Partners LLC were the representatives of the underwriters for our initial public offering.

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

- approximately \$4.0 million for Phase III studies of ZL-2306 in patients with ovarian cancer in China, \$0.8 million Phase II/III studies of ZL-2301 in patients with HCC in China and \$0.7 million for Phase II studies of ZL-3101 in patients with mild to moderate subacute eczema in China;
- approximately \$2.0 million for the construction of our large molecule drug product facility in Suzhou; and
- approximately \$3.0 million for working capital and other general corporate purpose.

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

### ITEM 15. CONTROLS AND PROCEDURES

#### A. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report, as required by Rule 13a-15(b) under the Exchange Act.

Based upon that evaluation, our management has concluded that, as of December 31, 2017, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file and furnish under the Exchange Act was recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, to allow timely decisions regarding required disclosure.

#### B. Management's Annual Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

### **C. Attestation Report of the Registered Public Accounting Firm**

This annual report does not include an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

### **D. Changes in Internal Control over Financial Reporting**

Prior to our initial public offering in September 2017, we were a private company with a limited number of accounting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the year ended December 31, 2016, we and our auditors, an independent registered public accounting firm, identified one material weakness in our internal control over financial reporting. As defined in the standards established by the PCAOB, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness that had been identified related to the lack of sufficient accounting personnel with U.S. GAAP knowledge and SEC financial reporting requirements for the purpose of financial reporting, and lack of accounting policies and procedures over financial reporting in accordance with U.S. GAAP.

To remediate our identified material weakness and improve our internal control over financial reporting, we have implemented a number of measures to address the material weakness that has been identified in connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2017. These measures include the follows:

- hired staff with extensive U.S. GAAP experience to our accounting team;
- developed and implemented an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes, and
- improved the capabilities of existing financial reporting personnel through training and education in the accounting and reporting requirements under U.S. GAAP and SEC rules and regulations.

As of December 31, 2017, based on the measures relating to formal process to identify and address risk of material misstatement related to U.S. GAAP reporting and other controls implemented as described above, we believe we have been able to remediate the identified material weakness as mentioned above.

Since our initial public offering, we have become subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act requires that we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F beginning with our annual report for the fiscal year ending December 31, 2018. In addition, beginning at the same time, our independent registered public accounting firm must report on the effectiveness of our internal control over financial reporting unless we continue to qualify as an emerging growth company. It is possible that, had we performed a formal assessment of our internal control over financial reporting or had our independent registered public accounting firm performed an audit of our internal control over financial reporting, additional internal control deficiencies may have been identified. See "Item 3. Key Information—D. Risk Factors—Risks Related to Our ADSs— If we fail to establish and maintain proper internal financial reporting controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired."

**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our board of directors has determined that Tao Fu, an independent director (under the standards set forth in Nasdaq Stock Market Rule 5605(a)(2) and Rule 10A-3 under the Exchange Act) and member of our audit committee, is an audit committee financial expert.

**ITEM 16B. CODE OF ETHICS**

Our board of directors has adopted a code of ethics applicable to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. This code is intended to qualify as a “code of ethics” within the meaning of the applicable rules of the SEC. Our code of ethics is available on our website at <http://ir.zailaboratory.com/phoenix.zhtml?c=254615&p=irol-govhighlights>. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this annual report. See “Item 6.C. Directors, Senior Management and Employees—Code of Ethics” for more information.

**ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES****Principal Accountant Fees and Services**

The following table sets forth the aggregate fees by the categories specified below in connection with certain professional services rendered by Deloitte Touche Tohmatsu Certified Public Accountants LLP, our independent registered public accounting firm, for the periods indicated. We did not pay any other fees to our auditors during the periods indicated below.

	<u>2017</u>	<u>2016</u>
	<u>US\$</u>	<u>US\$</u>
	(in thousands)	
Audit Fees(1)	\$ 405	\$ —

(1) “Audit fees” means the aggregate fees in each of the fiscal years listed for professional services rendered by our independent registered public accounting firm for the audit of our financial statements or services that are normally provided by the auditors in connection with and regulatory filing or engagements.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by Deloitte Touche Tohmatsu Certified Public Accountants LLP, including audit services, audit-related services, tax services and other services as described above, other than those for *de minimis* services which are approved by the Audit Committee prior to the completion of the audit.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

Not applicable.

**ITEM 16F. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT**

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

The Nasdaq Stock Market listing rules include certain accommodations in the corporate governance requirements that allow foreign private issuers, such as us, to follow “home country” corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. We currently follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Stock Market in respect of the following:

- the majority independent director requirement under Section 5605(b)(1) of the Nasdaq Stock Market listing rules;
- the requirement under Section 5605(d) of the Nasdaq Stock Market listing rules that a compensation committee comprised solely of independent directors governed by a compensation committee charter oversee executive compensation;
- the requirement under Section 5605(e) of the Nasdaq Stock Market listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors; and
- the requirement under Section 5605(b)(2) of the Nasdaq Stock Market listing rules that the independent directors have regularly scheduled meetings with only the independent directors present.

Cayman Islands law does not impose a requirement that the board consist of a majority of independent directors or that such independent directors meet regularly without other members present. Nor does Cayman Islands law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process.

**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

## PART III

### ITEM 17. FINANCIAL STATEMENTS.

See “Item 18. Financial Statements.”

### ITEM 18. FINANCIAL STATEMENTS.

The consolidated financial statements of Zai Lab Limited and its subsidiaries are included at the end of this Annual Report on Form 20-F.

### ITEM 19. EXHIBITS

#### EXHIBIT INDEX

Exhibit Number	Exhibit Title
1.1	<a href="#"><u>Fourth Amended and Restated Memorandum and Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
2.1	<a href="#"><u>Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
2.2	<a href="#"><u>Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
2.3	<a href="#"><u>Registrant’s Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
2.4	<a href="#"><u>Third Amended and Restated Shareholders Agreement between Zai Lab Limited and other parties named therein dated June 26, 2017 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.1#	<a href="#"><u>Zai Lab Limited 2015 Omnibus Equity Incentive Plan as amended on February 3, 2016 and April 10, 2016 (incorporated by reference to Exhibit 10.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.2+	<a href="#"><u>Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd. dated September 28, 2016 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.3*	<a href="#"><u>Amendment to Collaboration, Development and License Agreement by and between Tesaro, Inc. and Zai Lab (Shanghai) Co., Ltd., dated February 26, 2018.</u></a>
4.4+	<a href="#"><u>License Agreement by and between Bristol-Myers Squibb Company and Zai Lab (Hong Kong) Limited dated March 9, 2015 (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.5+	<a href="#"><u>License and Collaboration Agreement by and between Paratek Bermuda Ltd. and Zai Lab (Shanghai) Co., Ltd. dated April 21, 2017 (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.6+	<a href="#"><u>License and Transfer Agreement by and between GlaxoSmithKline (China) R&amp;D Co., Ltd and Zai Lab (Shanghai) Co., Ltd. dated October 18, 2016 (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.7+	<a href="#"><u>Assignment and Assumption Agreement by and among GlaxoSmithKline (China) R&amp;D Co., Ltd, Zai Lab (Shanghai) Co., Ltd. and Chengdu Bater Pharmaceutical Co., Ltd. dated October 13, 2016 (incorporated by reference to Exhibit 10.6 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>

Exhibit Number	Exhibit Title
4.8+	<a href="#"><u>Assignment and Assumption Agreement by and among GlaxoSmithKline (China) R&amp;D Co., Ltd, Zai Lab (Shanghai) Co., Ltd. and Traditional Chinese Medical Hospital, Xinjiang Medical University dated October 14, 2016 (incorporated by reference to Exhibit 10.7 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.9+	<a href="#"><u>License Agreement by and between Sanofi and Zai Lab (Hong Kong) Limited dated July 22, 2015 (incorporated by reference to Exhibit 10.8 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.10+	<a href="#"><u>License Agreement by and between UCB Biopharma SPRL and Zai Lab (Hong Kong) Limited dated September 17, 2015 (incorporated by reference to Exhibit 10.9 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.11*+	<a href="#"><u>License Agreement by and between Five Prime Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated December 19, 2017</u></a>
4.12#	<a href="#"><u>Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.10 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.13#	<a href="#"><u>Zai Lab Limited 2017 Cash Bonus Plan (incorporated by reference to Exhibit 10.11 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.14	<a href="#"><u>Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
4.15*#	<a href="#"><u>Third Amended and Restated Founder Employment Agreement between Ying Du and Zai Lab Limited dated November 10, 2017</u></a>
4.16*#	<a href="#"><u>Letter Agreement between Ying Du and Zai Lab (US) LLC dated December 11, 2017</u></a>
4.17*#	<a href="#"><u>Employment Agreement between William Ki Chul Cho and Zai Lab (Hong Kong) Limited dated March 2, 2018</u></a>
4.18#	<a href="#"><u>Founder Employment Agreement between Ning Xu and Zai Lab (Hong Kong) Limited dated May 6, 2014 (incorporated by reference to Exhibit 10.14 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.19#	<a href="#"><u>Employment Agreement between James Yan and Zai Lab (Hong Kong) Limited dated March 10, 2015 (incorporated by reference to Exhibit 10.15 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.20#	<a href="#"><u>Employment Agreement between Qi Liu and Zai Lab (Hong Kong) Limited dated November 1, 2015 (incorporated by reference to Exhibit 10.16 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.21#	<a href="#"><u>Employment Agreement between Harald Reinhart and Zai Lab (Hong Kong) Limited dated May 17, 2017 as amended on August 30, 2017 (incorporated by reference to Exhibit 10.17 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.22#	<a href="#"><u>Employment Agreement between Ying Du and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2017 (English translation) (incorporated by reference to Exhibit 10.18 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.23#	<a href="#"><u>Employment Agreement between Ning Xu and Zai Lab (Shanghai) Co., Ltd. dated July 1, 2017 (English translation) (incorporated by reference to Exhibit 10.19 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>

<b>Exhibit Number</b>	<b>Exhibit Title</b>
4.24#	<a href="#"><u>Employment Agreement between James Yan and Zai Lab (Shanghai) Co., Ltd. dated September 1, 2015 (English translation) (incorporated by reference to Exhibit 10.20 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.25#	<a href="#"><u>Employment Agreement between Qi Liu and Zai Lab (Shanghai) Co., Ltd. dated November 1, 2015 (English translation) (incorporated by reference to Exhibit 10.21 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.26#	<a href="#"><u>Zai Lab Limited 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.27#	<a href="#"><u>Form Restricted Share Unit Award Agreement (incorporated by reference to Exhibit 10.23 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.28#	<a href="#"><u>Form Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.24 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.29#	<a href="#"><u>Form of Non-Statutory Stock Option Award Agreement (incorporated by reference to Exhibit 10.25 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
4.30	<a href="#"><u>Jinchuang Building House Leasing Contract by and between Zai Lab (Shanghai) Co., Ltd. and Shanghai Jinchuang Property Co., Ltd. dated September 1, 2016 (English translation) (incorporated by reference to Exhibit 10.26 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)</u></a>
8.1	<a href="#"><u>Subsidiaries of the registrant (incorporated by reference to Exhibit 21.1 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)</u></a>
12.1*	<a href="#"><u>Certification of Chief Executive Officer Required by Rule 13a-14(a)</u></a>
12.2*	<a href="#"><u>Certification of Chief Financial Officer Required by Rule 13a-14(a)</u></a>
13.1**	<a href="#"><u>Certification of Chief Executive Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code</u></a>
13.2**	<a href="#"><u>Certification of Chief Financial Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code</u></a>
15.1*	<a href="#"><u>Consent of Deloitte Touche Tohmatsu Certified Public Accountants LLP, an independent accounting firm, regarding the consolidated financial statements of Zai Lab Limited</u></a>
15.2*	<a href="#"><u>Consent of Zhong Lun Law Firm</u></a>
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definitions Linkbase Document

\* Filed herewith

\*\* Furnished herewith

# Management contract or compensatory plan

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the Securities and Exchange Commission.



SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on annual report on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

**ZAI LAB LIMITED**

By: /s/ Samantha Du

Name: Samantha Du

Title: Chief Executive Officer

Date: April 30, 2018

**Zai Lab Limited**

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**Report of independent registered public accounting firm**

To the Board of Directors and Shareholders of Zai Lab Limited

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Zai Lab Limited (the "Company") and its subsidiaries (collectively referred to as the "Group") as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2017, and the related notes and the financial statement schedules included as Schedule I (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on the Group's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China

April 30, 2018

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

Zai Lab Limited

Consolidated balance sheets

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

	Note	As of December 31,	
		2016	2017
		\$	\$
<b>Assets</b>			
<b>Current assets:</b>			
Cash and cash equivalents	3	83,948,770	229,660,148
Prepayments and other current assets		143,527	954,506
<b>Total current assets</b>		<b>84,092,297</b>	<b>230,614,654</b>
Investments in equity investees	4	500,000	1,650,348
Prepayments for equipment		1,417,029	126,411
Property and equipment	5	1,246,058	11,853,764
Intangible assets		7,000	20,089
Long term deposits		267,980	306,825
Value added tax recoverable		1,376,921	5,062,137
<b>Total assets</b>		<b>88,907,285</b>	<b>249,634,228</b>
<b>Liabilities, mezzanine equity and shareholders' (deficit) equity</b>			
<b>Current liabilities:</b>			
Accounts payable		523,338	8,967,685
Warrant liabilities	8	3,900,000	—
Other payables	7	750,118	3,101,459
<b>Total current liabilities</b>		<b>5,173,456</b>	<b>12,069,144</b>
Deferred income		778,434	2,394,124
<b>Total liabilities</b>		<b>5,951,890</b>	<b>14,463,268</b>
<b>Commitments and contingencies (Note 16)</b>			
<b>Mezzanine equity</b>			
Series A1 convertible preferred shares (par value US\$0.00006 per share; 8,466,667 shares authorized, 8,466,665 shares issued and outstanding as of December 31, 2016)	8	10,028,572	—
Series A2 convertible preferred shares (par value US\$0.00006 per share; 8,904,032 shares authorized, 8,442,221 shares issued and outstanding as of December 31, 2016)	8	18,278,572	—
Series B1 convertible preferred shares (par value US\$0.00006 per share; 5,562,337 shares authorized, 5,562,335 shares issued and outstanding as of December 31, 2016)	8	53,100,000	—
Series B2 convertible preferred shares (par value US\$0.00006 per share; 3,973,098 shares authorized, 3,973,096 shares issued and outstanding as of December 31, 2016)	8	53,100,000	—
<b>Total mezzanine equity</b>		<b>134,507,144</b>	<b>—</b>
<b>Shareholders' (deficit) equity</b>			
Ordinary shares (par value of US\$0.00006 per share; 83,333,333 shares authorized, 9,657,175 and 49,912,570 shares issued and outstanding as of December 31, 2016 and 2017, respectively)		579	2,995
Subscription receivable		(5)	(18)
Additional paid-in capital		9,313,646	345,269,688
Accumulated deficit		(60,167,437)	(110,551,613)
Accumulated other comprehensive (loss) income		(698,532)	449,908
<b>Total shareholders' (deficit) equity</b>		<b>(51,551,749)</b>	<b>235,170,960</b>
<b>Total liabilities, mezzanine equity and shareholders' (deficit) equity</b>		<b>88,907,285</b>	<b>249,634,228</b>

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

**Zai Lab Limited****Consolidated statements of operations****(In U.S. dollars ("\$\$") except for number of shares)**

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
Operating expenses:			
Research and development	(13,587,145)	(32,149,157)	(39,341,518)
General and administrative	(2,762,292)	(6,380,144)	(12,049,518)
Loss from operations	(16,349,437)	(38,529,301)	(51,391,036)
Interest income	5,005	403,266	527,351
Changes in fair value of warrants	(1,980,000)	(1,920,000)	200,000
Other income	341,112	2,533,966	933,158
Other expense	(38,417)	(143)	(403,997)
Loss before income tax and share of loss from equity method investment	(18,021,737)	(37,512,212)	(50,134,524)
Income tax expense	—	—	—
Share of loss from equity method investment	—	—	(249,652)
Net loss	(18,021,737)	(37,512,212)	(50,384,176)
Net loss attributable to ordinary shareholders	(18,021,737)	(37,512,212)	(50,384,176)
Loss per share - basic and diluted	(2.07)	(3.97)	(2.32)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted	8,693,655	9,439,028	21,752,757

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

Zai Lab Limited

Consolidated statements of comprehensive loss

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

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
Net loss	(18,021,737)	(37,512,212)	(50,384,176)
Other comprehensive (loss) income, net of tax of nil:			
Foreign currency translation adjustments	(98,893)	(594,912)	1,148,440
Comprehensive loss	<u>(18,120,630)</u>	<u>(38,107,124)</u>	<u>(49,235,736)</u>

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

Zai Lab Limited

Consolidated statements of shareholders' (deficit) equity

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

	Ordinary shares		Additional paid in capital	Subscription receivable	Accumulated deficit	Accumulated other comprehensive loss	Total
	Number of Shares	Amount					
		\$	\$	\$	\$	\$	\$
Balance at January 1, 2015	8,166,666	490	1,687,048	—	(4,633,488)	(4,727)	(2,950,677)
Issuance of ordinary shares upon vesting of							
restricted shares	718,518	43	(42)	(1)	—	—	—
Share-based compensation	—	—	2,701,404	—	—	—	2,701,404
Net loss	—	—	—	—	(18,021,737)	—	(18,021,737)
Foreign currency translation	—	—	—	—	—	(98,893)	(98,893)
Balance at December 31, 2015	8,885,184	533	4,388,410	(1)	(22,655,225)	(103,620)	(18,369,903)
Issuance of ordinary shares upon vesting of							
restricted shares	771,991	46	(42)	(4)	—	—	—
Share-based compensation	—	—	4,925,278	—	—	—	4,925,278
Net loss	—	—	—	—	(37,512,212)	—	(37,512,212)
Foreign currency translation	—	—	—	—	—	(594,912)	(594,912)
Balance at December 31, 2016	9,657,175	579	9,313,646	(5)	(60,167,437)	(698,532)	(51,551,749)
Issuance of ordinary shares upon vesting of							
restricted shares	1,666,145	100	(87)	(13)	—	—	—
Exercise of shares option	100,834	6	65,494	—	—	—	65,500
Exercise of warrant	461,808	28	4,699,972	—	—	—	4,700,000
Conversion of convertible preferred shares to							
ordinary shares	28,443,275	1,707	163,605,437	—	—	—	163,607,144
Issuance of ordinary shares upon initial public offering, net of issuance cost of \$2,770,299	9,583,333	575	157,654,120	—	—	—	157,654,695
Share-based compensation	—	—	9,931,106	—	—	—	9,931,106
Net loss	—	—	—	—	(50,384,176)	—	(50,384,176)
Foreign currency translation	—	—	—	—	—	1,148,440	1,148,440
Balance at December 31, 2017	<u>49,912,570</u>	<u>2,995</u>	<u>345,269,688</u>	<u>(18)</u>	<u>(110,551,613)</u>	<u>449,908</u>	<u>235,170,960</u>

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

**Zai Lab Limited**
**Consolidated statements of cash flows**
**(In U.S. dollars ("\$\$") except for number of shares)**

	<b>Year ended December 31,</b>		
	<b>2015</b>	<b>2016</b>	<b>2017</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Operating activities</b>			
Net loss	(18,021,737)	(37,512,212)	(50,384,176)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation of property and equipment	125,774	198,224	545,705
Amortization of intangible assets	733	781	2,422
Share-based compensation	2,701,404	4,925,278	9,931,106
Share of loss from equity method investment	—	—	249,652
Loss on disposal of property and equipment	38,417	—	12,961
Change in fair value of warrants	1,980,000	1,920,000	(200,000)
Changes in operating assets and liabilities:			
Prepayments and other current assets	33,713	(74,507)	(810,979)
Long term deposits	—	(267,980)	(38,845)
Value added tax recoverable	—	(1,376,921)	(3,685,216)
Accounts payable	1,287,687	(929,716)	8,444,347
Other payables	327,500	242,187	1,950,152
Deferred income	61,599	716,835	1,615,690
Net cash used in operating activities	<u>(11,464,910)</u>	<u>(32,158,031)</u>	<u>(32,367,181)</u>
<b>Cash flows from investing activities:</b>			
Purchase of cost method investment	—	(500,000)	—
Disposal of cost method investment	—	—	500,000
Purchase of equity method investment	—	—	(1,900,000)
Purchase of property and equipment	(738,470)	(2,223,882)	(9,102,330)
Disposal of property and equipment	—	—	82,789
Purchase of intangible assets	—	(5,615)	(14,690)
Net cash used in investing activities	<u>(738,470)</u>	<u>(2,729,497)</u>	<u>(10,434,231)</u>
<b>Cash flows from financing activities:</b>			
Proceed from issuance of convertible preferred shares, net of issuance cost	18,278,572	106,200,000	29,100,000
Proceeds from exercise of warrants	—	—	1,000,000
Proceeds from exercises of stock options	—	—	65,500
Proceeds from issuance of ordinary shares upon initial public offering	—	—	160,424,994
Payment of initial public offering costs	—	—	(2,730,299)
Net cash provided by financing activities	<u>18,278,572</u>	<u>106,200,000</u>	<u>187,860,195</u>
Effect of foreign exchange rate changes on cash and cash equivalents	(66,770)	(524,398)	652,595
Net increases in cash and cash equivalents	6,008,422	70,788,074	145,711,378
Cash and cash equivalents - beginning of the year	7,152,274	13,160,696	83,948,770
Cash and cash equivalents - end of the year	<u>13,160,696</u>	<u>83,948,770</u>	<u>229,660,148</u>
<b>Supplemental disclosure on non-cash investing and financing activities:</b>			
Payables for purchase of property and equipment	—	—	413,657
Payables for initial public offering costs	—	—	40,000
Conversion of convertible preferred shares	—	—	163,607,144
Exercise of warrants	—	—	3,700,000

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



## Zai Lab Limited

### Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

#### 1. Organization and principal activities

Zai Lab Limited (the "Company") was incorporated on March 28, 2013 in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands. The Company and its subsidiaries (collectively referred to as the "Group") are principally engaged in discovering or licensing, developing and commercializing proprietary therapeutics that address areas of large unmet medical needs in the China market, including in the fields of oncology, autoimmune and infectious disease therapies.

As of December 31, 2017, the Group's significant operating subsidiaries are as follows:

<u>Name of company</u>	<u>Place of incorporation</u>	<u>Date of incorporation</u>	<u>Percentage of ownership</u>	<u>Principal activities</u>
Zai Lab (Hong Kong) Limited	Hong Kong	April 29, 2013	100%	Operating company for business development and R&D activities
Zai Lab (Shanghai) Co., Ltd.	The People's Republic of China ("PRC" or "China")	January 6, 2014	100%	Development and commercialisation of innovative medicines
Zai Lab (AUST) Pty., Ltd.	Australia	December 10, 2014	100%	Clinical trial activities
Zai Lab (Suzhou) Co., Ltd.	PRC	November 30, 2015	100%	Development and commercialisation of innovative medicines
Zai Biopharmaceutical (Suzhou) Co., Ltd.	PRC	June 15, 2017	100%	Development and commercialisation of innovative medicines

#### 2. Summary of significant accounting policies

##### (a) Basis of presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

##### (b) Principles of consolidation

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

##### (c) Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include estimating the useful lives of long-lived assets, assessing the impairment of long-lived assets, valuation of ordinary shares, share-based compensation expenses, recoverability of deferred tax assets and the fair value of the financial instruments. Management bases the estimates on historical experience and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

**(d) Foreign currency translation**

The functional currency of Zai Lab Limited and Zai Lab (Hong Kong) Limited are the United States dollar ("\$\$"). The Group's PRC subsidiaries determined their functional currency to be Chinese Renminbi ("RMB"). The Group's Australia subsidiary determined its functional currency to be Australia dollar ("A\$"). The determination of the respective functional currency is based on the criteria of Accounting Standard Codification ("ASC") 830, *Foreign Currency Matters*. The Group uses the United States dollar as its reporting currency.

Assets and liabilities are translated from each entity's functional currency to the reporting currency at the exchange rate on the balance sheet date. Equity amounts are translated at historical exchange rates, and expenses, gains and losses are translated using the average rate for the year. Translation adjustments are reported as cumulative translation adjustments and are shown as a separate component of other comprehensive loss in the consolidated statements of changes in shareholders' deficits and comprehensive loss.

Monetary assets and liabilities denominated in currencies other than the applicable functional currencies are translated into the functional currencies at the prevailing rates of exchange at the balance sheet date. Nonmonetary assets and liabilities are remeasured into the applicable functional currencies at historical exchange rates. Transactions in currencies other than the applicable functional currencies during the year are converted into the functional currencies at the applicable rates of exchange prevailing at the transaction dates. Transaction gains and losses are recognized in the consolidated statements of operations.

**(e) Cash and cash equivalents**

The Group considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash on hand, demand deposits and highly liquid investments with maturity of less than three months and are stated at cost plus interests earned, which approximates fair value.

**(f) Investments in equity investees**

The Group uses the equity method to account for an equity investment over which it has significant influence but does not own a majority equity interest or otherwise control. The Group records equity method adjustments in share of earnings and losses. Equity method adjustments include the Group's proportionate share of investee income or loss, adjustments to recognize certain differences between the Group's carrying value and its equity in net assets of the investee at the date of investment, impairments, and other adjustments required by the equity method. Dividends received are recorded as a reduction of carrying amount of the investment. Cumulative distributions that do not exceed the Group's cumulative equity in earnings of the investee are considered as a return on investment and classified as cash inflows from operating activities. Cumulative distributions in excess of the Group's cumulative equity in the investee's earnings are considered as a return of investment and classified as cash inflows from investing activities.

For equity investments over which the Group does not have significant influence or control, the cost method of accounting is used. Under the cost method, the Group carries the investment at cost and recognizes income to the extent of dividends received from the distribution of the equity investee's post-acquisition profits.

The Group is required to perform an impairment assessment of its investments whenever events or changes in business circumstances indicate that the carrying value of the investment may not be fully recoverable. An impairment loss is recorded when there has been a loss in value of the investment that is other than temporary. No impairment was recorded for the years ended December 31, 2015, 2016 and 2017.

**(g) Prepayments for equipment**

The prepayments for equipment purchase are recorded in long term prepayments considering the prepayments are all related to property and equipment.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

**(h) Property and equipment**

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	Useful life
Office equipment	3 years
Electronic equipment	3 years
Vehicle	4 years
Laboratory equipment	5 years
Manufacturing equipment	10 years
Leasehold improvements	lesser of useful life or lease term

Construction in progress represents property and equipment under construction and pending installation and is stated at cost less impairment losses if any.

**(i) Long term deposits**

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

**(j) Value added tax recoverable**

Value added tax recoverable represent amounts paid by the Group for purchases. The amounts were recorded as long-term assets considering they are expected to be deducted from future value added tax payables arising on the Group's revenues which it expects to generate in the future.

**(k) Intangible assets**

Intangible assets mainly consist of externally purchased software which are amortized over five years on a straight-line basis. As of December 31, 2016 and 2017, the original value of the Group's intangible assets is \$8,684 and \$24,377 with accumulated amortization of \$1,684 and \$4,288.

**(l) Impairment of long-lived assets**

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2015, 2016 and 2017, there was no impairment of the value of the Group's long-lived assets.

**(m) Fair value measurements**

The Group applies ASC topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 - Unobservable inputs which are supported by little or no market activity.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Group primarily include cash and cash equivalents, prepayments and other current assets, accounts payable, warrant liabilities and other payables. As of December 31, 2016 and 2017, the carrying values of cash and cash equivalents, prepayments and other current assets, accounts payable and other payable approximated their fair values due to the short-term maturity of these instruments. As of December 31, 2016, the warrant liabilities were recorded at fair value as determined on the respective issuance dates and subsequently adjusted to the fair value at reporting date. During the year ended December 31, 2017, the warrants were exercised to purchase 461,808 Series A2 convertible preferred shares. The Group determined the fair values of the warrant liabilities with the assistance of an independent third-party valuation firm.

Liabilities measured at fair value on a recurring basis as of December 31, 2016 are summarized below:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
	\$	\$	\$
Warrant liabilities	—	—	3,900,000

The Group has measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) as of the years ended December 31, 2016.

The Group used the binomial model to estimate the fair value of warrant liabilities using the following assumptions:

	<u>December 31, 2016</u>
Risk-free rate of return	2.9%
Vesting date	April 1, 2016
Maturity date	December 31, 2021
Estimated volatility rate	70%
Exercise price	2.16
Fair value of underlying preferred shares	9.84

The model requires the input of highly subjective assumptions including the risk-free rate of return, expected vesting date, maturity date, estimated volatility rate and fair value of underlying preferred share's price. The risk-free rate for periods within the contractual life is based on the US treasury bonds with maturity similar to the maturity of the warrants as of valuation dates plus a China country risk premium. On April 1, 2016, the investment amount met the \$7,000,000 threshold, therefore, the vesting date was on April 1, 2016. For maturity date, the terms state that it shall be the earlier of 6 years from grant and 90 days before the initial public offering ("IPO") date. Prior to 2017, the Group did not have a concrete plan to undertake an IPO, and as such, the maturity date was estimated to be December 31, 2021. For expected volatilities, the Group has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Group. The estimated fair value of the preferred shares was determined with assistance from an independent third-party valuation firm. The Group's management is ultimately responsible for the determination of the estimated fair value of its preferred shares.

The significant unobservable inputs used in the fair value measurement of the warrant liabilities include risk-free rate of return, interval between vesting date and maturity date, estimated volatility rate and fair value of underlying preferred shares. Significant decreases in interval between vesting date and maturity date, estimated volatility rate and fair value of underlying preferred shares would result in a significantly lower fair value measurement. Significant increases in risk-free rate of return would result in a significantly lower fair value measurement.

**Notes to the consolidated financial statements**

**For the years ended December 31, 2015, 2016 and 2017**

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

**(n) Revenue recognition**

The Group has not yet generated any revenues from the sale of goods or from the rendering of services.

Prior to the adoption of ASC 606, the Group will recognize any revenues when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the fee is fixed or determinable, and there is reasonable assurance that the related amounts are collectible in accordance with ASC 605, *Revenue Recognition*.

**(o) Research and development expenses**

Elements of research and development expenses primarily include (1) payroll and other related costs of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to the Group, (3) costs related to preclinical testing of the Group's technologies under development and clinical trials such as payments to contract research organizations ("CROs"), investigators and clinical trial sites that conduct our clinical studies (4) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group's research and development services and have no alternative future uses. The conditions enabling capitalization of development costs as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

**(p) Deferred income**

Deferred income consists of deferred income from government grants and American Depositary Receipts (the "ADR") Program Agreement with ADR depository bank (the "DB") in July 2017.

Government grants consist of cash subsidies received by the Group's subsidiaries in the PRC from local governments. Grants received as incentives for conducting business in certain local districts with no performance obligation or other restriction as to the use are recognized when cash is received. Cash grants of \$298,072, \$2,065,510 and \$855,158 were included in other income for the years ended December 31, 2015, 2016 and 2017, respectively. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Company may be required to refund the subsidy. Cash grants of \$778,434 and \$912,124 were recorded in deferred income as of December 31, 2016 and 2017 respectively, which will be recognized when the government specified performance obligation is satisfied.

According to the ADR arrangements, the Group will have the right to receive reimbursements after the closing of IPO as a return for using DB's services. All the reimbursements are subject to the compliance of the Group on all terms of the contract, including the non-existence of default conditions stipulated in the contracts. The Group performed detailed assessments over such conditions and deemed the potential for these conditions to materialize to be remote as of December 31, 2017. The reimbursements are recognized over the five-year contract term as other income. \$78,000 was recorded in other income for the year ended December 31, 2017, and \$1,482,000 was recorded in deferred income as of December 31, 2017.

**(q) Leases**

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

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

**(r) Comprehensive loss**

Comprehensive loss is defined as the changes in equity of the Group during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income*, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Group's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

**(s) Stock-based compensation**

*Awards granted to employees*

The Group grants share options to eligible employees, management and directors and accounts for these share based awards in accordance with ASC 718, *Compensation-Stock Compensation*.

Employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period.

All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

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

The Group, with the assistance of an independent third-party valuation firm, determined the fair value of the stock options granted to employees. The binomial option pricing model was applied in determining the estimated fair value of the options granted to employees.

*Awards granted to non-employees*

The Group has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 505, *Equity-Based Payments to Non-Employees*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the date on which the counterparty's performance is completed as there is no associated performance commitment. The expense is recognized in the same manner as if the Group had paid cash for the services provided by the non-employees in accordance with ASC 505.

**(t) Income taxes**

The Group uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Group evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which requires that realization of an uncertain income tax position be recognized in the financial statements. The benefit to be recorded in the financial statements is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. It is the Group's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

**(u) Earnings (loss) per share**

Basic earnings (loss) per ordinary share is computed by dividing net income (loss) attributable to ordinary shareholders by weighted average number of ordinary shares outstanding during the period.

The Group's convertible preferred shares are participating securities as the preferred shares participate in undistributed earnings on an as-if-converted basis. Accordingly, the Group uses the two-class method whereby undistributed net income is allocated on a pro rata basis to each participating share to the extent that each class may share income for the period. Undistributed net loss is not allocated to preferred shares because they are not contractually obligated to participate in the loss allocated to the ordinary shares.

Diluted earnings (loss) per ordinary share reflects the potential dilution that could occur if securities were exercised or converted into ordinary shares. The Group had convertible preferred shares, warrants, stock options and non-vested restricted shares, which could potentially dilute basic earnings (loss) per share in the future. To calculate the number of shares for diluted earnings (loss) per share, the effect of the convertible redeemable preferred shares and warrants is computed using the as-if-converted method; the effect of the stock options and non-vested restricted shares is computed using the treasury stock method. The computation of diluted earnings (loss) per share does not assume exercise or conversion of securities that would have an anti-dilutive effect.

**(v) Segment information**

In accordance with ASC 280, *Segment Reporting*, the Group's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment. The Group does not distinguish between markets or segments for the purpose of internal reporting. As the Group's long-lived assets are substantially located in and derived from the PRC, no geographical segments are presented.

**(w) Concentration of risks***Concentration of suppliers*

The following suppliers accounted for 10% or more of research and development expenses for the years ended December 31, 2015, 2016 and 2017:

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
A	5,703,000	*	*
B	*	14,625,500	*
C	*	*	7,651,617
D	*	*	7,104,015

\* Represents less than 10% of research and development expenses for the years ended December 31, 2015, 2016 and 2017.

*Concentration of credit risk*

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents and prepayments for equipment. The carrying amounts of cash and cash equivalents represent the maximum amount of loss due to credit risk. As of December 31, 2016 and 2017, all of the Group's cash and cash equivalents were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which management believes are of high credit quality and continually monitors the credit worthiness of these financial institutions. With respect to the prepayment to suppliers, the Company performs on-going credit evaluations of the financial condition of these suppliers.

Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

*Foreign currency risk*

Renminbi ("RMB") is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of the Group included aggregated amounts of RMB44,156,161 and RMB25,660,869, which were denominated in RMB, as of December 31, 2016 and 2017, respectively, representing 8% and 2% of the cash and cash equivalents as of December 31, 2016 and 2017, respectively.

**(x) Share consolidation ("reverse stock split")**

On August 30, 2017, the Company effected a six-to-one share consolidation of all the ordinary shares and preferred shares. All number of shares, par value and per share amounts for all periods presented in these consolidated financial statements and accompanying notes have been adjusted retrospectively, where applicable, to reflect this share consolidation.

**(y) Recent accounting pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, to clarify the principles of recognizing revenue and create common revenue recognition guidance between U.S. GAAP and International Financial Reporting Standards ("IFRS"). An entity has the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application. ASU 2014-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2016, and early adoption is not permitted. In August 2015, the FASB updated this standard to ASU 2015-14, the amendments in this Update defer the effective date of Update 2014-09 so that the Update should be applied to annual reporting periods beginning after December 15, 2017 and earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.

In May 2016, FASB issued ASU 2016-12 *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*. The amendments in this Update do not change the core principle of the guidance in Topic 606. Rather, the amendments in this Update affect only the narrow aspects of Topic 606. The areas improved include: (1) Assessing the Collectability Criterion in Paragraph 606-10-25-1(e) and Accounting for Contracts That Do Not Meet the Criteria for Step 1; (2) Presentation of Sales Taxes and Other Similar Taxes Collected from Customers; (3) Noncash Consideration; (4) Contract Modifications at Transition; (5) Completed Contracts at Transition; and (6) Technical Correction. The effective date and transition requirements for the amendments in this Update are the same as the effective date and transition requirements for Topic 606 (and any other Topic amended by Update 2014-09).

The Group is in a development stage, with no revenues to date.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize most leases on the balance sheet. This ASU requires lessees to recognize a right-of-use asset and lease liability for all leases with terms of more than 12 months. Lessees are permitted to make an accounting policy election to not recognize the asset and liability for leases with a term of twelve months or less. The ASU does not significantly change the lessees' recognition, measurement and presentation of expenses and cash flows from the previous accounting standard. Lessors' accounting under the ASC is largely unchanged from the previous accounting standard. In addition, the ASU expands the disclosure requirements of lease arrangements. Lessees and lessors will use a modified retrospective transition approach, which includes a number of practical expedients. The provisions of this guidance are effective for annual periods beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. The Group is currently evaluating this ASU to determine the full impact on its consolidated financial statements, as well as the impact of adoption on policies, practices and systems. As of December 31, 2017, the Group has \$3.0 million of future minimum operating lease commitments that are not currently recognized on its consolidated balance sheets (see Note 16). Therefore, the Group would expect changes to its consolidated balance sheets for the recognition of these and any additional leases entered into in the future upon adoption.



## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*. The guidance provides clarity and reduces diversity in practice and cost and complexity when accounting for a change to the terms or conditions of a share-based payment award. The amendments in this update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted. The Group does not expect the requirements of ASU 2017-09 will have a material impact on the consolidated financial statements.

## 3. Cash and cash equivalents

	<u>As of December 31,</u>	
	<u>2016</u>	<u>2017</u>
	\$	\$
Cash at bank and in hand	36,531,272	204,008,828
Cash equivalents	47,417,498	25,651,320
	<u>83,948,770</u>	<u>229,660,148</u>
Denominated in:		
US\$	77,463,141	224,878,393
RMB (note (i))	6,365,311	3,927,163
Australia dollar ("A\$")	120,318	854,592
	<u>83,948,770</u>	<u>229,660,148</u>

Note:

- (i) Certain cash and bank balances denominated in RMB were deposited with banks in the PRC. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

## 4. Investment in equity investees

In June 2017, the Group entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. ("JING"), an entity which will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Group will be RMB26.3 million (\$3.9 million) in cash, representing 20% of the equity interest of JING. On July 5, 2017, RMB13.1 million (\$1.9 million) was paid by the Group, and the remainder will be paid upon capital calls received from JING by the end of 2027. The Group accounts for this investment using the equity method of accounting because the Group does not control the investee but has the ability to exercise significant influence over the operating and financial policies of the investee. The Group recorded its share of loss in this investee of \$249,652 for the year ended December 31, 2017.

In October 2016, the Group invested \$500,000 in a private company over which the Group does not have significant influence or control and accounted for the investment using cost method of accounting. In April 2017, the Group disposed its investment to Quan Venture Fund I, L.P. for cash consideration of approximately \$500,000 and no gain/loss was recognized upon disposal (Note 10).

**5. Property and equipment**

Property and equipment consist of the following:

	<u>As of December 31,</u>	
	<u>2016</u>	<u>2017</u>
	\$	\$
Office equipment	49,432	273,339
Electronic equipment	66,271	160,772
Vehicle	76,636	81,360
Laboratory equipment	593,582	1,686,133
Manufacturing equipment	—	2,832,726
Leasehold improvements	465,428	3,227,150
Construction in progress	252,509	4,252,894
	<u>1,503,858</u>	<u>12,514,374</u>
Less: accumulated depreciation	(257,800)	(660,610)
Property and equipment, net	<u>1,246,058</u>	<u>11,853,764</u>

Depreciation expenses for the years ended December 31, 2015, 2016 and 2017 were \$125,774, \$198,224 and \$545,705, respectively.

**6. Income Tax***Cayman Islands*

Zai Lab Limited and ZLIP Holding Limited are incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, Zai Lab Limited and ZLIP Holding Limited are not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

*British Virgin Islands Taxation*

ZL Capital Limited is incorporated in the British Virgin Islands. Under the current laws of the British Virgin Islands, ZL Capital Limited is not subject to income tax.

*Australia*

Zai Lab (AUST) Pty., Ltd. is incorporated in Australia and is subject to corporate income tax at a rate of 30%. Zai Lab (AUST) Pty., Ltd. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

*Hong Kong*

Zai Lab (Hong Kong) Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with relevant Hong Kong tax laws. The applicable tax rate is 16.5% in Hong Kong. For the years ended December 31, 2015, 2016 and 2017, Zai Lab (Hong Kong) Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earned in Hong Kong for any of the periods presented. Under the Hong Kong tax law, Zai Lab (Hong Kong) Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

*PRC*

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

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

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

Loss before income taxes consists of:

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
Cayman	2,036,806	2,454,660	3,886,673
BVI	—	—	8,375
PRC	4,938,688	26,111,094	40,971,742
HK	9,869,007	8,010,908	6,240,462
AUST	1,177,236	935,550	(723,076)
	<u>18,021,737</u>	<u>37,512,212</u>	<u>50,384,176</u>

Reconciliations of the differences between the PRC statutory income tax rate and the Group's effective income tax rate for the years ended December 31, 2015, 2016 and 2017 are as follows:

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
Statutory income tax rate	25%	25%	25%
Share-based compensations	(3.68%)	(2.92%)	(3.27%)
Non-deductible expenses	(7.19%)	(1.59%)	(0.79%)
Effect of different tax rate of subsidiary operation in other jurisdictions	(7.15%)	(3.33%)	(3.06%)
Changes in valuation allowance	(6.98%)	(17.16%)	(17.88%)
Effective income tax rate	<u>—</u>	<u>—</u>	<u>—</u>

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

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
Deferred tax assets:			
Depreciation of property and equipment, net	2,415	3,892	5,964
Accrued expenses	72,408	—	—
Government grants	16,025	166,336	187,762
Net operating loss forwards	1,729,009	8,086,361	17,075,387
Less: valuation allowance	(1,819,857)	(8,256,589)	(17,269,113)
Deferred tax assets, net	<u>—</u>	<u>—</u>	<u>—</u>

The Group considers positive and negative evidence to determine whether some portion or all of the deferred tax assets will be more likely than not realized. This assessment considers, among other matters, the nature, frequency and severity of recent losses and forecasts of future profitability. These assumptions require significant judgment and the forecasts of future taxable income are consistent with the plans and estimates the Group is using to manage the underlying businesses. Valuation allowances are established for deferred tax assets based on a more likely than not threshold. The Group's ability to realize deferred tax assets depends on its ability to generate sufficient taxable income within the carry forward periods provided for in the tax law. In 2016 and 2017, the Group has determined that the deferred tax assets on temporary differences and net operating loss carry forwards are related to certain subsidiaries, for which the Group is not able to conclude that the future realization of those net operating loss carry forwards and other deferred tax assets are more likely than not. As such, it has fully provided valuation allowance for the deferred tax assets as of December 31, 2016 and 2017. Amounts of operating loss carry forwards were \$7,969,098, \$34,716,071 and \$72,137,289 for the year ended December 31, 2015, 2016 and 2017, respectively, which are expected to expire from 2019 to 2022.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

Movement of the valuation allowance is as follows:

	<u>2016</u>	<u>2017</u>
	\$	\$
Balance as of January 1,	(1,819,857)	(8,256,589)
Additions	(6,436,732)	(9,012,524)
Balance as of December 31,	<u>(8,256,589)</u>	<u>(17,269,113)</u>

Uncertainties exist with respect to how the current income tax law in the PRC applies to the Group's overall operations, and more specifically, with regard to tax residency status. The EIT Law includes a provision specifying that legal entities organized outside of the PRC will be considered residents for Chinese income tax purposes if the place of effective management or control is within the PRC. The implementation rules to the EIT Law provide that non-resident legal entities will be considered PRC residents if substantial and overall management and control over the manufacturing and business operations, personnel, accounting and properties, occurs within the PRC. Despite the present uncertainties resulting from the limited PRC tax guidance on the issue, the Group does not believe that the legal entities organized outside of the PRC within the Group should be treated as residents for EIT Law purposes. If the PRC tax authorities subsequently determine that the Company and its subsidiaries registered outside the PRC should be deemed resident enterprises, the Company and its subsidiaries registered outside the PRC will be subject to the PRC income taxes, at a rate of 25%. The Group is not subject to any other uncertain tax position.

## 7. Other payables

	<u>As of December 31,</u>	
	<u>2016</u>	<u>2017</u>
	\$	\$
Payroll	573,802	1,607,740
Professional service fee	23,721	714,764
Payables for purchase of property and equipment	—	413,657
Other taxes payable	—	17,793
Others	152,595	347,505
	<u>750,118</u>	<u>3,101,459</u>

## 8. Convertible preferred shares and warrants

Upon the completion of the Company's IPO on September 20, 2017, all of the outstanding Series A1, A2, B1, B2 and C convertible preferred shares were converted into 28,905,083 ordinary shares. The history of the issuance of the preferred shares is as following:

In August 2014 and April 2015, the Company issued 6,244,443 Series A1 convertible preferred shares ("Series A1 Preferred Shares") and 8,442,221 Series A2 convertible preferred shares ("Series A2 Preferred Shares") with a par value \$0.00006 per share to a group of investors for a cash consideration of \$8,028,572 or \$1.2857 per share and \$18,278,572 or \$2.1651 per share, respectively. In August 2014, \$2,000,000 in convertible loans issued in March and April of 2014 to certain investors who purchased Series A1 Preferred Shares were converted into 2,222,222 Series A1 Preferred Shares in connection with the offering at a per share price of \$0.90.

On December 31, 2015, as an inducement to participate in the contemplated issuance of Series B1 Preferred Shares and Series B2 Preferred Shares, the Company entered into an agreement with one investor to issue warrants to purchase up to 461,808 Series A2 Preferred Shares at \$2.1651 per share, as adjusted from time to time pursuant to the agreement. The fair value of the warrants of \$1,980,000 was expensed on the date of issuance (as opposed to being treated as a cost of equity issuance because the warrants would have become exercisable after the passage of time in the absence of an equity offering).

**Notes to the consolidated financial statements**

**For the years ended December 31, 2015, 2016 and 2017**

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

In January and April 2016, the Company issued 5,562,335 Series B1 convertible preferred shares ("Series B1 Preferred Shares") and 3,973,096 Series B2 convertible preferred shares ("Series B2 Preferred Shares") with a par value of \$0.00006 per share to a group of investors including existing preferred share investors for a cash consideration of \$53,100,000 or \$9.5464 per share and \$53,100,000 or \$13.3649 per share, respectively.

In June 2017, the Company issued 1,998,958 Series C convertible redeemable preferred shares ("Series C Preferred Shares") with a par value of \$ 0.00006 per share to a group of investors including existing preferred share investors for a cash consideration of \$30,000,000 or \$15.0078 per share.

On July 19, 2017, the investor holding the warrants exercised the warrants to purchase 461,808 Series A2 Preferred Shares at \$2.1651 per share.

The key terms of the Series A1, A2, B1, B2 and C Preferred Shares are as follows:

*Conversion rights*

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

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

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

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

*Voting rights*

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

*Dividends*

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

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

**Notes to the consolidated financial statements**

**For the years ended December 31, 2015, 2016 and 2017**

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

*Liquidation preference*

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

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

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

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

- (1) Series C Preferred Shares;
- (2) Series B1 and B2 Preferred Shares;
- (3) Series A1 and A2 Preferred Shares.

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

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

*Redemption*

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

The key terms of the warrants are as follows:

*Vesting date*

The warrants were vested on April 1, 2016.

*Exercise period*

If not previously exercised, the warrants shall expire on the earlier of (1) the sixth (6th) anniversary of the issue date or (2) ninety (90) days prior to the date on which the Company consummates a QIPO.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

The Company has classified the Series A1, A2, B1, B2 and C Preferred Shares as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event outside of the Company's control (i.e. a liquidation event or failure to complete the QIPO within required period). The holders of the Series A1, A2, B1, B2 and C Preferred Shares have a liquidation preference and will not receive the same form of consideration upon the occurrence of the conditional event as the ordinary shareholders would. The holders of the Series A1, A2, B1, B2 and C Preferred Shares have the ability to convert the instrument into the Company's ordinary shares. The conversion option of the convertible preferred shares did not qualify for bifurcation accounting because the conversion option was clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily convertible into cash.

The Company has determined that there was no beneficial conversion feature ("BCF") attributable to the Series A1, A2, B1, B2 and C Preferred Shares, as the effective conversion price was greater than the fair value of the ordinary shares on the respective commitment date.

The Company concluded that redemption of that the Series A1, A2, B1, B2 and C Preferred Shares was not probable due to the remote likelihood of a liquidation event and the expected successful QIPO within five years. Therefore, no adjustment was made to the initial carrying amount of the Series A1, A2, B1, B2 and C Preferred Shares.

The warrants are freestanding instruments and are recorded as liabilities in accordance with ASC480. The Series A1, A2, B1, B2 and C Preferred Shares were initially recorded as mezzanine equity equal to the proceeds received. The warrants are initially recognized at fair value, with subsequent changes in fair value recorded in gain or loss. For the year ended December 31, 2015 and 2016, the Company recognized a loss from the increase in fair value of the warrants of \$2.0 and \$1.9 million respectively. For the year ended December 31, 2017, the Company recognized a gain from the decrease in fair value of the warrants of \$0.2 million.

## 9. Loss per share

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

	<u>For the year ended December 31,</u>		
	<u>2015</u>	<u>2016</u>	<u>2017</u>
<b>Numerator:</b>			
Net loss attributable to ordinary shareholders	(18,021,737)	(37,512,212)	(50,384,176)
<b>Denominator:</b>			
Weighted average number of ordinary shares- basic and diluted	8,693,655	9,439,028	21,752,757
Net loss per share-basic and diluted	<u>(2.07)</u>	<u>(3.97)</u>	<u>(2.32)</u>

The Group has determined that its convertible preferred shares are participating securities as the preferred shares participate in undistributed earnings on an as-if-converted basis. The holders of the preferred shares are entitled to receive dividends on a pro rata basis, as if their shares had been converted into ordinary shares. Accordingly, the Group used the two-class method of computing earnings per share, for ordinary and preferred shares according to participation rights in undistributed earnings. However, undistributed net loss is only allocated to ordinary shareholders because holders of preferred shares were not contractually obligated to share losses.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

As a result of the Group's net loss for the three years ended December 31, 2015, 2016 and 2017, preferred shares, share options, non-vested restricted shares and warrants outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	As of December 31,		
	2015	2016	2017
Number of Series A1 Shares outstanding	8,466,665	8,466,665	—
Number of Series A2 Shares outstanding	8,442,221	8,442,221	—
Number of Series B1 Shares outstanding	—	5,562,335	—
Number of Series B2 Shares outstanding	—	3,973,096	—
Share options	4,309,232	7,228,141	6,548,377
Non-vested restricted shares	2,948,148	2,309,490	693,333
Warrants	461,808	461,808	—

## 10. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of December 31, 2017:

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

The Group paid expenditures to its related party:

**Research and development expenditures**

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
Qiagen (Suzhou) Translational Medicine Co. Ltd.	96,656	—	—

On April 30, 2017, the Group disposed its investment in a cost method investee to Quan Venture Fund I, L.P. for a cash consideration of \$500,000 and no gain/loss was recognized upon disposal.

## 11. Share-based compensation

*Share options*

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the "2015 Plan") which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group ("Option Pool"). On October 22, 2015, March 9, 2016 and August 25, 2016, the Board of Directors approved the increase in the Option Pool to 7,369,767 ordinary shares. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting one year after the grant date and the remainder of the awards vesting on a monthly basis thereafter.

In March and October 2015, the Group granted 870,449 and 3,438,783 share options to certain of the Group's management and employees at an exercise price of \$0.6 per share, respectively. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting one year after the grant date and the remainder of the awards vesting on a monthly basis thereafter.

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



**Notes to the consolidated financial statements**

**For the years ended December 31, 2015, 2016 and 2017**

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

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

In August and December 2016, the Group granted 416 and 416 share options to certain individual advisors of the Group at an exercise price of \$1.74 per share. These options granted have a contractual term of 10 years and generally vest over a three year period, with 33.33% of the awards vesting anniversary year after the grant date.

In May 2017, the Group granted 158,313 share options to certain management and employees of the Group at an exercise price of \$3.0 per share under the 2015 Plan. These options granted have a contractual term of 10 years and generally vest over a four or five year period, with 25% or 20% of the awards vesting on each annual anniversary after the grant date.

In May 2017, the Group granted 4,583 share options to certain individual advisors of the Group at an exercise price of \$3.0 per share. These options granted have a contractual term of 10 years and generally vest over a three year period, with 33.33% of the awards vesting anniversary year after the grant date.

In connection with the completion of the IPO, the Board of Directors has approved the 2017 Equity Incentive Plan (the "2017 Plan") and all equity-based awards will be granted under the 2017 Plan subsequent to the IPO.

In September 2017, the Group granted 101,584 share options to certain management and employees of the Group at an exercise price of \$18.0 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting anniversary year after the grant date.

The binomial option-pricing model was applied in determining the estimated fair value of the options granted. The model requires the input of highly subjective assumptions including the estimated expected stock price volatility and, the exercise multiple for which employees are likely to exercise share options. For expected volatilities, the Group has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Group. For the exercise multiple, prior to the IPO, the Group had no historical exercise patterns as reference, thus the exercise multiple is based on management's estimation, which the Group believes is representative of the future exercise pattern of the options. The risk-free rate for periods within the contractual life of the option is based on the US treasury bonds with maturity similar to the maturity of the options as of valuation dates plus a China country risk premium. Prior to the completion of the Company's IPO, the estimated fair value of the ordinary shares, at the option grant dates, was determined with assistance from an independent third-party valuation firm. The Group's management is ultimately responsible for the determination of the estimated fair value of its ordinary shares. With the completion of the Company's IPO, a public trading market for the ADSs has been established, the Company uses the current share price as the fair value of underlying ordinary shares.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

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

	March 2015	October 2015	March 2016	August 2016	December 2016	May 2017	September 2017
Risk-free rate of return	3.1%	3.1%	2.8%	2.5%	3.4%	3.2%	3.5%
Contractual life of option	10 years	10 years	10 years	10 years	10 years	10 years	10 years
Estimated volatility rate	70%	70%	70%	70%	70%	70%	70%
Expected dividend yield	0%	0%	0%	0%	0%	0%	0%
Fair value of underlying ordinary shares	1.62	1.92	7.14	8.04	8.04	9.60	27.93

A summary of option activity under the Plan during the years ended December 31, 2015, 2016 and 2017 is presented below:

	Number of options	Weighted average exercise price \$	Weighted average remaining contractual term Years	Aggregate intrinsic value \$
Outstanding at January 1, 2015	—	—	—	—
Granted	4,309,232	0.60	—	—
Outstanding at December 31, 2015	4,309,232	0.60	9.68	18,874,438
Granted	2,918,993	1.53	—	—
Forfeited	(84)	1.74	—	—
Outstanding at December 31, 2016	7,228,141	0.97	9.00	53,677,170
Granted	264,480	8.76	—	—
Exercised	(100,834)	0.65	—	—
Forfeited	(843,410)	1.11	—	—
Outstanding at December 31, 2017	6,548,377	1.28	8.06	130,668,851
Vested and Exercisable as of December 31, 2017	2,307,319	0.80	7.84	47,134,503
Vested or expected to vest as of December 31, 2017	6,548,377	1.28	8.06	130,668,851

The weighted-average grant-date fair value of the options granted in 2015, 2016 and 2017 were \$1.62, \$6.94 and \$13.92 per share, respectively. The Group recorded compensation expense related to the options of \$419,709, \$3,524,733 and \$4,751,933 for the year ended December 31, 2015, 2016 and 2017, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
General and administrative	124,871	1,472,993	2,215,282
Research and development	294,838	2,051,740	2,536,651
Total	419,709	3,524,733	4,751,933

As of December 31, 2017, there was \$18,419,319 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 3.05 years.

**Notes to the consolidated financial statements**

**For the years ended December 31, 2015, 2016 and 2017**

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

*Ordinary shares issued to Red Kingdom Investment Limited ("Red Kingdom")*

Red Kingdom is a company incorporated in the British Virgin Islands in August 2013 and owned by a group of senior management including the Chief Executive Officer of the Company (the "CEO") of the Company and advisors of the Group and third-party investors. Red Kingdom has no activities and does not have employees. All the shareholders of the Red Kingdom have delegated their voting rights to the CEO of the Company.

On April 3, 2014, the Company issued 8,083,333 shares to Red Kingdom which are corresponding to the total outstanding shares of Red Kingdom for total consideration of \$141,971. One share of Red Kingdom is entitled to indirectly all of the economic rights associated with the underlying ordinary shares of the Company. Of these shares, 7,847,500 shares were held by members of senior management and certain advisors of the Group, who paid par value.

In April and May 2014, Red Kingdom entered into restricted share arrangements with the members of senior management of the Group to secure their services, pursuant to which all of their 6,459,167 ordinary shares of the Red Kingdom became subject to transfer restrictions (the "Restricted Shares"). In addition, the Restricted Shares shall initially be unvested and subject to repurchase by Red Kingdom at par value upon voluntary or involuntary termination of employment by those senior management (the "Repurchase Right"). One fifth of the Restricted Shares shall vest and be released from the restrictions and Repurchase Right on each yearly anniversary from the date of the agreement. Accordingly, the Group measured the fair value of the non-vested Restricted Shares at grant date and recognizes the amount as compensation expense over the five year deemed service period using a graded vesting attribution model on a straight-line basis.

In April 2014, Red Kingdom entered into a restricted share arrangement with one of its advisors whereby all of their 350,000 ordinary shares of Red Kingdom became subject to transfer restrictions (the "Advisor Restricted Shares"). The Advisor Restricted Shares shall vest and be released from the Repurchase Right at the rate of twenty percent (20%) of the total number of Advisor Restricted Shares as each the contractually agreed milestones within each year (collectively, the "Milestones") are determined to have been achieved by the Company. Accordingly, the Group measures the service expense based on the fair value of the Restricted Shares when the milestones are achieved.

The 1,038,333 shares the Company issued to Red Kingdom corresponded to the shares of Red Kingdom held by advisors of the Group, purchased for par value in 2014 are not subject to the transfer restrictions or other repurchase rights, and so were considered vested immediately at the date of grant and expensed.

On December 15, 2015, 1,921,000 unvested Restricted Shares granted to the CEO were deemed vested by the Company and the unrecognized share-based compensation of \$1,152,600 as of the modification date was immediately recognized as compensation expense in the consolidated statements of operations.

On June 15, 2017, pursuant to the Board's resolution, Red Kingdom distributed all of the ordinary shares that it held in the Group to all Red Kingdom shareholders, in accordance with the Articles of Association of Red Kingdom. All the prior restricted share arrangements in force as of the distribution date between Red Kingdom and members of senior management and advisors were amended to assign the rights and obligations of Red Kingdom thereunder to the Group (the "Transfer"). Before the Transfer, 811,667 restricted shares of Red Kingdom have been vested and 1,329,999 non-vested restricted shares of Red Kingdom have been repurchased by Red Kingdom due to the termination of employment by certain members of senior management and allocated to the founders of Red Kingdom at par value in 2017.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

The following table summarized the non-vested restricted shares activities of Red Kingdom in 2017:

	Numbers of non-vested restricted shares	Weighted average grant date fair value \$
Non-vested as of January 1, 2017	2,784,999	0.60
Vested	(811,667)	0.60
Forfeited	(1,329,999)	0.60
Transferred to the Company	(643,333)	0.60
Non-vested as of December 31, 2017	—	

*Non-vested restricted shares*

On April 3, 2014, the Company entered into a restricted share arrangement with Samantha Du, founder and Chairman and CEO to secure her services, pursuant to which all of her 3,500,000 ordinary shares of the Company became subject to transfer restrictions. In addition, the restricted shares shall initially be unvested and subject to repurchase by the Company at par value upon voluntary or involuntary termination of employment by the CEO (the "Repurchase Right"). One fifth of the restricted shares shall vest and be released from the restrictions and Repurchase Right on each yearly anniversary from the date of the agreement. The CEO retains the voting rights of such non-vested restricted shares and any additional securities or cash received as the result of ownership of such shares, such as a share dividend, become subject to restriction in the same manner. This arrangement has been accounted for as a performance-based plan. Accordingly, the Group measured the fair value of the non-vested restricted shares as of April 3, 2014 and is recognizing the amount as compensation expense over the five year deemed service period using a graded vesting attribution model for each separately vesting portion of the non-vested restricted shares.

On August 10, 2015, the Company entered into a restricted share arrangement with an individual advisor to secure their services, for 166,667 ordinary shares authorized for grant. In general, restrictions limit the sale or transfer of these shares during a three year period, and restrictions lapse proportionately over the three year period. During the three year period the Company upon voluntary or involuntary termination of service agreement by the individual advisor will repurchase unvested restricted shares at par (the "Repurchase Right"). On July 15, 2016 and August 25, 2016, 58,333 and 75,000 ordinary shares were authorized for grant to the individual advisor with the same Repurchase Right. The Repurchase Right terminates over the three years commencing August 10, 2015, July 15, 2016 and August 25, 2016 in 36 equal monthly instalments thereafter, or immediately prior to the consummation of an IPO of the Company. Any additional securities or cash received as the result of ownership of such shares, such as a share dividend, become subject to restriction in the same manner. For all restricted shares, the individual advisor has delegated his voting rights to the CEO of the Company. This arrangement has been accounted for as a reverse stock split followed by the grant of a restricted stock award under a performance-based plan. Accordingly, the Group measures the fair value at the date the services are completed which is monthly.

In March and May 2017, pursuant to the board resolution of the Company, the Repurchase Right to all the remaining 2,100,000 non-vested restricted shares of the CEO which were subject to the restricted share arrangement dated April 3, 2014 was removed and the unrecognized share-based compensation of \$840,000 as of the modification date was immediately recognized as an expense in the consolidated statements of operations.

In Sep 2017, pursuant to the successful IPO of the Company, the Repurchase Right to all the remaining 134,516 non-vested restricted shares of the individual advisor which were subject to the restricted share arrangement dated August 10, 2015, July 15, 2016 and August 25, 2016 was terminated and the unrecognized share-based compensation of \$2,421,288 as of the modification date was immediately recognized as an expense in the consolidated statements of operations.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

On September 20, 2017, 50,000 ordinary shares were authorized for grant to the independent directors. One third of the restricted shares shall vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately be forfeited. This arrangement has been accounted for as a performance-based plan. Accordingly, the Group measured the fair value of the non-vested restricted shares as of September 20, 2017.

The following table summarized the Group's non-vested restricted share activity in 2017:

	Numbers of non-vested restricted shares	Weighted average grant date fair value \$
Non-vested as of January 1, 2017	2,309,490	1.31
Granted	50,000	27.93
Vested	(2,309,490)	1.03
Transferred from Red Kingdom	643,333	0.60
Non-vested as of December 31, 2017	<u>693,333</u>	<u>2.57</u>

As of December 31, 2017, there was \$1,517,160 of total unrecognized compensation expense related to non-vested Restricted Shares. The Group recorded compensation expense related to the restricted shares of \$2,281,695, \$1,400,545 and \$5,179,173 for the year ended December 31, 2015, 2016 and 2017, respectively, which were classified in the accompanying consolidated statements of operations as follows:

	Year ended December 31,		
	2015	2016	2017
	\$	\$	\$
General and administrative	964,012	825,822	3,848,165
Research and development	1,317,683	574,723	1,331,008
Total	<u>2,281,695</u>	<u>1,400,545</u>	<u>5,179,173</u>

## 12. Accumulated other comprehensive loss

The movement of accumulated other comprehensive loss is as follows:

	Foreign currency translation adjustments \$
Balance as of January 1, 2015	(4,727)
Other comprehensive loss	(98,893)
Balance as of December 31, 2015	(103,620)
Other comprehensive loss	(594,912)
Balance as of December 31, 2016	(698,532)
Other comprehensive income	1,148,440
Balance as of December 31, 2017	<u>449,908</u>

## 13. Licenses and collaborative arrangement

*License and collaboration agreement with Bristol-Myers Squibb Company ("BMS")*

In March 2015, the Group entered into a collaboration and license agreement with BMS, under which the Group obtained an exclusive license under certain patents and know-how of BMS to develop, manufacture, use, sell, import and commercialize brivanib, BMS's proprietary multi-targeted kinase inhibitor, in mainland China, Hong Kong and Macau, or the licensed territory, in the licensed field of diagnosis, prevention, treatment or control of

oncology indications, with the right to expand the licensed territory to include Taiwan and Korea under certain conditions. BMS retains the non-exclusive right to use the licensed compounds to conduct internal research and the exclusive right to use the licensed compounds to manufacture compounds that are not brivanib.

BMS has the option to elect to co-promote the licensed products in the licensed territory. If BMS exercises its co-promotion option, BMS will pay the Group an option exercise fee, and the Group will share with BMS the operating profits and losses of the licensed products in the licensed territory. If BMS does not exercise its co-promotion option, the Group will pay BMS milestone payments for the achievement of certain development and sales milestone events, and also tiered royalties at certain percentage rates on the net sales of the licensed products in the licensed territory, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the twelfth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group also has the right to opt-out of the commercialization of the licensed products in its licensed territory under certain conditions. If the Group elects to opt-out, BMS will have the right to commercialize the licensed products in the Group's licensed territory and will pay the Group royalties on the net sales of the licensed products in its licensed territory. BMS has the option to use the data generated by the Group from the Group's development of the licensed products to seek regulatory approval of the licensed products outside the Group's licensed territory, and if BMS exercises such option, BMS will be obligated to make certain payments to the Group, including upfront, milestone and royalty payments.

The agreement may be terminated by either party for the other party's uncured material breach, safety reasons or failure of the development of the licensed products. In addition, the Group has the right to terminate the agreement for convenience after a certain specified time period upon advance notice to BMS. BMS may also terminate the agreement for our bankruptcy or insolvency.

*License and collaboration agreement with Sanofi*

In July 2015, the Group entered into a license agreement with Sanofi, under which the Group obtained an exclusive and worldwide license under certain patents and know-how of Sanofi to develop, manufacture, use, sell, import and commercialize Sanofi's ALK inhibitor, or the licensed compound (also known as ZL-2302), for any oncology indications in humans. Sanofi retains the non-exclusive right to use the licensed compound to conduct internal research.

Under the terms of the agreement, the Group made upfront payments to Sanofi totalling \$0.5 million which were recorded as research and development expenses in 2015. If the Group successfully develops and commercializes the licensed product, the Group will make milestone payments to Sanofi for the achievement of certain development milestone events. In addition, the Group will pay to Sanofi tiered royalties at certain percentage rates of the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and country-by-country basis. If the Group sublicenses, transfers or assigns (other than through a change of control transaction) the right to the licensed product to third parties, the Group is also required to pay to Sanofi a share of its sublicense income.

The Group at any time has the right to terminate this agreement for any reason or no reason at all by providing Sanofi with prior written notice.

*License and collaboration agreement with UCB Biopharma Sprl ("UCB")*

In September 2015, the Group entered into a license agreement with UCB, under which the Group obtained an exclusive and worldwide license under certain patents and know-how of UCB to develop, manufacture, use, sell, import and commercialize UCB's proprietary antibody UCB3000 or the licensed compound (also known as ZL-1101), for the treatment, prevention and diagnosis of any human diseases. UCB retains the non-exclusive right to use the licensed compound for its own research purposes.

Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

Under the terms of the agreement, the Group made upfront payments to UCB totalling \$0.8 million which was recorded as a research and development expense in 2016. If the Group successfully develops and commercializes the licensed products, the Group will make milestone payments to UCB for the achievement of certain development and sales milestone events. In addition, the Group will pay to UCB royalties at certain percentage rates on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and country-by-country basis. If the Group sublicenses the right to the licensed product to third parties, the Group is also required to pay to UCB a share of its sublicense income.

The Group has the right to terminate this agreement by providing UCB with prior written notice.

*License and collaboration agreement with Hanmi Pharm, Co., Ltd. ("Hanmi")*

In November 2015, the Group entered into a collaboration and license agreement with Hanmi under which the Group obtained an exclusive right of license under certain patents and know-how of Hanmi to develop, manufacture, use, sell, import and commercialize Hanmi's EGFR mutation specific TKI HM61713, or the licensed compound (also known as ZL-2303) for the treatment, diagnosis or prevention of any diseases or conditions in human. Hanmi retains the non-exclusive right to use the licensed compound for its own research purposes. Hanmi has the right of first negotiation to acquire the rights to the licensed products back from the Group upon successful completion of certain clinical development work.

Under the terms of the agreement, the Group made upfront payments amounted \$6.0 million and \$1.0 million to Hanmi in 2015 and 2016, respectively. If the Group successfully develop and commercialize the licensed products, the Group will make milestone payments to Hanmi for the achievement of certain development milestone events. In addition, the Group will pay to Hanmi royalties at certain percentage rates on the net sales of the licensed products in its licensed territory, until date of expiration of the latest of valid claim that claims the composition-of-matter of the licensed product, the expiration date of any regulatory data exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product.

The Group has the right to terminate this agreement by providing Hanmi with prior written notice.

*License and collaboration agreement with Tesaro Inc., ("Tesaro")*

In September 2016, the Group entered into a collaboration, development and license agreement with Tesaro, under which the Group obtained an exclusive license for certain patents and know-how that Tesaro licensed from Merck, Sharp & Dohme Corp. (a subsidiary of Merck & Co. Inc.), or Merck Corp., and AstraZeneca UK Limited to develop, manufacture, use, sell, import and commercialize Tesaro's proprietary PARP inhibitor, niraparib, in mainland China, Hong Kong and Macau, or the licensed territory, in the licensed field of treatment, diagnosis and prevention of any human diseases or conditions (other than prostate cancer). Tesaro has the option to elect to co-promote the licensed products in the Group's licensed territory.

Under the terms of the agreement, the Group made an upfront payment of \$15.0 million to Tesaro which was recorded as a research and development expense in 2016. If the Group successfully develops and commercializes the licensed products, the Group will make a milestone payment to Tesaro for the achievement of a certain development milestone event. In addition, if Tesaro does not exercise its co-promotion option, the Group will pay Tesaro milestone payments for the achievement of certain sales milestone events, and also tiered royalties at certain percentages of net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group has the right to terminate this agreement by providing Tesaro with prior written notice.

Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

*License and collaboration agreement with GlaxoSmithKline (China) R&D Co., Ltd ("GSK China")*

In October 2016, the Group entered into a license and transfer agreement with GSK China, an affiliate of GSK, under which GSK China transferred to the Group its rights under certain patents, know-how, inventory and regulatory materials to develop, manufacture, use and commercialize FUGAN and GRAPE, two formulations comprising extracts from traditional Chinese herbs, for the treatment, diagnosis and prevention of human diseases. In connection with such transfer, GSK China also assigned to the Group its agreements with Chengdu Bater Pharmaceutical Co., Ltd, or Bater, and Traditional Chinese Medical Hospital, Xinjiang Medical University, or Xinjiang, relating to FUGAN and GRAPE.

Under the terms of the agreement, the Group made an upfront payment to GSK China of \$0.7 million (RMB4.5 million) which was recorded as a research and development expense in 2016. The Group made a milestone payment of \$0.3 million (RMB2.0 million) to Bater for the achievement of milestone by enrolling the first patient in a Phase II Clinical Trial of the Product in 2017. The Group will make further milestone payments to GSK China for the achievement of certain development milestone events. In addition, the Group will pay to GSK China tiered royalties at certain percentage rates on the net sales of FUGAN and GRAPE. The Group also assumed the obligation to make milestone payments under the assigned agreements with Bater and Xinjiang for milestones achieved after the assignment of the agreements to the Group.

If the Group sublicenses, sells or otherwise divests the patents and know-how acquired from GSK China to third parties before the completion of a certain development phase, the Group is also required to pay to GSK China a share of its income attributed to such sublicense, sale, or divestiture.

The Group may not terminate the agreement before the completion of the Phase II Study of FUGAN unless for causes beyond the reasonable control of the Group. Subject to the completion of the Phase II Study of FUGAN, the Group has the right to terminate the agreement upon prior written consent.

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

In April 2017, the Group entered into a collaboration, development and license agreement with Paratek, under which the Group obtained both an exclusive license under certain patents and know-how of Paratek and an exclusive sub-license under certain intellectual property that Paratek licensed from Tufts University to develop, manufacture, use, sell, import and commercialize omadacycline in mainland China, Hong Kong, Macau and Taiwan, or licensed territory, in the field of all human therapeutic and preventative uses other than biodefense, or the licensed field. Paratek retains the right to manufacture the licensed product in the licensed territory for use outside the licensed territory. The Group also granted to Paratek a non-exclusive license to certain of intellectual property for Paratek Bermuda Ltd.

Under the terms of the agreement, the Group made an upfront payment of \$7.5 million to Paratek which was recorded as a research and development expense in 2017. The Group will make a milestone payment to Paratek for the achievement of certain development milestone and sales milestone event. In addition, we will pay to Paratek tiered royalties at certain percentage rates on the net sales of licensed products, until the later of the abandonment, expiration or invalidation of the last-to-expire licensed patent covering the licensed product, or the eleventh anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

The Group has the right to terminate this agreement for any or no reason by providing Paratek with prior written notice with no penalty.

*License and collaboration agreement with Five Prime Therapeutics, Inc. ("Five Prime")*

On December 19, 2017, the Group and Five Prime entered into an exclusive license agreement for FPA144 in Greater China and global strategic development collaboration.

Under the terms of the agreement, Five Prime has granted the Group an exclusive license to develop and commercialize FPA144 in the Greater China territory: China, Hong Kong, Macau, and Taiwan. The Group will be responsible for conducting the Phase 3 FIGHT trial in Greater China, including screening, enrolment and



**Notes to the consolidated financial statements**

**For the years ended December 31, 2015, 2016 and 2017**

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

treatment of patients, and for commercialization of FPA144 in the Greater China territory. Five Prime will manufacture and supply FPA144 for the study. A Joint Steering Committee will be formed between the companies to oversee development, regulatory and commercialization activities in greater China.

The Group paid upfront fee of \$5.0 million in January 2018, and will make milestone payments of \$39.0 million for the achievement of certain development and regulatory milestones to Five Prime. In addition, the Group will pay to Five Prime a royalty percentage on net sales of FPA144 in Greater China ranging from the high teens to the low twenties. Given the strategic importance of China to the development and commercialization of FPA144 and to align the interests of the two companies globally, the Group is also eligible to receive a low single-digit royalty from Five Prime on net sales of FPA144 outside of Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Five Prime.

As noted above, the Group has entered into various license and collaboration agreements with third party licensors to develop and commercialize drug candidates. Based on the terms of these agreements the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. The Group made \$0.3 million milestone payment under these agreements for the years ended December 31, 2017. Based on management's evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Group up to an aggregate of approximately \$400.8 million in future milestone payments upon the achievement of contractually specified development milestones, such as regulatory approval for the drug candidates, which may be before the Group has commercialized the drug or received any revenue from sales of such drug candidate, which may never occur.

**14. Restricted net assets**

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

In accordance with the Company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group's PRC subsidiary was established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

During the years ended December 31, 2016 and 2017, no appropriation to statutory reserves was made because the PRC subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Group's PRC subsidiary is restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulation in the PRC may further restrict the Group's PRC subsidiary from transferring funds to the Group in the form of dividends, loans and advances. As of December 31, 2016 and 2017, amounts restricted are the paid-in capital of the Group's PRC subsidiaries, which amounted to \$39,215,714 and \$80,951,618, respectively.

## Notes to the consolidated financial statements

For the years ended December 31, 2015, 2016 and 2017

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

## 15. Employee defined contribution plan

Full time employees of the Group in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that the Group's PRC subsidiary make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Group has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were \$79,878, \$288,666 and \$579,094 for the years ended December 31, 2015, 2016 and 2017, respectively.

## 16. Commitments and Contingencies

## (a) Operating lease commitments

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

There are no restrictions placed upon the Group by entering into these leases. Total expenses under these operating leases were \$148,274, \$285,742 and \$916,612 for the years ended December 31, 2015, 2016 and 2017, respectively.

Future minimum lease payments under operating lease agreements at December 31, 2017 were as follows:

	<u>Year ended</u> <u>December 31,</u>
	\$
2018	1,311,102
2019	1,302,945
2020	358,342
2021	53,692
2022 and thereafter	—
Total lease commitment	<u>3,026,081</u>

## (b) Purchase commitments

As of December 31, 2017, the Group's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statement was \$4,926,073 which is expected to be incurred within one year.

## (c) Capital commitments

The Group's total capital commitment to its underlying investment in JING is RMB 26.3 million (\$3.9 million). As of December 31, 2017, the Group's unfunded commitment to JING was RMB 13.2 million (\$2.0 million).

## (d) Contingencies

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 13).

**17. Subsequent events**

In first quarter of 2018, the Group granted 1,153,750 share options to certain management and employees of the Group at the exercise price ranging from \$20.74 to \$24.58 per share under the 2017 Plan. These options granted have a contractual term of 10 years and generally vest over a five year period, with 20% of the awards vesting on the anniversary date one year after the grant date.

On January 1, 2018, 37,500 ordinary shares were authorized for grant to the independent directors. The restricted shares shall vest and be released from the restrictions in full on the first anniversary from the date of the agreement.

On March 2, 2018, 100,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares shall vest and be released from the restrictions on each yearly anniversary of the date of the agreement.

On March 29, 2018, the Group and Hanmi entered into the agreement to terminate the license and collaboration agreement between the Group and Hanmi. No payment is due from one party to another and the Group has no accrued payment obligation to Hanmi as of the effective date of termination thereafter.

On April 25, 2018, the Group entered into a license and collaboration agreement with Entasis Therapeutics Holdings Inc. ("Entasis"), under which the Group obtained an exclusive right to develop and commercialize Entasis's broad-spectrum intravenous inhibitor of  $\beta$ -lactamases or ETX2514 in the Asia-Pacific region for the treatment of a variety of serious multidrug-resistant infections caused by *Acinetobacter baumannii*. The Group is obligated to pay \$5.0 million non-refundable upfront fees to Entasis upon entering the agreement and is contingently obligated to make future milestone payments upon the achievement of contractually specified development milestones.

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed balance sheets

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

	As of December 31,	
	2016	2017
	\$	\$
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	24,813,050	181,910,618
Prepayments and other current assets	—	450,333
<b>Total current assets</b>	<b>24,813,050</b>	<b>182,360,951</b>
Investment in subsidiaries	62,042,345	54,885,326
<b>Total assets</b>	<b>86,855,395</b>	<b>237,246,277</b>
<b>Liabilities, mezzanine equity and shareholders' deficits</b>		
<b>Liabilities</b>		
Current liabilities:		
Warrant liabilities	3,900,000	—
Other payables	—	593,317
<b>Total current liabilities</b>	<b>3,900,000</b>	<b>593,317</b>
Deferred income	—	1,482,000
<b>Total liabilities</b>	<b>3,900,000</b>	<b>2,075,317</b>
<b>Mezzanine equity</b>		
Series A1 convertible preferred shares (par value US\$0.00006 per share; 8,466,667 shares authorized, 8,466,665 shares issued and outstanding as of December 31, 2016)	10,028,572	—
Series A2 convertible preferred shares (par value US\$0.00006 per share; 8,904,032 shares authorized, 8,442,221 shares issued and outstanding as of December 31, 2016)	18,278,572	—
Series B1 convertible preferred shares (par value US\$0.00006 per share; 5,562,337 shares authorized, 5,562,335 shares issued and outstanding as of December 31, 2016)	53,100,000	—
Series B2 convertible preferred shares (par value US\$0.00006 per share; 3,973,098 shares authorized, 3,973,096 shares issued and outstanding as of December 31, 2016)	53,100,000	—
<b>Total mezzanine equity</b>	<b>134,507,144</b>	<b>—</b>
<b>Shareholders' (deficit) equity</b>		
Ordinary shares (par value of US\$0.00006 per share; 83,333,333 shares authorized, 9,657,175 and 49,912,570 shares outstanding as of December 31, 2016 and 2017, respectively)	579	2,995
Subscription receivable	(5)	(18)
Additional paid-in capital	9,313,646	345,269,688
Accumulated deficit	(60,167,437)	(110,551,613)
Additional other comprehensive (loss) income	(698,532)	449,908
<b>Total shareholders' (deficit) equity</b>	<b>(51,551,749)</b>	<b>235,170,960</b>
<b>Total liabilities, mezzanine equity and shareholders' (deficit) equity</b>	<b>86,855,395</b>	<b>237,246,277</b>

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed statements of operations and comprehensive loss

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

	Year Ended December 31,		
	2015	2016	2017
	\$	\$	\$
<b>Operating Expenses:</b>			
General and administrative	(56,806)	(534,660)	(4,114,144)
<b>Loss from operations</b>	<b>(56,806)</b>	<b>(534,660)</b>	<b>(4,114,144)</b>
Interest income	—	—	50,060
Changes in fair value of warrants	(1,980,000)	(1,920,000)	200,000
Equity in loss of subsidiaries	(15,984,931)	(35,057,552)	(46,598,092)
Other income	—	—	78,000
<b>Loss before income tax</b>	<b>(18,021,737)</b>	<b>(37,512,212)</b>	<b>(50,384,176)</b>
Income tax expense	—	—	—
<b>Net loss attributable to ordinary shareholders</b>	<b>(18,021,737)</b>	<b>(37,512,212)</b>	<b>(50,384,176)</b>
<b>Net loss</b>	<b>(18,021,737)</b>	<b>(37,512,212)</b>	<b>(50,384,176)</b>
Other comprehensive (loss) income, net of tax of nil:			
Foreign currency translation adjustment	(98,893)	(594,912)	1,148,440
<b>Comprehensive loss</b>	<b>(18,120,630)</b>	<b>(38,107,124)</b>	<b>(49,235,736)</b>

Additional financial information of parent company -

Financial statements schedule I

Zai Lab Limited

Financial information of parent company

Condensed statements of cash flows

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

	Year Ended December 31,		
	2015	2016	2017
	\$	\$	\$
<b>Cash flows from Operating activities:</b>			
Net loss	(18,021,737)	(37,512,212)	(50,384,176)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Share based compensation	56,806	534,660	3,346,039
Change of fair value of warrants	1,980,000	1,920,000	(200,000)
Equity in loss of subsidiaries	15,984,931	35,057,552	46,598,092
Changes in operating assets and liabilities:			
Prepayments and other current assets	—	—	(450,333)
Other payables	—	—	553,317
Deferred income	—	—	1,482,000
Net cash provided by operating activities	<u>—</u>	<u>—</u>	<u>944,939</u>
<b>Cash flows from investing activities:</b>			
Investment in subsidiaries	(21,500,000)	(84,501,020)	(31,707,566)
Net cash used in investing activities	<u>(21,500,000)</u>	<u>(84,501,020)</u>	<u>(31,707,566)</u>
<b>Cash flows from financing activities:</b>			
Proceed from issuance of convertible preferred shares, net of issuance cost	18,278,572	106,200,000	29,100,000
Proceeds from exercise of warrants	—	—	1,000,000
Proceeds from exercises of stock options	—	—	65,500
Proceeds from issuance of ordinary shares upon initial public offering	—	—	160,424,994
Payment of initial public offering costs	—	—	(2,730,299)
Net cash provided by financing activities	<u>18,278,572</u>	<u>106,200,000</u>	<u>187,860,195</u>
Effect of foreign exchange rate changes on cash and cash equivalent	<u>—</u>	<u>—</u>	<u>—</u>
Net (decrease) increases in cash and cash equivalents	(3,221,428)	21,698,980	157,097,568
Cash and cash equivalents-beginning of the year	6,335,498	3,114,070	24,813,050
Cash and cash equivalents-end of the year	<u>3,114,070</u>	<u>24,813,050</u>	<u>181,910,618</u>

**Additional financial information of parent company -**

**Financial statements schedule I**

**Zai Lab Limited**

**Financial information of parent company**

**Notes to schedule I**

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

1. Schedule I has been provided pursuant to the requirements of Rule 12-04(a) and 5-04(c) of Regulation S-X, which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.
2. The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements except that the equity method has been used to account for investments in its subsidiaries. For the parent company, the Company records its investments in subsidiaries under the equity method of accounting as prescribed in ASC 323, *Investments-Equity Method and Joint Ventures*. Such investments are presented on the Condensed Balance Sheets as "Investment in subsidiaries". Ordinarily under the equity, an investor in an equity method investee would cease to recognize its share of the losses of an investee once the carrying value of the investment has been reduced to nil absent an undertaking by the investor to provide continuing support and fund losses. For the purpose of this Schedule I, the parent company has continued to reflect its share, based on its proportionate interest, of the losses of subsidiaries regardless of the carrying value of the investment even though the parent company is not obligated to provide continuing support or fund losses.
3. As of December 31, 2016 and 2017, there were no material contingencies, significant provisions of long term obligations, mandatory dividend or redemption requirements of redeemable stocks or guarantees of the Company.

**AMENDMENT TO  
COLLABORATION, DEVELOPMENT AND LICENSE AGREEMENT**

THIS AMENDMENT TO COLLABORATION, DEVELOPMENT AND LICENSE AGREEMENT (the “**Amendment**”) is made and entered into as of February 26, 2018 by and among Tesaro, Inc., a Delaware corporation (“**Tesaro Inc.**”), Tesaro Development Ltd., a Bermuda corporation (“**TSRO Ltd.**” and together with Tesaro Inc., “**Tesaro**”), and Zai Lab (Shanghai) Co., Ltd., a limited liability company organized under the laws of the People’s Republic of China (“**Zai**” and together with Tesaro, the “**Parties**”).

WHEREAS, the Parties have previously entered into that certain Collaboration, Development and License Agreement dated as of September 28, 2016 (the “**Existing Agreement**”); and

WHEREAS, the Parties desire to amend certain provisions of the Existing Agreement in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

1. Co-Marketing Right. Section 2.8 of the Existing Agreement is hereby amended by replacing such section with the following section”

“2.8 *Reserved.*”

2. Effect of Amendment. This Amendment shall be effective as of the Effective Date (as defined in the Existing Agreement). Except as specifically amended by this Amendment, the Existing Agreement shall remain in full force and effect in accordance with its terms.

3. Governing Law. This Amendment shall be governed by and construed exclusively in accordance with the laws of the State of New York, United States of America, without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the laws of the State of New York to the rights and duties of the parties hereto.

4. Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Amendment, or the interpretation, breach, termination, validity or invalidity thereof, shall be resolved in accordance with the procedures set forth in Section 14 of the Existing Agreement.

5. Counterparts. This Amendment may be executed by means of electronic signature (by PDF or facsimile) in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

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IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their respective duly authorized officers.

**ZAI LAB (SHANGHAI) CO., LTD.**

By: /s/ Ying Du  
Ying (Samantha) Du  
Chairperson and CEO

CHOP:

**TESARO, INC.**

By: /s/ Leon O. Moulder Jr.  
Leon O. Moulder, Jr.  
CEO

**TESARO DEVELOPMENT LTD.**

By: /s/ Joseph Farmer  
Joseph Farmer  
Director

\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## Exhibit 4.11

**LICENSE AND COLLABORATION AGREEMENT**

This **LICENSE AND COLLABORATION AGREEMENT** (this “**Agreement**”) is made as of December 19, 2017 (the “**Effective Date**”), by and between **FIVE PRIME THERAPEUTICS, INC.**, a Delaware corporation (“**Five Prime**”), having a place of business at 111 Oyster Point Boulevard, South San Francisco, California 94080, USA, and **ZAI LAB (SHANGHAI) CO., LTD.**, a limited company organized under the laws of P.R. of China (“**Zai**”), having a place of business at 4560 Jinke Rd, Bldg. 1, 4/F, Pudong, Shanghai, China, 201210. Five Prime and Zai are referred to in this Agreement individually as a “**Party**” and collectively as the “**Parties**.”

**RECITALS**

**WHEREAS**, Five Prime is a biopharmaceutical company that is developing a proprietary FGFR2b antibody known as FPA144 for the treatment of cancer and controls certain patents and know-how relating to FPA144;

**WHEREAS**, Zai is a biopharmaceutical company engaged in the research, development and commercialization of pharmaceutical products in the greater China region; and

**WHEREAS**, Zai wishes to obtain from Five Prime an exclusive license to develop and commercialize FPA144 in the Territory, and Five Prime is willing to grant such a license to Zai, all in accordance with the terms and conditions set forth herein.

**AGREEMENT**

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

**ARTICLE 1  
DEFINITIONS**

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

**1.1** “**Active Ingredient**” means the clinically active material(s) that provide pharmacological activity in a pharmaceutical product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies).

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

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**1.3** “**Antibody**” means any full-length antibody, antigen-binding fragment thereof, and chemically modified antibody or antigen-binding fragment thereof (including any pegylated versions and regardless of whether containing amino acid substitutions, in all cases, to the extent still constituting an antibody or antigen-binding fragment thereof), all of the foregoing whether naturally occurring, artificially produced, raised in an artificial system, or created through modification of an antibody produced in any of the foregoing ways or otherwise.

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

**1.5** “**Biosimilar Product**” means, with respect to a Licensed Product in a particular country, any pharmaceutical product that: (a) has received all necessary approvals by the applicable Regulatory Authorities in such country to market and sell such product as a pharmaceutical product, including all required pricing and reimbursement approvals; (b) is marketed or sold by a Third Party that has not obtained the rights to market or sell such product as a licensee, sublicensee or distributor of Five Prime or Zai or any of their respective Affiliates, licensees or sublicensees with respect to such Licensed Product; and (c) is approved as (i) a “biosimilar” (in the United States) of such Licensed Product, (ii) a “similar biological medicinal product” (in the EU) with respect to which such Licensed Product is the “reference medicinal product”, or (iii) if not in the US or EU, the foreign equivalent of a “biosimilar” or “similar biological medicinal product” of such Licensed Product; in each case for use in such country pursuant to an expedited regulatory approval process governing approval of generic biologics based on the then-current standards for regulatory approval in such country (e.g., the Biologics Price Competition and Innovation Act of 2009 or an equivalent under foreign law) and where such regulatory approval was based in significant part upon clinical data generated by Five Prime, Zai or their respective Affiliates or sublicensees with respect to such Licensed Product.

**1.6** “**Business Day**” means a day other than a Saturday, Sunday or a day on which banking institutions in San Francisco, California or Shanghai, China are required by Applicable Laws to remain closed.

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

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

**1.9** “**CFDA**” means the China Food and Drug Administration, and local counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

**1.10** “**CFDA Submission Timeline**” has the meaning set forth in Section 5.1(c).

**1.11** “**cGMP**” means all applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4,

\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(c) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (d) the equivalent Applicable Laws in any relevant country or region, each as may be amended and applicable from time to time.

**1.12** “*Clinical Trial*” means any human clinical trial of a Licensed Product.

**1.13** “*Change of Control*” means, with respect to a Party:

(a) the acquisition by any individual, Entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) who or which constitute(s) a Third Party (a “*Specified Person*”) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended) of fifty percent (50%) or more of the combined voting power of the then-outstanding voting securities of such Party entitled to vote generally in the election of directors of such Party (the “*Outstanding Voting Securities*”); provided, however, that for the purposes of this sub-section (a), the following acquisitions of securities of such Party shall not constitute a Change of Control of such Party, notwithstanding that any such acquisition would constitute a Change of Control of such Party in the absence of this proviso: (x) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by such Party or any Affiliate of such Party or (y) any acquisition by a Specified Person pursuant to a transaction which complies with subsection (b) of this definition;

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

(c) such Party or any of its Affiliates sells or transfers to any Specified Person(s) in one or more related transactions properties or assets representing all or substantially all of such Party’s business or assets to which the subject matter of this Agreement relates at the time of such sale or transfer.

**1.14** “*Collaboration IP*” means all Inventions that are made jointly by the Parties or solely by a Party and that are not FPA144 Collaboration IP. For the avoidance of doubt, “Collaboration IP” includes all Inventions as defined above in the therapeutic, diagnostic and process development fields, including any diagnostic assays, technologies and platforms, and any Companion Diagnostics, including any Companion Diagnostics that are in development as of the Effective Date and any Companion Diagnostics that are developed in the future, shall be deemed within Collaboration IP, solely to the extent that each of the foregoing are not FPA144 Collaboration IP.

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**1.15** “**Commercialization**” or “**Commercialize**” means all activities directed to marketing, promoting, advertising, exhibiting, distributing, detailing, selling (and offering for sale or contracting to sell) or otherwise commercially exploiting (including pricing and reimbursement activities) a Licensed Product in the Field in the Territory (including importing and exporting activities in connection therewith).

**1.16** “**Commercialization Plan**” means, with respect to a Licensed Product, the written strategic and tactical plans and commercial budget for the Commercialization of such Licensed Product in the Territory.

**1.17** “**Commercially Reasonable Efforts**” means, with respect to a Party’s obligations or activities under this Agreement, the carrying out of such obligations or activities with a level of effort and resources consistent with the commercially reasonable practices normally devoted by a similarly situated company, as part of an active and continuing program of development and commercialization of a pharmaceutical product of similar market potential, at a similar stage of its product life, taking into account all relevant factors, including but not limited to, the competitiveness of the marketplace and the proprietary position, regulatory status, and relative safety and efficacy of such product.

**1.18** “**Competing Antibody Product**” means any product that is or incorporates any Antibody (other than the Licensed Antibody) that is directed to FGFR2 or FGFR2b as an intended therapeutic mechanism of action.

**1.19** “**Confidential Information**” of a Party means, subject to Section 10.2, all Know-How, unpublished patent applications and other non-public information and data of a financial, commercial, business, operational or technical nature of such Party that is disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, in each case in connection with this Agreement or the Confidentiality Agreement, whether made available orally, visually, in writing or in electronic form. All FPA144 Collaboration IP shall be deemed Confidential Information of Five Prime notwithstanding the fact that such information may be generated and disclosed to Five Prime by Zai, and all Collaboration IP shall be deemed the Confidential Information of the owning Party, pursuant to Section 13.1(a).

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

**1.21** “**CTA**” means a Clinical Trial Application submitted to the CFDA for approval to conduct human clinical trials.

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

**1.23** “*Dollar*” or “*\$*” means the U.S. dollar, and “*\$*” shall be interpreted accordingly.

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

**1.25** “*FDA*” means the United States Food and Drug Administration or any successor entity thereto.

**1.26** “*FGFR Target(s)*” means, individually or collectively, as the context indicates, the fibroblast growth factor receptor (“*FGFR*”) targets commonly known as FGFR1, FGFR2, FGFR3 and FGFR4, including any isoforms of the foregoing.

**1.27** “*Field*” means the treatment or prevention of any disease or condition in humans.

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

**1.29** “*Five Prime IP*” means Five Prime Know-How and Five Prime Patents.

**1.30** “*Five Prime Know-How*” means, subject to Section 2.7(c), all Know-How Controlled by Five Prime as of the Effective Date or at any time during the Term that is

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necessary or reasonably useful for the Development, manufacture or Commercialization of Licensed Products in the Field in the Territory, including all Know-How within the FPA144 Collaboration IP and all Know-How within the Five Prime-owned Collaboration IP; provided, however, that Five Prime Know-How shall exclude all Know-How that comes into Five Prime's Control as a result of a Change of Control of Five Prime.

**1.31** “*Five Prime Patents*” means, subject to Section 2.7(c), all Patents in the Territory Controlled by Five Prime as of the Effective Date or at any time during the Term that cover a Licensed Product (including composition of matter and methods of using, making or detecting Licensed Products), including all Patents in the Territory claiming FPA144 Collaboration IP, Five Prime's interest in the Joint Patents and all other Patents claiming Five Prime-owned Collaboration IP; provided, however, that Five Prime Patents shall exclude all Patents that come into Five Prime's Control as a result of a Change of Control of Five Prime. **Exhibit A** includes the Five Prime Patents that are owned or exclusively licensed by Five Prime and that are existing as of the Effective Date; provided, that, for the avoidance of doubt, any Patent that otherwise meets the definition of a Five Prime Patent shall still be considered a Five Prime Patent even if such Patent is not identified on **Exhibit A**.

**1.32** “*FPA144 Collaboration IP*” means all Inventions that are made jointly by the Parties or solely by a Party and that specifically relate to one or more of the following: (i) an antibody or antigen-binding fragment thereof that binds to FGFR2, including any Licensed Antibody or Licensed Tool Antibody; (ii) FGFR2; or (iii) a composition of matter of or a method of using, making or detecting any of (i) or (ii). For the avoidance of doubt, “FPA144 Collaboration IP” includes all Inventions in the therapeutic, diagnostic, and process development fields, including any diagnostic assays, technologies and platforms, and any Companion Diagnostics, including any Companion Diagnostics that are in development as of the Effective Date and any Companion Diagnostics that are developed in the future, provided that such Invention specifically relates to one or more of the foregoing (i)-(iii).

**1.33** “*FPA144-004 Study*” means Five Prime's global Registrational Trial of FPA144 in front-line gastric cancer and GEJ cancer titled “FIGHT: A Phase 1/3 Study of FPA144 versus Placebo in Combination with Modified FOLFOX6 in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Cancer” with corresponding protocol number FPA144-004, as may be amended from time to time.

**1.34** “*FTE*” means the equivalent of the work of a full-time individual for [\*\*\*].

**1.35** “*FTE Rate*” means a rate of [\*\*\*] per FTE per year, to be pro-rated on an hourly basis of [\*\*\*] per FTE per hour, assuming [\*\*\*] for an FTE.

**1.36** “*Fully Burdened Manufacturing Cost*” means, with respect to any Licensed Product supplied by or on behalf of Five Prime to Zai hereunder:

(a) if such Licensed Product (or any precursor or intermediate thereof) is manufactured by a Third Party manufacturer, (i) the actual Third Party costs of such manufacturing incurred by Five Prime, including the costs of raw materials (including any costs

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incurred by Five Prime for time spent by Five Prime personnel to draft authorization letters or other documentation necessary for Zai to obtain such raw materials, at the FTE Rate), intermediates and components, reference materials or standards required for release testing, materials necessary to support stability studies (including methods, reference materials and consumables), drug substance and drug product manufacturing, labeling and packaging, quality assurance and stability testing, characterization testing, quality control (“QC”) release testing of drug substance and drug product, quality assurance (“QA”) batch record review and release of product, storage and freight, shipping, tariffs, customs clearance and export fees, plus (ii) any internal costs incurred by Five Prime in association with such manufacturing, including for process development, project management (at the FTE Rate), manufacturing oversight (including at the FTE Rate for any Five Prime person-in-plant) and quality control and assurance; plus

(b) if such Licensed Product (or any precursor or intermediate thereof) is manufactured by Five Prime or its Affiliate, the actual, fully burdened cost of such manufacturing, including the cost of raw materials (including any costs incurred by Five Prime for time spent by Five Prime personnel to draft authorization letters or other documentation necessary for Zai to obtain such raw materials, at the FTE Rate), direct labor and benefits, a proportionate share of indirect manufacturing costs, including idle plant capacity reserved specifically for such Licensed Product based on anticipated product volumes in the ensuing [\*\*\*], intellectual property acquisition and licensing costs (including royalties, upfront fees, etc.) paid by Five Prime with respect to the manufacture of such Licensed Product, and all other reasonable and customary manufacturing-related costs for such Licensed Product, including actual product inventory write-offs, factory, plant or equipment start-up or start-up amortization costs, scale-up expenses, failed lots, and freight in/out and sales and excise taxes imposed thereon, customs and duty and charges levied by government authorities, and all costs of packaging. Such fully burdened costs shall be calculated in accordance with GAAP.

1.37 “GAAP” means United States generally accepted accounting principles, consistently applied.

1.38 “GCP” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) (the “ICH Guidelines”) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.39 “GEJ” means gastroesophageal junction.

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**1.40** “*GLP*” means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

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

**1.42** “*IND*” means an investigational new drug application or equivalent application filed with a Regulatory Authority in a given country, which application is required to commence human clinical trials in such country. For the avoidance of doubt, a CTA is an IND.

**1.43** “*Indication*” means a separate and distinct disease, disorder or medical condition that a Licensed Product is intended to treat, prevent, cure, or ameliorate, or that is the subject of a Clinical Trial and where it is intended that the data and results of such Clinical Trial (if successful) shall be used to support a Regulatory Submission and approval that is intended to result in distinct labeling within the indications section of the label relevant to usage in such disease, disorder or medical condition that is separate and distinct from another disease, disorder or medical condition. For clarity, each different histologic or genetic subtype or line of therapy (e.g., well-differentiated or poorly-differentiated gastric cancer, non-small cell lung cancer and small cell lung cancer, first-line gastric cancer and second-line gastric cancer) shall be deemed a different Indication.

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

**1.45** “*JPT*” has the meaning set forth in Section 3.2(g).

**1.46** “*JSC*” has the meaning set forth in Section 3.2(a).

**1.47** “*Know-How*” means any information and materials, including discoveries, improvements, modifications, processes, methods, assays, designs, protocols, formulas, data, inventions, algorithms, forecasts, profiles, strategies, plans, results, know-how and trade secrets (in each case, patentable, copyrightable or otherwise), but excluding any Patents and any information that is not Confidential Information.

**1.48** “*License*” has the meaning set forth in Section 2.1(b).

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**1.49** “**Licensed Antibody**” means Five Prime’s proprietary afucosylated FGFR2b antibody known as FPA144 and having the structure set forth in **Exhibit B**, and all fragments, conjugates, derivatives or modifications thereof.

**1.50** “**Licensed Product**” means any pharmaceutical product containing the Licensed Antibody (whether alone as the sole Active Ingredient or as a combination with other Active Ingredient(s), provided that such other Active Ingredient(s) is not proprietary to Five Prime), in any form, presentation, formulation or dosage form.

**1.51** “**Licensed Tool Antibodies**” means Five Prime’s proprietary tool antibodies known as GAL-FR21 and FPR2-D (mouse) and all fragments, conjugates, derivatives or modifications thereof.

**1.52** “**NDA-C**” means a New Drug Application (as defined by the CFDA), or any successor application having substantially the same function, or its foreign equivalent for approval to market or sell a pharmaceutical product in the Territory.

**1.53** “**Net Sales**” means with respect to a Licensed Product, the gross amount billed or invoiced by or for the benefit of Zai and its Affiliates, licensees and sublicensees (each of the foregoing, a “**Seller**”) to independent, unrelated persons (“**Buyers**”) in *bona fide* arm’s length transactions with respect to such Licensed Product, less the following deductions, in each case to the extent actually allowed and taken by such Buyers and not otherwise recovered by or reimbursed to Seller in connection with such Licensed Product:

(a) transportation charges and other charges directly related thereto, such as insurance, in each case, to the extent actually incurred;

(b) sales, excise taxes [\*\*\*] paid by the Seller and any other governmental charges or taxes imposed specifically upon the sale of such Licensed Product and actually paid;

(c) discounts and chargebacks actually granted, allowed or incurred in connection with the sale of such Licensed Product that are not otherwise attributable to other products of Zai and its Affiliates;

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

(e) amounts written off by reason of uncollectible debt if and when actually written off or allowed, after commercially reasonable debt collection efforts have been exhausted, provided that such amounts shall be added back to Net Sales if and when collected; and

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

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No deduction shall be made for any item of cost incurred by any Seller in Developing or Commercializing Licensed Products except as permitted pursuant to clauses (a) to (f) of the foregoing sentence; provided that Licensed Products transferred to Buyers in connection with [\*\*\*] shall give rise to Net Sales only to the extent that any Seller invoices or receives amounts therefor. If a single item falls into more than one of the categories set forth in clauses (a)-(f) above, such item may not be deducted more than once.

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

Sales between Zai and its Affiliates and sublicensees shall be disregarded for purposes of calculating Net Sales except if such purchaser is a distributor to which risk of loss of such Licensed Product transfers or is an end user.

If a Licensed Product is sold in the form of a combination product containing both a Licensed Antibody and one or more Active Ingredient(s) (whether co-formulated or co-packaged) that is not a Licensed Antibody (a "**Combination Product**"), the Net Sales of such Licensed Product for the purpose of calculating royalties owed under this Agreement for sales of such Licensed Product, shall be determined as follows: first, Zai shall determine the actual Net Sales of such Combination Product (using the above provisions) and then such amount shall be multiplied by the fraction  $A/(A+B)$ , where A is the invoice price of such Licensed Product, if sold separately, and B is the total aggregate invoice price of all other Active Ingredients in such Combination Product if sold separately. In each case, A and B shall be adjusted on a pro rata basis to account for dosing differences between the amounts of Active Ingredient(s) included in the Combination Product relative to the amounts of Active Ingredient(s) included in the separately sold product. If any other Active Ingredient in such Combination Product is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by a fraction  $A/C$  where A is the invoice price of such Licensed Product if sold separately, and C is the invoice price of such Combination Product. If neither such Licensed Product nor any other Active Ingredient in such Combination Product is sold separately, the adjustment to Net Sales shall be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of such Licensed Product in such Combination Product to the total fair market value of such Combination Product.

With respect to any sale of any Licensed Product in a given country for any substantive consideration other than monetary consideration on arm's length terms (which has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary consideration), for purposes of calculating the Net Sales, such Licensed Product shall be deemed to be sold exclusively for cash at the average Net Sales price charged to Third Parties for cash sales of such Licensed Product in such country during the applicable reporting period (or if there were only *de minimis* cash sales in such country, at the fair market value as determined in good faith based on pricing in comparable markets). Notwithstanding the foregoing, Net Sales shall not include amounts (whether actually existing or deemed to exist for purposes of calculation) for Licensed Products distributed for use in Clinical Trials.

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

**1.54** "**Pan-FGFR Inhibitor**" means a molecule or pharmaceutical product that (a) broadly inhibits multiple FGFR Targets as its therapeutic mechanism of action (including at least one FGFR Target that is not FGFR2 or FGFR2b) and (b) is no more selective for FGFR2 or FGFR2b than any other FGFR Target.

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

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

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

**1.58** "**Phase 3 Clinical Trial**" means a controlled or uncontrolled human Clinical Trial of a Licensed Product that would satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations, regardless of whether such trial is referred to as a "phase 3 clinical trial" in the Global Development Plan or the Territory Development Plan.

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

**1.60** "**Registrational Trial**" means a human Clinical Trial that satisfies at least one of the following criteria (regardless of whether such trial is referred to as a "phase 1 clinical trial", a "phase 2 clinical trial", a "phase 2b clinical trial" or a "phase 3 clinical trial"):

(a) it would, based on interactions with a Regulatory Authority or otherwise prior to the initiation of such trial, satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations;

(b) it is designed in a manner to allow for the addition of additional patients such that it could satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations; or

(c) it is otherwise intended, at the time of initiation, to support (either alone or together with other Phase 3 Clinical Trials) an application for marketing approval of a new product (or a new indication or expanded use for an already approved product).

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**1.61** “**Regulatory Approval**” means, with respect to a Licensed Product in a region in the Territory, all approvals that are necessary for the commercial sale of such Licensed Product in such region in the Territory, excluding any pricing and reimbursement approvals.

**1.62** “**Regulatory Authority**” means any applicable Government Authority responsible for granting Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products, including the CFDA, and any corresponding national or regional regulatory authorities.

**1.63** “**Regulatory Exclusivity**” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical product, including any such right that may become available following the Effective Date, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, pediatric exclusivity, rights conferred in the United States under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (but excluding any patent term extension mechanism), or rights similar thereto outside the United States, but in all cases excluding Patents and patent term extensions based on such rights.

**1.64** “**Regulatory Submissions**” means any filing, application or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals and any pricing or reimbursement approvals, as applicable, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to a Licensed Product.

**1.65** “**Tax**” or “**Taxes**” means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon). For the avoidance of doubt, Taxes includes value add taxes (“**VAT**”).

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

**1.67** “**Third Party**” means any Person other than a Party or an Affiliate of a Party; provided that, solely for purposes of the definition of “Change of Control”, Third Party shall not include any “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

**1.68** “**United States**” means the United States of America.

**1.69** “**Upstream License Agreements**” has the meaning set forth in Section 2.3.

**1.70** “**Upstream Licensors**” has the meaning set forth in Section 2.3.

**1.71** “**Valid Claim**” means: (a) a claim in an issued Patent that has not: (i) expired or been canceled; (ii) been declared invalid by an unreversed and unappealable or unappealed decision of a court or other appropriate body of competent jurisdiction; (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (iv) been abandoned in accordance with or as permitted by the terms of this Agreement or by written agreement of the Parties; or (b) a claim that has been pending [\*\*\*] or less from the date that the first action on the merits (excluding restriction requirements, notices to file missing parts, and the like) was received in a patent application in which such claim is examined, and that has not been abandoned (without the possibility of refiling) or finally rejected by the applicable governmental

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authority or court (and from which no appeal is or can be taken). For clarity, if a claim is canceled and refiled in a continuing application, the period of pendency is calculated from the date that the first action on the merits as to that claim was first received.

1.72 “[\*\*\*] *Agreements*” means, collectively, [\*\*\*].

1.73 “*Working Group*” has the meaning set forth in Section 3.3(h).

1.74 “*Zai Collaboration IP*” means all Collaboration IP that is owned by Zai pursuant to Section 13.1(a).

1.75 “*Zai IP*” means all Patents and Know-How (i) Controlled by Zai as of the Effective Date or (ii) that thereafter comes into Zai’s Control independent of this Agreement, and in each case, that are used or applied by or on behalf of Zai or its Affiliates or sublicensees in the Development, manufacture or Commercialization of Licensed Products. For clarity, Zai IP may include inventions that are broadly applicable to the Development, manufacture or Commercialization of pharmaceutical products generally, including Licensed Products.

1.76 “*Zai Patents*” means all Patents in the Zai IP.

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

<b>Definition</b>	<b>Section</b>
Acquisition Affiliate	2.9(a)
Agreement	Preamble
Alliance Manager	3.1
Anti-Corruption Laws	11.7(a)(i)
Arbitration Notice	15.3(a)
Arbitrators	15.3(b)
[***]	2.3
Business Combination Transaction	1.13(b)
Buyer	1.53
CFDA Submission Timeline	5.1(c)
Combination Product	1.53
Companion Diagnostics	5.10(a)
Competing Product	2.8(a)
Competing Program	2.9(a)
Confidentiality Agreement	16.6
Continuing Technology Transfer	4.1
Deficient Site	5.6(b)
Disclosing Party	10.1(a)
Effective Date	Preamble
Ex-Territory Infringement	13.3(a)
Examined Party	9.8
Exclusive License	2.1(a)
Exclusive Tail Expiration Date	14.1
Executive Officers	3.2(f)
Facility-fit Assessment	7.2(b)
Five Prime	Preamble
Five Prime Indemnitee(s)	12.1
Five Prime Specifications	7.2(c)
[***]	2.3
Global Allocation Cap	5.4
Global Brand Elements	8.4(c)
Global Development Plan	5.3
ICH Guidelines	1.38
Indemnified Party	12.3
Indemnifying Party	12.3
Initial Technology Transfer	4.1
Joint Patent	13.1(c)(ii)
JPT	3.2(g)
JSC	3.2(a)
License	2.1(b)
[***]	2.3

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Losses	12.1
Manufacturing Assumption Notice	7.2(d)
Manufacturing Notice	7.2(b)
Outstanding Voting Securities	1.13(a)
QA	1.36(a)
QC	1.36(a)
Oversight Plan	6.9
Party/Parties	Preamble
Paying Party	9.9(b)
Public Official	11.7(d)
Publication	10.4
Receiving Party	10.1(a)
Recipient	9.9(b)
Replacement Site	5.6(b)
Research License	2.1(b)
Review Period	10.4
Royalty Term	9.3(b)
Rules	15.3(a)
Safety Agreement	6.4(a)
SEC	10.6(c)
Seller	1.53
Specified Person	1.13(a)
Technology Transfer	4.1
Term	14.1
Territory Development Plan	5.2
Upstream License Agreements	2.3
Upstream Licensors	2.3
VAT	1.65
VAT Credit	9.10
VAT Withholding	9.10
Working Group	3.2(h)
Zai	Preamble
Zai Indemnitee(s)	12.2
Zai Specifications	7.2(c)

## ARTICLE 2 LICENSE

### 2.1 License Grants to Zai.

(a) Subject to the terms and conditions of this Agreement, Five Prime hereby grants to Zai (i) an exclusive (subject to Five Prime's retained rights as set forth in Section 2.4), royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2, under the Five Prime IP to Develop, make, have made, distribute, use, sell, offer for sale, import and otherwise Commercialize Licensed Products in the Field in the Territory (the "*Exclusive License*"), and (ii) a non-exclusive license, with the right to grant sublicenses solely in

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accordance with Section 2.2, under the Five Prime IP to perform the Development activities in the Field outside of the Territory that are assigned to Zai under the Global Development Plan to the extent permitted by this Agreement.

(b) Subject to the terms and conditions of this Agreement, Five Prime hereby grants to Zai a non-exclusive license (with the right to grant sublicenses solely in accordance with Section 2.2) under the Five Prime IP to conduct research using the Licensed Tool Antibodies in furtherance of the Development and Commercialization of Licensed Products in the Field in the Territory (the “*Research License*” and together with the Exclusive License, the “*License*”).

## 2.2 Right to Sublicense.

(a) Subject to the terms and conditions of this Agreement, Zai shall have the right to grant sublicenses of the License: (i) to its Affiliates, provided that such sublicense shall automatically terminate if such sublicensee ceases to be an Affiliate of Zai; and (ii) subject to Section 5.9, to contract research organizations, contract manufacturers, distributors and other Third Party subcontractors for the sole purpose of (x) with respect to the Exclusive License, performing Zai’s obligations with respect to the Development, manufacture and Commercialization of Licensed Products in the Field in the Territory; provided that Zai may not grant a sublicense under the Exclusive License [\*\*\*], in each case ((A) and (B)), without Five Prime’s prior written consent, such consent not to be unreasonably withheld, conditioned or delayed; or (y) with respect to the Research License, conducting research using the Licensed Tool Antibodies in furtherance of the Development and Commercialization of Licensed Products in the Field in the Territory. Notwithstanding the foregoing, Zai shall obtain Five Prime’s prior written consent if Zai wishes to sublicense all or substantially all of Zai’s rights or obligations under this Agreement with respect to any region within the Territory.

(b) Each sublicense shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement, and Zai shall ensure that its sublicensees comply with the terms and conditions of this Agreement. Zai may fulfill any of its obligations under this Agreement itself or through its Affiliates and sublicensees, provided however that Zai will remain directly responsible for all its obligations under this Agreement, regardless of whether any such obligation is delegated, subcontracted or sublicensed to any of its Affiliates or sublicensees. Zai shall provide Five Prime with written notice of any sublicense within [\*\*\*] after it becomes effective (including the identity of the sublicensee and the region in which such rights have been sublicensed) and shall provide Five Prime with a true and complete copy of each sublicense agreement, subject to Zai’s right to redact any confidential or proprietary information contained therein that is not necessary for Five Prime to determine compliance with this Agreement, and an English translation thereof [\*\*\*], which translation will be a certified translation if requested by Five Prime; [\*\*\*]. Zai will provide Five Prime with copies of any quality oversight or audit reports, including certified English translations thereof if requested by Five Prime[\*\*\*], from audits that Zai has conducted on any sublicensees or subcontractors that Zai

engages to fulfill its obligations under this Agreement to the extent such reports are relevant to such sublicensees’ or subcontractors’ conduct of such obligations no later than [\*\*\*] after receiving or preparing, as applicable, any such report.

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**2.3 Upstream Licenses.** Zai acknowledges and agrees that: (a) Five Prime obtained the rights to certain Five Prime IP [\*\*\*] under certain license agreements with the Upstream Licensors (collectively, the “**Upstream License Agreements**”); (b) the License constitutes a sublicense under each applicable Upstream License Agreement, subject to this Section 2.3; and (c) each such sublicense is subject to the terms and conditions of the applicable Upstream License Agreements [\*\*\*]. Without limiting the foregoing, Zai acknowledges that Zai’s right under the Exclusive License to make and have made Licensed Products may be subject to the consent of the Upstream Licensors.

**2.4 Five Prime Retained Rights.** Notwithstanding the exclusive nature of the Exclusive License, Five Prime expressly retains the rights to use the Five Prime IP in the Field in the Territory in order to perform its obligations under this Agreement and to conduct research and Development activities under the Global Development Plan, in each case whether directly or through its Affiliates, licensees or contractors. For clarity, Five Prime retains the exclusive right to practice, license and otherwise exploit the Five Prime IP outside the scope of the License.

**2.5 License Grants to Five Prime.** Zai hereby grants to Five Prime during the Term:

(a) a non-exclusive, fully-paid, royalty-free, perpetual, irrevocable and sublicenseable (through multiple tiers) license under the Zai IP to develop, make, have made, distribute, use, sell, offer for sale, import and otherwise commercialize Licensed Products (i) outside the Territory and (ii) in the Territory solely as necessary for Five Prime to perform its obligations under this Agreement and to conduct research and Development activities under the Global Development Plan; and

(b) an exclusive, fully-paid, royalty-free, perpetual, irrevocable and sublicenseable (through multiple tiers) license under the Zai Collaboration IP to develop, make, have made, distribute, use, sell, offer for sale, import and otherwise commercialize Licensed Products outside the Territory.

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

**2.7 Reimbursement for Third Party Sublicense.**

(a) If, during the Term, Five Prime obtains Control of any intellectual property rights from a Third Party [\*\*\*], which intellectual property rights are necessary for the Development, manufacture or Commercialization of Licensed Products in the Field in the Territory (“**Third Party IP Rights**”), then such Third Party IP Rights shall be included in the Five Prime IP and sublicensed to Zai, subject to the terms and conditions of this Agreement and the agreement between Five Prime and such Third Party. Five Prime shall notify Zai in writing of such Third Party IP Rights, including a description thereof and any payments that Five Prime is obligated to pay in connection with the grant, maintenance or exercise of the sublicense to Zai, and Zai hereby agrees to reimburse Five Prime (a) with respect to any such payments that solely pertain to the Development, manufacture or Commercialization of Licensed Products in the Territory[\*\*\*], and (b) with respect to any such payments that pertain to the Development, manufacture or Commercialization of Licensed Products both inside and outside of the Territory, [\*\*\*].

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(b) Notwithstanding the foregoing Section 2.7(a), in the event that Zai determines in good faith that the non-financial terms of a license of any Third Party IP Rights that would be applicable to Zai as a sublicensee thereof pursuant to Section 2.7(a) would materially adversely affect Zai's business or its anticipated business activities, then Zai shall have the right to decline such sublicense of Third Party IP Rights from Five Prime; provided that, in any agreement under which Five Prime obtains any such Third Party IP Rights, [\*\*\*].

(c) If Zai desires to exercise its right pursuant to Section 2.7(b) to decline a sublicense to any Third Party IP Rights, then Zai shall notify Five Prime in writing within [\*\*\*] after Five Prime's notice pursuant to Section 2.7(a) and the definitions of Five Prime Patents and Five Prime Know-How shall be deemed to exclude any such Third Party IP Rights, as applicable, and, for the avoidance of doubt, such Third Party IP Rights shall not be included within the scope of the License.

## 2.8 Non-Compete.

(a) Subject to Section 2.9, during the Term, Zai shall not, and shall ensure that its Affiliates do not, engage in, independently or for or with any Third Party, any research, development, manufacture or commercialization of any molecule or pharmaceutical product that is directed to FGFR2 or FGFR2b as an intended therapeutic mechanism of action (each a "**Competing Product**") other than Licensed Products in accordance with this Agreement. Notwithstanding the foregoing, the restrictions set forth in this Section 2.8(a) shall not apply to (i) that certain pan-FGFR molecule known as ZL-2301, and (ii) any Pan-FGFR Inhibitor that is directed to at least one target that is a non-FGFR Target (e.g., endothelial growth factor receptor) as an intended therapeutic mechanism of action.

(b) Subject to Section 2.9, during the Term, Five Prime shall not, and shall ensure that its Affiliates do not, engage in, independently or for or with any Third Party, any research, development, manufacture or commercialization of any Competing Product in the Territory, other than Licensed Products in accordance with this Agreement. Notwithstanding the foregoing, the restrictions set forth in this Section 2.8(b) shall not apply to any Pan-FGFR Inhibitor that is directed to at least one target that is a non-FGFR Target (e.g., endothelial growth factor receptor) as an intended therapeutic mechanism of action.

## 2.9 Acquisition Products and Programs.

(a) Notwithstanding the restrictions in Section 2.8(a) and 2.8(b), if a Third Party becomes an Affiliate of a Party after the Effective Date as a result of a Change of Control of such Party (each such Third Party, an "**Acquisition Affiliate**"), and, as of the closing date of such Change of Control transaction such Third Party is engaged in a program directed to the research, development, manufacture or commercialization of a Competing Product that, if conducted by a Party, would cause such Party to be in breach of its exclusivity obligations set forth in Section 2.9(a) or 2.8(b) (such Third Party program, a "**Competing Program**"), then Section 2.8(a) or 2.8(b), as applicable, shall not apply with respect to such Competing Program, and such Acquisition Affiliate may continue such Competing Program after such Change of Control and such continuation shall not constitute a breach of a Party's exclusivity obligations set forth in Section 2.8(a) or 2.8(b), as applicable; *provided that* (A) at the time of the closing date of the relevant Change of Control transaction, an IND has been filed by or on behalf of such Acquisition Affiliate for at least one Competing Product arising from such Competing Program, and (B) such Acquisition Affiliate conducts such Competing Program independently of the

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activities of this Agreement and does not use or have access to any intellectual property or Confidential Information of either Party for the conduct of such Competing Program.

(b) Without limiting Section 2.9(a), following the closing date of any relevant Change of Control transaction, the restrictions set forth in Section 2.8(a) and Section 2.8(b), as applicable, shall not apply with respect to Acquisition Affiliates; provided that (i) such Acquisition Affiliate does not use or have access to any intellectual property or Confidential Information of either Party for the conduct of a Competing Program, and (ii) following such closing date and for the remainder of the Term, any such Acquisition Affiliate shall not engage in (independently or for or with any Third Party) any research, development, manufacture or commercialization of any Competing Antibody Product either (1) anywhere in the world (with respect to any Acquisition Affiliate of Zai) or (2) in the Territory (with respect to any Acquisition Affiliate of Five Prime).

#### 2.10 Restrictions on Sublicensees and Licensees.

(a) Zai shall incorporate into any sublicense with a Third Party entered into during the Term that grants such Third Party the right to Develop or Commercialize Licensed Products in the Territory (other than as a service provider acting on Zai's behalf) a provision (and shall use commercially reasonable efforts to enforce such provision), preventing such Third Party from engaging in, independently or for or with any other Third Party, any research, development, manufacture or commercialization of any Competing Product, other than Licensed Products in accordance with the terms of such sublicense agreement and this Agreement, as such terms are applicable to the activities of such Third Party. Notwithstanding the foregoing, Zai shall not be required to include any obligation in such sublicense agreement restricting such Third Party from (i) researching, developing, manufacturing or commercializing any Pan-FGFR Inhibitor or (ii) continuing any Competing Program that such Third Party was already conducting at the time of entry into such sublicense agreement if an IND was filed by or on behalf of such Third Party for at least one Competing Product from such Competing Program prior to such time.

(b) Five Prime shall incorporate into any license with a Third Party entered into during the Term that grants such Third Party the right to Develop or Commercialize Licensed Products (other than as a service provider acting on Five Prime's behalf) a provision (and shall use commercially reasonable efforts to enforce such provision), preventing such Third Party from engaging in, independently or for or with any other Third Party, any research, development, manufacture or commercialization of any Competing Product in the Territory, other than Licensed Products in accordance with the terms of such license agreement. Notwithstanding the foregoing, Five Prime shall not be required to include any obligation in such license agreement restricting such Third Party from (i) researching, developing, manufacturing or commercializing any Pan-FGFR Inhibitor in the Territory or (ii) or continuing any Competing Program that such Third Party was already conducting at the time of entry into such sublicense agreement if an IND was filed by or on behalf of such Third Party for at least one Competing Product from such Competing Program prior to such time.

### ARTICLE 3 GOVERNANCE

3.1 **Alliance Managers.** Each Party shall appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (the "**Alliance Manager**"), which Zai Alliance Manager shall be fluent in English. The Alliance Managers

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shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, provided that all communications between the Parties shall be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC (as a non-voting participant), JPT and Working Group meetings. An Alliance Manager may also bring any matter to the attention of the JSC, JPT or applicable Working Group if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

### 3.2 Joint Steering Committee.

**(a) Formation.** No later than [\*\*\*] following the Effective Date, The Parties shall establish a joint steering committee (the "**JSC**") to monitor and coordinate the Development, manufacture and Commercialization of Licensed Products in the Field in the Territory. The JSC will be composed of an equal number of representatives from each Party and a minimum of [\*\*\*] representatives of each Party, with (i) at least [\*\*\*] from Zai who are fluent in English, (ii) at least [\*\*\*] of each Party that have direct knowledge and expertise in the development, manufacture and commercialization of products similar to Licensed Products; [\*\*\*], and (iii) at least [\*\*\*] of each Party holding the position of [\*\*\*] or above in such Party.

**(b) Role.** The JSC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement; (ii) review, discuss and approve the overall strategy for the Development, manufacture, and Commercialization of Licensed Products in the Field in the Territory; (iii) review and discuss the initial Territory Development Plan and review, discuss and approve any amendments thereto in accordance with Section 5.2; (iv) review and discuss any amendments to the Global Development Plan in accordance with Section 5.3; (v) review and discuss the Commercialization Plan and amendments thereto; (vi) establish and oversee the JPT and Working Groups as necessary or advisable to further the purpose of this Agreement; (vii) discuss potential implications of Zai's decision to file and hold Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory in its own name (to the extent such actions are permitted under Applicable Law) and (viii) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

**(c) Limitation of Authority.** The JSC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; or (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

**(d) Meetings.** The JSC shall hold meetings at such times as it elects to do so, but shall meet no less frequently than [\*\*\*] per Calendar Year. The JSC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communication method; provided that all such meetings shall be conducted in English; provided further, that at least [\*\*\*] each Calendar Year during the period commencing on the Effective Date and ending on the date the JSC is disbanded pursuant to Section 3.2(i), such meetings will be conducted in person at locations selected alternatively by Five Prime and Zai or such other location as the Parties may agree. [\*\*\*]. The Alliance Managers shall jointly prepare and

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circulate minutes for each JSC meeting within [\*\*\*] of each such meeting and shall ensure that such minutes are reviewed and approved by their respective companies within [\*\*\*] thereafter.

**(e) Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of the JSC (in a non-voting capacity), JPT or Working Group in the event that the planned agenda for such JSC, JPT or Working Group 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 and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

**(f) Decision-Making.** All decisions of the JSC shall be made by unanimous vote, with each Party's representatives having one vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach a decision as to such matter within [\*\*\*] after such matter was brought to the JSC for resolution, such matter shall be referred to the [\*\*\*] of Five Prime (or

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an executive officer of Five Prime designated by the [\*\*\*] of Five Prime who has the power and authority to resolve such matter) and the [\*\*\*] of Zai (or an executive officer of Zai designated by the [\*\*\*] of Zai who has the power and authority to resolve such matter) (collectively, the “**Executive Officers**”) for resolution. If the Executive Officers cannot resolve such matter within [\*\*\*] after such matter has been referred to them, then:

(i) Zai shall have the final decision-making authority with respect to any Territory-specific activities related to the Development or Commercialization of Licensed Products in the Field in the Territory that are not part of the Global Development Plan, including amendments to the Territory Development Plan; provided that: (1) Zai’s decision is consistent with its obligations to use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products; (2) Zai’s decision to amend the Territory Development Plan must be consistent with the Global Development Plan; and (3) Zai shall not make any decision that would reasonably be expected to (A) result in a material quality, safety, toxicity or side effect concern; (B) materially adversely affect the continued Development or Commercialization of Licensed Products outside the Territory; or (C) cause Five Prime to be in violation of Applicable Laws as the owner and holder of Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory. [\*\*\*]; and

(ii) Five Prime shall have the final decision-making authority with respect to any Development activities in the Territory and outside the Territory in each case that are part of the Global Development Plan, which may affect a global study or Development of Licensed Products outside the Territory, or which are related to Five Prime’s obligations under Applicable Law as the owner and holder of Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory; provided that Five Prime shall not make any decision that would materially increase Zai’s obligations or expenses above those set forth in the then-current Global Development Plan without Zai’s written consent or unless such actions are reasonably necessary for Five Prime to comply with Applicable Laws as the owner and holder of Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory.

(g) **Joint Project Team.** No later than [\*\*\*] following the Effective Date, the JSC will form a joint project team (the “**JPT**”) to coordinate and oversee the day-to-day performance of the activities and obligations of the Parties under this Agreement. The JPT will be composed of representatives from each Party who have direct knowledge and expertise in each of the following functional areas: clinical, clinical operations, pharmaceutical development, regulatory, safety, manufacturing, intellectual property, marketing and commercial, in each case, as such functional areas relate to products similar to Licensed Products; provided that [\*\*\*] of Zai’s representatives in the JPT shall be fluent in English. The JPT shall meet as frequently as and shall operate as the JSC may determine. The JPT may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications method. The JPT and its activities shall be subject to the oversight of, and shall report to, the JSC and the JSC shall resolve all disputes that arise within the JPT within [\*\*\*] after any such matter is brought to the JSC for resolution. In no event shall the authority of the JPT exceed the authority of the JSC. Each Party shall be responsible for all of its own expenses of participating in the JPT.

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(h) **Working Groups.** From time to time, the JSC may establish joint working groups (each, a “*Working Group*”) on an “as-needed” basis to oversee specific functional areas or activities and coordinate the day-to-day performance of such activities under this Agreement, which establishment of Working Groups shall be reflected in the minutes of the meetings of the JSC. Each such Working Group shall be constituted, shall meet as frequently as and shall operate as the JSC may determine; provided that [\*\*\*] of Zai’s representatives in any such Working Group shall be fluent in English. Working Groups may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications method. Each Working Group and its activities shall be subject to the oversight of, and shall report to, the JSC, and the JSC shall resolve all disputes that arise within a Working Group within [\*\*\*] after any such matter is brought to the JSC for resolution. In no event shall the authority of any Working Group exceed the authority of the JSC. Each Party shall be responsible for all of its own expenses of participating in any Working Group.

(i) **Discontinuation of JSC.** The JSC shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the JSC, or (b) Five Prime providing written notice to Zai of its intention to disband and no longer participate in 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 decisions of the JSC shall be decisions between the Parties, subject to the other terms and conditions of this Agreement.

#### ARTICLE 4 TECHNOLOGY TRANSFERS

**4.1 Technology Transfer.** Within [\*\*\*] of the Effective Date, Five Prime will provide and transfer to Zai the Five Prime Know-How (other than manufacturing-related Know-How, the transfer of which shall be performed under Section 4.2) that exists on the Effective Date and was not previously provided to Zai (the “*Initial Technology Transfer*”). Thereafter, during the Term, Five Prime shall [\*\*\*\*], provide Zai with a summary of additional Five Prime Know-How (if any) developed [\*\*\*], (b) transfer any such Five Prime Know-How to Zai [\*\*\*], and (c) provide Zai with reasonable access to Five Prime personnel involved in the research and Development of Licensed Products, either in-person at Five Prime’s facility or by teleconference (the “*Continuing Technology Transfer*,” and together with the Initial Technology Transfer and the manufacturing technology transfer under Section 4.2, the “*Technology Transfer*”). For the avoidance of doubt, Five Prime personnel shall not be obligated to travel to Zai’s facilities.

**4.2 Manufacture Technology Transfer.** Notwithstanding Section 4.1, Zai acknowledges that the transfer of certain Five Prime Know-How related to the manufacture of Licensed Products, including chemistry, cell line technology, manufacturing and controls information and other biologic manufacturing and process development technology, may be subject to the consent of [\*\*\*]. Five Prime shall use commercially reasonable efforts to obtain such consent and, upon obtaining such consent, to transfer such manufacturing-related Five Prime Know-How to Zai to enable Zai to manufacture Licensed Products, provided that Zai shall reasonably cooperate with Five Prime in connection with such consent and transfer, including by providing information requested by [\*\*\*] and agreeing to reasonable covenants that [\*\*\*] may require to protect their respective interests in connection with such transfer. [\*\*\*] For the avoidance of doubt, [\*\*\*].

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### 4.3 Technology Transfer Costs. [\*\*\*]

## ARTICLE 5 DEVELOPMENT PROGRAM

### 5.1 Diligence and Responsibilities.

(a) Zai shall be responsible for and use Commercially Reasonable Efforts to (i) Develop and Commercialize Licensed Products in the Field in the Territory in accordance with the Territory Development Plan, and (ii) perform the Development activities assigned to Zai under the Global Development Plan to support the global Development and registration of Licensed Products.

(b) Zai shall use Commercially Reasonable Efforts to conduct the tasks assigned to it in the Territory Development Plan and each Party shall use Commercially Reasonable Efforts to conduct the tasks assigned to it in the Global Development Plan and achieve the objectives set forth therein. Each Party shall conduct such tasks in a timely, professional manner and in compliance with the Territory Development Plan and Global Development Plan, as applicable, and all Applicable Laws, including GLP, GCP and cGMP.

(c) No later than [\*\*\*] following the Effective Date, the Parties will cooperate to finalize a written timeline (the “**CFDA Submission Timeline**”) for Regulatory Submissions to the CFDA, which CFDA Submission Timeline may be amended upon mutual agreement by the Parties from time to time.

(d) Without limiting the foregoing, Zai shall use Commercially Reasonable Efforts to (i) make all Regulatory Submissions to the CFDA pursuant to and in accordance with Section 6.1 for the FPA144-004 Study in accordance with the CFDA Submission Timeline; provided that Zai will obtain Five Prime’s prior written consent in the event Zai desires to submit the NDA-C to the CFDA earlier than the timeline for such submission set forth in the CFDA Submission Timeline; (ii) engage principal investigators and support the initiation of Clinical Trial sites in the Territory that are specified in the Global Development Plan; (iii) support global registration of Licensed Products by recruiting patients in the Territory for Clinical Trials conducted pursuant to the Global Development Plan; and (iv) Develop, obtain Regulatory Approval for (which shall, for clarity, be on Five Prime’s behalf except to the extent otherwise permitted under Applicable Law) and Commercialize Licensed Products in the Territory in accordance with the Territory Development Plan and the Global Development Plan. With respect to the FPA144-004 Study, Zai shall additionally, in accordance with the Global Development Plan, use Commercially Reasonable Efforts to (A) enroll and treat the [\*\*\*] patient in the FPA144-004 Study in PRC on or prior to [\*\*\*], as such date may be updated by mutual agreement of the Parties from time to time; and (B) enroll and treat at least [\*\*\*] patients in the FPA144-004 Study in the PRC, which number of patients may be updated by mutual agreement of the Parties from time to time. For the avoidance of doubt, if Five Prime engages a contract research organization to conduct a Clinical Trial that includes the Territory and one or more countries outside of the Territory pursuant to the Global Development Plan, Zai shall coordinate with such contract research organization (including any local Affiliate of a global contract research organization or global service provider) with respect to the tasks assigned to Zai under the Global Development Plan.

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**5.2 Territory Development Plan.** Except for the activities allocated to Zai under the Global Development Plan pursuant to Section 5.3, all Development by Zai of Licensed Products in the Territory under this Agreement shall be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 5.2 and Section 3.2, the “**Territory Development Plan**”). Following the Effective Date, and at least [\*\*\*] prior to Zai’s planned initiation of Development activities in the Territory, Zai shall provide to Five Prime an initial draft of the Territory Development Plan for Five Prime’s review and comment, which Territory Development Plan shall contain in reasonable detail all major Development activities (including all Clinical Trials) and the timelines for achieving such activities. Zai shall take such comments into consideration in good faith and incorporate such comments where appropriate prior to finalizing the initial Territory Development Plan. From time to time thereafter, but at least every [\*\*\*], Zai shall propose amendments to the Territory Development Plan in consultation with Five Prime and submit such proposed updated or amended Territory Development Plan to the JSC for review, discussion and approval. Once approved by the JSC, the amended Territory Development Plan shall become effective. For clarity, the Territory Development Plan and amendments thereto must be consistent with the Global Development Plan and the Global Development Plan shall take precedent in case of any conflict or inconsistency between the Territory Development Plan and the Global Development Plan.

**5.3 Global Development Plan.** Five Prime’s global Development of Licensed Products will be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 5.3, the “**Global Development Plan**”). The Parties shall discuss and agree upon the initial Global Development Plan within [\*\*\*] following the Effective Date. In addition to Zai’s Development activities under the Territory Development Plan, Zai shall support the global Development of Licensed Products by conducting certain Development activities in the Territory in accordance with and as set forth in the Global Development Plan. The Global Development Plan shall include (i) an outline of all major Development activities (including all Clinical Trials) for Licensed Products by Five Prime, (ii) details and timelines of the Development activities in the Territory assigned to Zai to support the FPA144-004 Study, (iii) details and timelines of any other Development activities (including Clinical Trials) in the Territory assigned to Zai to support global Development of the Licensed Product, and (iv) unless otherwise agreed to by Zai, the allocation to Zai of responsibility for any Development activities included within the initial Global Development Plan that are to be conducted in the Territory, except with respect to Taiwan, which Development activities for the FPA144-004 Study shall be allocated to Five Prime, and which other Development activities in Taiwan shall be subject to further discussion between the Parties. From time to time, Five Prime may make and implement amendments to the then-current Global Development Plan. To the extent such amendments are (x) material, and (y) relate to the Territory, Five Prime shall submit such proposed amendments to the JSC for review and discussion before adopting such amendments.

**5.4 Development Costs.** Zai shall be solely responsible for the costs and expenses incurred by Zai in the Development of Licensed Products in the Territory, including the performance of Development activities under the Territory Development Plan and the Development activities assigned to Zai under the Global Development Plan. Zai shall be responsible for (i) all costs related to the conduct of the FPA144-004 Study incurred for activities in the Territory (except with respect to such costs in Taiwan), and (ii) all Third Party out-of-pocket costs related to the global conduct of the FPA144-004 Study to the extent allocated to Zai

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in accordance with **Exhibit C**; provided, that the aggregate amount of Third Party out-of-pocket costs related to the global conduct of the FPA144-004 Study that Zai will be responsible for pursuant to (ii) of this Section 5.4 will not exceed [\*\*\*] (the “**Global Allocation Cap**”), provided that any such costs related to [\*\*\*] will not be subject to the Global Allocation Cap. Five Prime shall invoice Zai [\*\*\*] for the foregoing costs incurred by Five Prime, and Zai shall pay the amount invoiced within [\*\*\*] after the date of any such invoice. If Zai does not enroll and treat at least [\*\*\*] patients in the FPA144-004 Study in the PRC, Zai shall pay to Five Prime the development costs incurred by Five Prime in enrolling that number of patients in the FPA144-004 Study outside the PRC equal to the difference between (x) [\*\*\*] and (y) the number of patients Zai does enroll and treat in the FPA144-004 Study in the PRC, such development costs to be calculated based on the average “per patient” development costs in the FPA144-004 Study in the PRC during the course of the study, which costs shall include all costs with respect to which Zai is responsible pursuant to the preceding sentence. For example, [\*\*\*], Zai would pay Five Prime [\*\*\*]. Zai shall pay to Five Prime any amount due pursuant to the preceding sentence within [\*\*\*] after the date [\*\*\*].

### 5.5 Development Records.

(a) Zai shall maintain reasonably complete, current and accurate records of all Development activities conducted by or on behalf of Zai, its Affiliates or its sublicensees pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are compliant with 21 C.F.R. §11, and in accordance with Applicable Laws of both the United States and the Territory. All such records related to the FPA144-004 Study shall be in English. Zai will obtain Five Prime’s written consent prior to destroying any records relating to the Development of Licensed Products. 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. Zai shall document all non-clinical studies and Clinical Trials in formal written study reports in accordance with Applicable Laws and national and international guidelines (*e.g.*, GCP, GLP and GMP). Upon Five Prime’s request, Zai shall, and shall cause its Affiliates and sublicensees to, (i) provide Five Prime with copies of such records, and (ii) allow Five Prime to access, review and copy such records (including access to relevant databases). If any such records are not in English, Zai shall provide Five Prime with an English translation of such records promptly following Five Prime’s request thereof, which translation shall be a certified translation upon Five Prime’s request; [\*\*\*]. Five Prime shall have the right to use the data and results generated by or on behalf of Zai, its Affiliates and sublicensees hereunder to Develop, manufacture and Commercialize Licensed Products outside the Territory. Each Party shall ensure that all records or other documents that it transmits to the other Party electronically under this Agreement are transmitted over secure systems that include adequate encryption safeguards that prevent unauthorized access and maintain data security.

### 5.6 Clinical Trial Audit Rights.

(a) Upon reasonable notification by Five Prime and at Five Prime’s cost and expense, Five Prime or its representatives shall be entitled to conduct an audit of any Clinical Trial sites engaged by Zai or its Affiliates or sublicensees to conduct Zai’s obligations under (i) the Global Development Plan, to ensure that such Clinical Trials are conducted in compliance with the Global Development Plan and all Applicable Laws and (ii) the Territory Development Plan, to ensure such Clinical Trials are conducted in compliance with GCP and meet Five

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Prime's global Clinical Trial standards. No later than [\*\*\*] following the completion of any such audit, Five Prime will provide Zai with a written summary of Five Prime's findings, including any deficiencies or other areas of remediation that Five Prime identifies during such audit. Zai will use Commercially Reasonable Efforts to remediate any such deficiencies within [\*\*\*] following Zai's receipt of such report, at Zai's cost and expense.

(b) With respect to the FPA144-004 Study, to the extent Five Prime reasonably determines, in its sole discretion, that any deficiencies with respect to a Clinical Trial site identified pursuant to Section 5.6(a) (each, a "**Deficient Site**") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Zai's conduct of the FPA144-004 Study at such Deficient Site, then Zai will use its best efforts to promptly remove such Deficient Site from the FPA144-004 Study and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") within the Territory, which Replacement Site shall be compliant in all respects with Applicable Laws and Five Prime's global Clinical Trial standards, at Zai's cost and expense; provided that if Zai is unable to replace any Deficient Site with a Replacement Site or, in Five Prime's discretion, is unable to do so in a timely manner so as not to jeopardize the Parties' ability to meet the timelines for Regulatory Submissions set forth in the CFDA Submission Timeline, then Five Prime may replace such Deficient Site with one or more Replacement Sites outside the Territory.

(c) Zai will provide Five Prime with copies of all quality oversight or audit reports, including English translations thereof, prepared in connection with any audit that Zai, its Affiliates or sublicensees conduct of a Clinical Trial site that Zai, its Affiliates or sublicensees have engaged or are evaluating to potentially engage to fulfill Zai's obligations under the Global Development Plan or the Territory Development Plan no later than [\*\*\*] after receiving or preparing, as applicable, any such report. If Five Prime believes in good faith that any such quality oversight or audit report may be necessary in connection with obtaining or maintaining Regulatory Approvals for a Licensed Product or for other communications with Regulatory Authorities outside of the Territory, then upon Five Prime's request, any such translation shall be a certified translation; [\*\*\*].

**5.7 Development Reports.** Zai shall provide Five Prime with [\*\*\*] written reports summarizing its, its Affiliates' and its sublicensees' Development of Licensed Products, including a summary of the data, timelines and results of such Development, which reports shall be in English. Zai shall also establish a secure link that includes adequate encryption safeguards to provide Five Prime with electronic access to such information. Without limiting the foregoing, such reports shall contain sufficient detail to enable Five Prime to assess Zai's compliance with its Development obligations hereunder. Such reports shall be Confidential Information of Zai pursuant to Article 10. Zai shall promptly respond to Five Prime's reasonable requests from time to time for additional information regarding significant Development activities. The Parties shall discuss the status, progress and results of Development activities at JSC meetings.

**5.8 Data Exchange and Use.** In addition to its adverse event and safety data reporting obligations pursuant to Section 6.4, each Party shall promptly provide the other Party with copies of all data and results and all supporting documentation (e.g. protocols, CRFs, analysis plans) Controlled by such Party that are generated by or on behalf of such Party or its Affiliates or sublicensees, if applicable, in the Development of Licensed Products. Zai shall have the right to use and reference such data and results provided by Five Prime, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approval and any pricing

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or reimbursement approvals, as applicable, of Licensed Products in the Territory. Five Prime and its designees shall have the right to use and reference such data and results provided by Zai, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products outside the Territory.

### 5.9 Subcontractors.

(a) Zai shall have the right to engage subcontractors for purposes of conducting activities assigned to it under this Agreement or for which it is responsible under this Agreement; provided that Zai may not subcontract, without the prior written consent of Five Prime, any activities [\*\*\*]. Zai shall cause any subcontractor engaged by it to be bound by written obligations of confidentiality and non-use consistent with this Agreement prior to performing any activities. Zai shall cause its subcontractors to assign to Zai (or, in the case of academic institutions and Third Party manufacturers, use reasonable efforts to cause such subcontractor to so assign) all intellectual property made by such subcontractor in the course of performing such subcontracted work, which intellectual property will be deemed to be FPA144 Collaboration IP or Collaboration IP, whichever is applicable, and, to the extent assigned or required to be assigned to Zai, owned in accordance with Section 13.1. Zai shall remain directly responsible for any obligations under this Agreement that have been delegated or subcontracted to any subcontractor and shall be directly responsible for the performance of its subcontractors.

(b) Notwithstanding the foregoing, Zai shall obtain Five Prime's written approval, such approval not to be unreasonably withheld, conditioned or delayed, prior to engaging any contract research organization or any other major vendor (e.g., central testing labs, centralized radiologic review) to perform services (x) under the Territory Development Plan or the Global Development Plan that are required to be performed in compliance with GCP, or (y) related to any Development activities assigned to Zai under the Global Development Plan, including with respect to the FPA144-004 Study or any subsequent Clinical Trial for which Five Prime may seek global registration for the Licensed Product in the Territory, [\*\*\*].

### 5.10 Development of Companion Diagnostics.

(a) In connection with the Development of Licensed Products, Five Prime shall use Commercially Reasonable Efforts to develop companion diagnostic products to be used in connection with Licensed Products ("**Companion Diagnostics**"). Without limiting Zai's reimbursement obligations under Section 5.4 (which pertain to the Development of Licensed Products, including the manufacture and use of Companion Diagnostics to screen patients for such Development, rather than the development of Companion Diagnostics, which is addressed in this Section 5.10), Five Prime shall be responsible for the cost and expenses it incurs to develop and commercialize Companion Diagnostics outside the Territory, provided that Zai shall reimburse Five Prime for: (i) all costs incurred by Five Prime that are related to the development, registration and commercialization of Companion Diagnostics solely in the Territory, and (ii) [\*\*\*] of all costs incurred by Five Prime that are related to the development of Companion Diagnostics both in and outside the Territory. Five Prime shall invoice Zai for such costs on a [\*\*\*] and Zai shall pay the amount invoiced within [\*\*\*] after the date of any such invoice.

(b) If Five Prime believes in good faith that no Companion Diagnostic developed by or on behalf of Five Prime will receive Regulatory Approval [\*\*\*], the Parties shall meet to discuss and agree upon an alternative plan for Five Prime to engage a Third Party diagnostics company to develop, obtain Regulatory Approval for, and commercialize a Companion Diagnostic in the Territory. [\*\*\*]

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**ARTICLE 6  
REGULATORY**

**6.1 Zai's Responsibilities.**

(a) Zai shall be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the obtaining of Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products from Regulatory Authorities in the Territory, provided that, Zai shall conduct such regulatory activities (and any and all regulatory activities delegated to Zai in this Agreement or by Five Prime during the Term in connection with the Development and Commercialization of the Licensed Product in the Territory during such time that Five Prime is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory) as the express and authorized regulatory agent of record for Five Prime in the Territory, and provided further, that such actions shall be taken on behalf of Five Prime and for the benefit of Zai in the Territory. Notwithstanding the foregoing, to the extent permitted under Applicable Law, Zai may file and hold Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory; provided that, Zai undertakes any such activities in compliance with this Agreement to the same extent as if Zai were acting as Five Prime's authorized regulatory agent under this Agreement and, prior to taking any such activities, Zai shall submit a reasonably detailed plan for undertaking the same to the JSC for review and discussion. Each Party shall keep the other Party informed of regulatory developments related to Licensed Products in the Territory and shall promptly notify the other Party in writing of any decision by any Regulatory Authority in the Territory regarding any Licensed Product.

(b) Zai shall provide to Five Prime for review and comment drafts of all Regulatory Submissions, including certified English translations thereof if requested by Five Prime, [\*\*\*] and shall consider in good faith any comments received from Five Prime and incorporate such comments where required by Applicable Law. In addition, each Party shall notify the other Party of any Regulatory Submissions and any comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and shall provide the other Party with copies thereof as soon as reasonably practicable, but in all events within [\*\*\*] after submission or receipt. If any such Regulatory Submission, comment or correspondence is not in English, Zai shall also provide Five Prime with a certified English translation [\*\*\*]; provided, that Zai shall provide Five Prime with a written English summary of any comments or other correspondences received from a Regulatory Authority with respect to a Regulatory Submission [\*\*\*]. Five Prime shall have the right to review and comment on such Regulatory Submissions and Zai shall take such comments into consideration and incorporate such comments where appropriate.

(c) Each Party shall provide the other Party with notice no later than [\*\*\*] after receiving notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Licensed Product. Zai shall lead any such meeting or discussion, provided, however, that Five Prime or its designee shall have the right, but not the obligation, to attend and participate in such meeting or discussion. If Five Prime elects not to attend such meeting or discussion, Zai shall provide Five Prime with a written summary thereof in English promptly following such meeting or discussion.

**6.2 Five Prime's Responsibilities.** Except if filed or obtained by Zai in its own name, as permitted under Section 6.1, Five Prime shall own and hold all Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for Licensed Products in the Territory for the benefit of Zai, and shall, promptly upon Zai's

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request, provide access to and copies of such Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals to Zai, as applicable. Five Prime shall cooperate with Zai in obtaining any Regulatory Approvals and any pricing or reimbursement approvals, as applicable, for a Licensed Product in the Territory by providing, to the extent Controlled by Five Prime, prompt access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for Licensed Products, both inside and outside of the Territory. Zai shall reimburse Five Prime's actual internal expenses and costs at the FTE Rate for FTEs engaged to, and out-of-pocket expenses and costs incurred by Five Prime to, provide such access and any further assistance to Zai.

**6.3 Right of Reference.** Each Party hereby grants to the other Party the right of reference to all Regulatory Submissions pertaining to Licensed Products in the Field submitted by or on behalf of such Party or its Affiliates. Zai may use such right of reference to Five Prime's Regulatory Submissions solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field in the Territory as Five Prime's authorized regulatory agent of record or on its own behalf to the extent permitted by Applicable Law. Five Prime may use the right of reference to Zai's Regulatory Submissions, if any, solely for the purpose of seeking, obtaining and maintaining regulatory approval of Licensed Products outside the Territory. Each Party shall bear its own costs and expenses associated with providing the other Party with the right of reference pursuant to this Section 6.3.

**6.4 Adverse Events Reporting.**

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

(b) Zai shall maintain an adverse event database for Clinical Trials conducted in the Territory under the Territory Development Plan, at its sole cost and expense. Zai shall be responsible for reporting to the applicable Regulatory Authorities in the Territory, on Five Prime's behalf during such time that Five Prime is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory, all quality complaints, adverse events and safety data related to Licensed Products for all Clinical Trials conducted in the Territory under the Territory Development Plan or the Global Development Plan, as well as responding, on Five Prime's behalf during such time that Five Prime is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory, to safety issues

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and to all requests of Regulatory Authorities related to Licensed Products in the Territory. Zai shall provide to Five Prime access to Zai's adverse event database for the Territory. Five Prime shall maintain a global adverse event database for Clinical Trials conducted under the Global Development Plan at Five Prime's cost and expense, except for any costs allocated to Zai pursuant to Section 5.4.

(c) Zai shall be responsible for complying with all Applicable Laws governing adverse events in the Territory. Zai shall notify Five Prime on a timely basis of any adverse events occurring in the Territory. Zai shall submit copies of reports of adverse events to Five Prime simultaneously with submission to the applicable Regulatory Authorities in the Territory. Each Party shall notify the other in a timely manner and in any event within [\*\*\*] of receiving any serious adverse event reports from Clinical Trials that the applicable Party is monitoring, notice from a Regulatory Authority, independent review committee, data safety monitoring board or another similar clinical trial or post-marketing monitoring body alleging significant concern regarding a patient safety issue or other material information relevant to the safety or efficacy of Licensed Products.

**6.5 Safety and Regulatory Audits.** Upon reasonable notification, Five Prime or its representatives shall be entitled to conduct an audit of safety and regulatory systems, procedures or practices of Zai, its Affiliates, sublicenses or subcontractors (including Clinical Trial sites) relating to Licensed Products. Zai shall promptly notify Five Prime of any inspection of Zai, its Affiliates, sublicenses or subcontractors (including Clinical Trial sites) by any Regulatory Authority relating to Licensed Products and shall provide Five Prime with all information pertinent thereto. Five Prime shall have the right, but not the obligation, to be present at any such inspection. Zai shall also permit Regulatory Authorities outside the Territory to conduct inspections of Zai, its Affiliates, sublicenses or subcontractors (including Clinical Trial sites) relating to Licensed Products, and shall ensure that such Affiliates, sublicensees and subcontractors permit such inspections. Zai will provide Five Prime with a written summary in English of any findings of a Regulatory Authority following a regulatory audit within [\*\*\*] following any such audit, and will provide Five Prime with an unredacted copy of any report issued by such Regulatory Authority, including a English translation thereof, which translation shall be certified if requested by Five Prime[\*\*\*].

**6.6 No Harmful Actions.** If either Party believes that the other Party is taking or intends to take any action with respect to a Licensed Product in such other Party's territory that could have a material adverse impact upon the regulatory status of any Licensed Product in its respective territory, then such Party shall have the right to bring the matter to the attention of the JSC and the Parties shall discuss in good faith a resolution to such concern. Without limiting the foregoing, unless the Parties otherwise agree (or unless otherwise set forth in the Global Development Plan): (a) neither Party shall communicate with any Regulatory Authority having jurisdiction outside of its respective territory with respect to any Licensed Product, unless so ordered by such Regulatory Authority, in which case such Party shall immediately notify the other Party of such order; and (b) neither Party shall submit any Regulatory Submissions or seek regulatory approvals for any Licensed Product in the other Party's respective territory.

**6.7 Notice of Regulatory Action.** If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Zai relating to any Licensed Antibody or Licensed Product, then Zai shall notify Five Prime of such contact, inspection or notice or action within [\*\*\*] thereof. Five Prime shall have the right to review and

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comment on any responses to Regulatory Authorities that pertain to a Licensed Antibody or Licensed Product, provided that Zai shall have the final decision-making authority with respect to such responses to the extent relating solely to such Licensed Antibody or Licensed Product in the Territory, but shall incorporate all such reasonable comments of Five Prime during such time that Five Prime is the holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory. The costs and expenses of any regulatory action in the Territory shall be borne solely by Zai. Zai shall, and shall ensure that its Affiliates and sublicensees will, maintain adequate records to permit the Parties to trace the distribution, sale and use of Licensed Products in the Territory. In addition, each Party shall promptly notify the other of any information it receives regarding any threatened or pending action, inspection or communication by or from a Third Party that would reasonably be expected to materially affect the Development of the Licensed Antibodies or Licensed Products.

**6.8 Further Assurances.** The Parties shall work together and take all actions, including amending this Agreement, as necessary, to give effect to Zai's rights and obligations as the Party responsible, as permitted and to the extent described herein, for the Development, Commercialization, and manufacture of the Licensed Products in the Territory. In addition, if following a change in Applicable Law during the Term, Zai is permitted to own and hold the Regulatory Submissions, Regulatory Approvals and any pricing or reimbursement approvals, as applicable, held by Five Prime for Licensed Products in the Territory, then, promptly following Zai's request, Five Prime shall transfer such Regulatory Submissions and Regulatory Approvals to Zai. Zai shall reimburse Five Prime for all costs (including internal costs at the FTE Rate and out-of-pocket costs) incurred by Five Prime in relation to any such transfer.

**6.9 Oversight Plan.** Promptly following the Effective Date, but in no event later than [\*\*\*] thereafter, Zai and Five Prime shall develop and agree upon a set of written oversight procedures that will apply to Zai and any entity acting on behalf of Zai, in each case, in connection with the performance of activities undertaken as the authorized regulatory agent of record for Five Prime in the Territory (the "**Oversight Plan**"). Such Oversight Plan shall contain processes and procedures intended to provide Zai with the ability to effectively Develop and Commercialize the Product in the Territory on its own behalf, while ensuring that Five Prime is able to fulfill its obligations under Applicable Law as the owner or holder of Regulatory Approvals and Regulatory Submissions for the Licensed Product in the Territory, that Zai complies with Five Prime's standard operating procedures applicable to third party service providers of Five Prime and the management and oversight thereof, and that Five Prime (or its designee) will maintain the requisite level of oversight and control with respect to such activities sufficient to allow Five Prime to comply with its legal, regulatory and internal obligations with respect thereto. Notwithstanding the foregoing, the processes and procedures set forth in the Oversight Plan shall not materially alter Zai's rights or increase Zai's obligations under this Agreement.

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**ARTICLE 7  
MANUFACTURING**

**7.1 Supply by Five Prime.**

**(a) Development Supply.**

**(i)** Subject to Section 7.2, Five Prime shall have the sole right, either by itself or through a Third Party contract manufacturer, to manufacture and supply to Zai all Licensed Antibody and Licensed Products required by Zai for Development use in the Territory under the Territory Development Plan and for Zai's Development-related responsibilities under the Global Development Plan, including the conduct of the FPA144-004 Study.

**(ii)** Except as set forth in Section 7.1(a)(iii), Five Prime shall supply the Licensed Antibody and Licensed Products pursuant to this Section 7.1(a) at a transfer price equal to Five Prime's Fully Burdened Manufacturing Cost. Five Prime shall invoice Zai for the Licensed Antibody and Licensed Product upon delivery in accordance with Section 7.1(a)(iv) and Zai shall pay the amount invoiced within [\*\*\*] after the date of the invoice.

**(iii)** For the FPA144-004 Study, Five Prime shall supply Licensed Products to Zai at the following transfer price: [\*\*\*]; [\*\*\*] and shall pay any invoices that Five Prime sends to Zai with respect thereto within [\*\*\*] of the date of the invoice. For clarity, if a patient is dosed [\*\*\*], Five Prime will continue to supply Licensed Products to Zai [\*\*\*] for such patient for the remainder of the FPA144-004 Study.

**(iv)** Delivery of Licensed Antibodies and Licensed Products supplied by Five Prime for Development use shall take place FCA (Incoterms 2010) at Five Prime's or its contract manufacturer's facility. Zai shall be responsible for obtaining all licenses or other authorizations for the exportation and importation of such Licensed Antibody or Licensed Product, and Zai shall contract for shipment and insurance of such Licensed Antibody or Licensed Product from Five Prime's or its contract manufacturer's facility, at Zai's cost and expense. Zai shall also be responsible for the clinical packaging, labeling, QC/QA/QP release, storage, customs clearance and distribution of such Licensed Product, at Zai's cost and expense.

**(b) Commercial Supply.** The Parties shall use Commercially Reasonable Efforts to agree within [\*\*\*] following the Effective Date on the principal terms of a commercial supply agreement (the "**Commercial Supply Agreement**") pursuant to which Zai may purchase commercial supply of a Licensed Product (vial drug product, labeled or unlabeled) from Five Prime at Five Prime's Fully Burdened Manufacturing Cost in order to fulfill Zai's obligations under this Agreement, which terms shall be consistent with the terms and conditions of this Agreement and the terms and conditions of any agreement between Five Prime and its Third Party manufacturing partner(s), to the extent applicable to commercial supply of Licensed Product in the Field in the Territory. At Zai's request, the Parties shall negotiate such Commercial Supply Agreement in accordance with such agreed-upon terms and conditions, provided that the Parties shall endeavor to enter into such Commercial Supply Agreement at least [\*\*\*] prior to the earlier of [\*\*\*]. In the event of a supply failure by Five Prime (to be defined in the Commercial Supply Agreement), then, notwithstanding, and without the need to comply with, Sections 7.2(a) or (b), Zai shall have the right to manufacture itself the Licensed Products (including the Licensed Antibody for use therein), subject to and in accordance with Section 7.2(d).

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## 7.2 Supply by Zai.

(a) Subject to the consent of the Upstream Licensors, Zai shall have the right to manufacture Licensed Products in the Territory for (i) Development use in the Territory under the Territory Development Plan and (ii) Commercial use in the Territory, in each case, at Zai's cost and expense, subject to and only after the completion of the following with respect to such Licensed Product: [\*\*\*]. Zai agrees that Zai's manufacturing process with respect to a Licensed Product and finished Licensed Product will at all times be in accordance with the Zai Specifications with respect to such Licensed Product and cGMP and ICH Guidelines. In addition, Zai shall have the right at any time during the Term, provided that at such time Zai has not yet begun to manufacture Licensed Products in the PRC, to request that Five Prime qualify as a back-up supplier of Licensed Product a contract manufacturing organization outside of the PRC identified and engaged by Zai, subject to [\*\*\*]. Following any such request by Zai and receipt of the consents, as applicable, described in the preceding sentence, Five Prime shall cooperate with Zai and such contract manufacturing organization to effect a transfer of manufacturing technology to such contract manufacturing organization and to qualify such contract manufacturing organization as a manufacturer of Licensed Products for regulatory purposes. Zai shall reimburse Five Prime's [\*\*\*], in each case, incurred by Five Prime in connection with the qualification of any back-up supplier and any assistance rendered to effect a transfer of manufacturing technology to a contract manufacturing organization and to qualify such contract manufacturing organization pursuant to this Section 7.2(a). Five Prime shall invoice Zai for the foregoing costs and expenses incurred by Five Prime, if any, pursuant to this Section 7.2(a) and Zai shall pay the amount invoiced within [\*\*\*] after the date of any such invoice.

(b) If Zai decides to manufacture a Licensed Product pursuant to Section 7.2(a), Zai shall provide Five Prime with written notice thereof, which notice shall specify whether Zai desires to manufacture such Licensed Product for Development or Commercialization (a "**Manufacturing Notice**"). Promptly after Five Prime's receipt of a Manufacturing Notice, Zai shall (i) provide Five Prime with such information and documents that Five Prime may reasonably request to conduct a quality and technical audit of Zai's manufacturing facilities, systems, processes and capabilities that Zai will use in the manufacture, testing and release of such Licensed Product, and (ii) as part of such quality and technical audit, cooperate with Five Prime to allow Five Prime or its representatives to conduct an on-site audit of such manufacturing facilities, systems, processes and capabilities, which on-site audit shall occur during normal business hours. The Parties will endeavor to complete such audit within [\*\*\*] after Five Prime's receipt of the relevant Manufacturing Notice, unless Zai is unable to facilitate the completion of such audit by Five Prime within such [\*\*\*] period due to delays outside of Zai's reasonable control (e.g., official holidays within the Territory), in which case the Parties will endeavor to complete such audit within [\*\*\*]. No later than [\*\*\*] following the completion of such audit, Five Prime will provide to Zai a written report of Five Prime's assessment, [\*\*\*], including a conclusion in which Five Prime either approves such facilities, systems, processes and capabilities or describes any deficiencies that Five Prime has identified as requiring remediation before Five Prime approves such facilities, systems, processes and capabilities (the "**Facility-fit Assessment**"). Unless Zai disputes the existence or significance of such deficiencies within [\*\*\*] of its receipt of a Facility-fit Assessment that describes such deficiencies (which dispute shall be addressed pursuant to the following sentence), the Parties

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will cooperate to develop a plan for remediation with respect to such deficiencies within a reasonable period of time thereafter. In the event that Zai believes that any deficiencies identified by Five Prime are incorrect or would not have a material effect on the quality of the Licensed Product manufactured in such Zai facilities (as compared to Licensed Product produced by or on behalf of Five Prime), then [\*\*\*] Following Zai's remediation of all deficiencies, Zai will notify Five Prime and Five Prime will provide Zai with a revised Facility-fit Assessment, which shall again be subject to the terms of this Section 7.2(b). Zai shall not initiate manufacture of the applicable Licensed Product until Five Prime has approved Zai's manufacturing facilities, systems, processes and capabilities in accordance with this Section 7.2(b) or the Third Party expert has determined that all deficiencies identified in the applicable Facility-fit Assessment do not exist, have been successfully remediated by Zai or would not have a material effect on the quality of the applicable Licensed Product manufactured by Zai.

(c) Promptly following Five Prime's approval of Zai's facilities, systems, processes and capabilities in accordance with Section 7.2(b) or Zai's delivery of a Manufacturing Assumption Notice in accordance with Section 7.2(d), as applicable, Five Prime will provide Zai with Five Prime's written process and quality specifications for the manufacturing of such Licensed Product (the "**Five Prime Specifications**"). Zai will prepare written process and quality specifications for the manufacture of such Licensed Product applicable to Zai's manufacturing facilities, systems, processes and capabilities, including how they relate to drug substance, drug product, in-process intermediates, raw materials and reference material (the "**Zai Specifications**"), which Zai Specifications will be reasonably consistent with the Five Prime Specifications for such Licensed Product, and will provide such Zai Specifications to Five Prime for Five Prime's review and comment. Within [\*\*\*] following its receipt of such Zai Specifications, Five Prime will either (i) approve the Zai Specifications, or (ii) provide Zai with a written response to the Zai Specifications that includes a description of any deficiencies or limitations Five Prime has identified with respect thereto, and the Parties will cooperate to develop a plan for remediation with respect to any deficiencies or limitations within a reasonable period of time thereafter. Following Zai's remediation of all deficiencies, Zai will provide Five Prime with a revised draft of the Zai Specifications for Five Prime's review and approval. Zai will promptly notify Five Prime in writing if Zai amends the Zai Specifications with respect to a Licensed Product at any time following Five Prime's approval of such Zai Specifications.

(d) In addition to the foregoing, in the event of a commercial supply failure (as defined in the Commercial Supply Agreement), Zai may decide to manufacture a Licensed Product (including, for clarity, the Licensed Antibody for use therein) and, if it makes such decision, shall provide Five Prime with written notice thereof (the "**Manufacturing Assumption Notice**"). Promptly after Five Prime's receipt of the Manufacturing Assumption Notice pursuant to this Section 7.2(d), Zai shall (i) cooperate with Five Prime to ensure that the Zai Specifications are agreed pursuant to Section 7.2(c) prior to any manufacture of a Licensed Product, (ii) provide Five Prime with such information and documents that Five Prime may reasonably request to ensure that Zai has the capability to manufacture such Licensed Product in accordance with all Applicable Laws (including GMP and ICH Guidelines), and (iii) complete any studies or testing required by and obtain any qualifications and Regulatory Approvals (including manufacturing licenses) from any Regulatory Authorities or other Governmental Authorities necessary to manufacture such Licensed Product in the Territory. Thereafter, and on a continuing basis for so long as Zai manufactures the Licensed Product, Zai shall (1) ensure that Zai's manufacturing process with respect to a Licensed Product and finished Licensed Product will at all times be in

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accordance with the Zai Specifications with respect to such Licensed Product and cGMP and ICH Guidelines and (2) complete any additional studies or testing required to maintain any qualifications and Regulatory Approvals (including manufacturing licenses) from any Regulatory Authorities or other Governmental Authorities necessary to continue to manufacture such Licensed Product in the Territory.

(e) At Five Prime's request, the Parties shall negotiate a commercial supply agreement pursuant to which Five Prime may purchase commercial supply of a Licensed Product (vialed drug product, labeled or unlabeled) from Zai for use or sale outside the Territory at Zai's Fully Burdened Manufacturing Cost, provided that Zai shall have no obligation to enter into such commercial supply agreement prior to the date that Five Prime approves the Zai Specifications with respect to such Licensed Product.

## ARTICLE 8 COMMERCIALIZATION

**8.1 Commercialization Diligence.** Zai shall be responsible for, and shall use Commercially Reasonable Efforts to Commercialize each Licensed Product that obtains Regulatory Approval in the Field in the Territory. Zai shall conduct all Commercialization of Licensed Products in the Field in the Territory in accordance with the Commercialization Plan for such Licensed Product, at its sole cost and expense. Without limiting the foregoing, Zai shall achieve First Commercial Sale of each Licensed Product within [\*\*\*] after obtaining Regulatory Approval for such Licensed Product.

**8.2 Commercialization Plan.** The Commercialization Plan with respect to a Licensed Product shall contain in reasonable detail the major Commercialization activities, including revenue targets, planned for such Licensed Product in the Territory and the timelines for achieving such activities. Zai shall deliver an initial draft of the Commercialization Plan to Five Prime for Five Prime's review no later than [\*\*\*] prior to the anticipated date of the first filing of the first Regulatory Approval for a Licensed Product in the Territory. Five Prime shall have the right to comment on such Commercialization Plan and Zai shall take such comments into consideration and incorporate such comments where appropriate prior to finalizing such Commercialization Plan. Thereafter, from time to time, but at least every [\*\*\*], Zai shall propose updates or amendments to the Commercialization Plan in consultation with Five Prime to reflect changes in such plans, including those in response to changes in the marketplace, relative commercial success of such Licensed Product, and other relevant factors that may influence such plan and activities. Zai shall submit the proposed updated or amended Commercialization Plan to the JSC for review and discussion before adopting such update or amendment.

**8.3 Commercialization Reports.** For each Calendar Year following the first Regulatory Approval for any Licensed Product in the Territory, Zai shall provide to Five Prime annually within [\*\*\*] after the end of such Calendar Year a written report that summarizes the Commercialization activities on a Licensed Product-by-Licensed Product and region-by-region basis performed by or on behalf of Zai, its Affiliates and sublicensees in the Territory since the prior report provided by Zai. Such report shall contain sufficient detail to enable Five Prime to assess Zai's compliance with its Commercialization obligations in Section 8.1. Such reports shall be Confidential Information of Zai pursuant to Article 10. Zai shall provide updates to any such report at each meeting of the JSC, JPT and any Working Group established by the JSC to oversee Commercialization-related activities under this Agreement.

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#### 8.4 Coordination of Commercialization Activities.

(a) The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of Licensed Products in and outside the Territory. As such, the Parties shall coordinate such activities where appropriate, which may include scientific and medical communication and product positioning.

(b) Each Party shall keep the other Party timely informed on the status of any application for pricing or reimbursement approval for Licensed Products in its territory, including any discussion with Regulatory Authority with respect thereto. Each Party shall have the right to determine the price of Licensed Products sold in its territory and neither Party shall have the right to direct, control or approve the pricing of Licensed Products in the other Party's territory.

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

**8.5 Diversion.** Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates and sublicensees shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory; provided that each Party shall have the right to attend conferences and meetings of congresses in the other Party's territory and to promote and market Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 8.5. Neither Party shall engage, nor permit its Affiliates or sublicensees to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of Licensed Products located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or sublicensees receive any order for Licensed Products for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates or sublicensees to, deliver or tender (or cause to be delivered or tendered) any Licensed Products for use in the other Party's territory.

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**ARTICLE 9  
PAYMENTS**

**9.1 Upfront Payment.** Zai shall pay to Five Prime a one-time, non-refundable, non-creditable upfront payment of five million Dollars (\$5,000,000) within [\*\*\*] after the Effective Date.

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

Milestone Event	Milestone Payment
<b>Development Milestones</b>	
1.[***]	[***]

<b>Regulatory Milestones</b>	
2.[***]	[***]
3.[***]	[***]
4.[***]	[***]
5.[***]	[***]
6.[***]	[***]
7.[***]	[***]

**(a) Milestone Conditions.**

**(i)** Each milestone payment set forth above shall be payable only once for each Licensed Product. Licensed Products with different Active Ingredients (or different combinations of Active Ingredients) shall be deemed different Licensed Products.

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

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### 9.3 Royalty Payments to Five Prime.

(a) **Royalty Rates.** Subject to the remainder of this Section 9.3, Zai shall make quarterly non-refundable, non-creditable royalty payments to Five Prime on the Net Sales of all Licensed Products sold in the Territory, calculated by multiplying the applicable royalty rate set forth below by the aggregate amount of Net Sales of all Licensed Products sold in the Territory in the applicable Calendar Quarter.

Patient Enrollment by Zai	Royalty Rate
1.[***]	[***]
2. [***]	[***]

(b) **Royalty Term.** The Royalty Payments payable under this Section 9.3 shall be payable on a Licensed Product-by-Licensed Product and region-by-region basis from the First Commercial Sale of such Licensed Product in such region until the latest of: (i) the 11<sup>th</sup> anniversary of the date of the First Commercial Sale of such Licensed Product in such region; (ii) the expiration of the last Valid Claim (including any patent term adjustments or extensions) within the Five Prime Patents that covers such Licensed Product (including composition of matter, method of use or making) in such region; and (iii) the expiration of all Regulatory Exclusivity for such Licensed Product in such region (the “**Royalty Term**”).

#### (c) Royalty Reductions.

(i) **Biosimilar Product.** If a Licensed Product is generating Net Sales in a region during the applicable Royalty Term at a time when a Biosimilar Product with respect to such Licensed Product is being sold in such region, then the royalty rate applicable to Net Sales of such Licensed Product in such region in such Calendar Quarter shall be reduced by the following percentage of the royalty rate that would otherwise be owed on such Net Sales of such Licensed Product in such region under Section 9.3(a), for so long as the Biosimilar Product is being sold in such region during the Royalty Term: [\*\*\*].

(ii) **Third Party Royalties.** If Zai determines in its reasonable judgment, following consultation with Five Prime, that a license under any Patent controlled by a Third Party in a region in the Territory is necessary for the Development, manufacture or Commercialization of the Licensed Product that is sold or offered for sale in such region, then Zai shall have the right to deduct from the royalty payment that would otherwise have been due under Section 9.3(a) with respect to Net Sales of such Licensed Product in such region in a particular Calendar Quarter an amount equal to [\*\*\*] of [\*\*\*] paid by Zai to such Third Party pursuant to such license [\*\*\*]. In the event Five Prime disputes whether such Third Party license is necessary, the matter shall be referred to the Chief Patent Counsels of Zai and Five Prime, or such other person at each Party holding a similar position designated by Zai or Five Prime. The Chief Patent Counsels shall meet promptly to discuss and resolve the matter. In the event that the Chief Patent Counsels cannot agree on a resolution to the matter, then the Parties shall refer such matter for resolution to an independent patent attorney mutually agreed upon by the Parties who has at least [\*\*\*] of experience in the biologics field (or who has such other similar credentials as mutually agreed by the Parties), and such attorney’s decision on the matter shall be binding upon the Parties.

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



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

(d) **Royalty Reports and Payments.** Within [\*\*\*] after the end of each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of the first Licensed Product is made anywhere in the Territory, Zai shall provide Five Prime with a report that contains the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product and region-by-region basis: (i) the amount of Net Sales of such Licensed Product, (ii) a calculation of the royalty payment due on such Net Sales, including any royalty reduction made in accordance with Section 9.3(c), and (iii) the exchange rate used for converting any Net Sales recorded in a currency other than Dollars. Promptly following the delivery of the applicable quarterly report, Five Prime shall invoice Zai for the royalties due to Five Prime with respect to Net Sales by Zai, its Affiliates and their respective sublicensees for such Calendar Quarter, and Zai shall pay such amounts to Five Prime in Dollars within [\*\*\*] following Zai's receipt of such invoice, [\*\*\*]. If requested by Five Prime, the Parties will meet to discuss [\*\*\*]. In the event that the Parties agree in good faith (or it is otherwise finally determined pursuant to Section 15.2 or 15.3) that [\*\*\*].

#### 9.4 Royalty Payments to Zai.

(a) **Royalty Rate.** Subject to the remainder of this Section 9.4 and provided that Zai enrolled and treated at least [\*\*\*] patients in the FPA144-004 Study in the PRC, Five Prime shall make quarterly [\*\*\*] royalty payments to Zai, as calculated by multiplying [\*\*\*] by the aggregate amount of Net Sales (applying such definition *mutatis mutandis* to Five Prime in place of Zai) of all Licensed Products sold outside the Territory in the applicable Calendar Quarter.

(b) **Royalty Term.** The royalty payments payable under this Section 9.4 shall be payable on a Licensed Product-by-Licensed Product basis from the First Commercial Sale of such Licensed Product outside the Territory until the tenth (10<sup>th</sup>) anniversary of the date of such First Commercial Sale of such Licensed Product.

(c) **Royalty Reports and Payments.** Within [\*\*\*] after each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of the first Licensed Product is made anywhere outside the Territory, Five Prime shall provide Zai with a report that contains the following information for the applicable Calendar Quarter, on a Licensed Product-by-Licensed Product basis: (i) the amount of Net Sales (applying such definition *mutatis mutandis* to Five Prime in place of Zai) of such Licensed Product, (ii) a calculation of the royalty payment due on such Net Sales, and (iii) the exchange rate used for converting any Net Sales recorded in a currency other than Dollars. Substantially concurrent with the delivery of the applicable quarterly report, but in any event within [\*\*\*] after each Calendar Quarter, Five Prime shall pay in Dollars all royalties due to Zai with respect to such Net Sales by Five Prime, its Affiliates and their respective sublicensees for such Calendar Quarter.

9.5 **Payments to Third Parties.** Subject to Section 2.7, each Party shall be solely responsible for any payments due to Third Parties under any agreement entered into by such Party [\*\*\*].

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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

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

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

**9.9 Taxes.**

**(a) Taxes on Income.** Except as set forth in this Section 9.9 or Section 9.10, each Party shall be solely responsible for the payment of any and all Taxes levied on account of all payments it receives under this Agreement.

**(b) Tax Cooperation.** The Parties agree to cooperate with one another in accordance with Applicable Laws and use reasonable efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. To the extent either Party (the "**Paying Party**") is required to deduct and withhold Taxes on any payment to the other Party (the "**Recipient**"), the Paying Party shall (i) pay the amount of such Taxes to the proper Governmental Authority in a timely manner; and (ii) promptly transmit to the Recipient an official tax certificate or other evidence of such payment sufficient to enable the Recipient to claim such payment of Taxes on the Recipient's applicable tax returns. The Paying Party shall provide the Recipient with advance notice prior to withholding any Taxes from payments payable to the Recipient and shall provide

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the Recipient with a commercially reasonable period of time to claim an exemption or reduction in otherwise applicable Taxes. The Recipient shall provide the Paying Party any tax forms that may be reasonably necessary in order for the Paying Party to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty, to the extent the Paying Party is legally able to do so. The Recipient shall use reasonable efforts to provide any such tax forms to the Paying Party in advance of the due date. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Paying Party if the Paying Party is the Party bearing such withholding Tax under this Section 9.9. In addition, the Parties shall cooperate in accordance with Applicable Laws to minimize indirect Taxes (such as value added tax, sales tax, consumption tax and other similar Taxes) in connection with this Agreement. In the event of any inconsistency between this Section 9.9(b) and Section 9.10, Section 9.10 shall take precedence.

(c) **Changes in Domicile.** Notwithstanding anything to the contrary in this Agreement, if the Paying Party assigns, transfers or otherwise disposes of some or all of its rights and obligations to any Person and if, as a result of such action, the withholding or deduction of Tax required by Applicable Laws with respect to payments under this Agreement is increased, then any amount payable to the Recipient under this Agreement shall be increased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), the Recipient receives an amount equal to the sum it would have received had no such withholding been made.

(d) **Returns.** All transfer, documentary, sales, use, stamp, registration and other such Taxes, and any conveyance fees, recording charges and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated hereby, if any, shall be borne and paid by the Paying Party. The Paying Party shall prepare and timely file all tax returns required to be filed in respect of any such Taxes. The Parties shall reasonably cooperate in accordance with Applicable Laws to minimize transfer Taxes in connection with this Agreement.

**9.10 VAT Credits; Gross-Up.** [\*\*\*].

**9.11 Blocked Currency.** If by Applicable Law in a country or region in the Territory, conversion into Dollars or transfer of funds of a convertible currency to the United States becomes restricted, forbidden or substantially delayed, then Zai shall promptly notify Five Prime and, thereafter, amounts accrued in such country or region under this article 9 shall be paid to Five Prime (or its designee) in such country or region in local currency by deposit in a local bank designated by Five Prime and to the credit of Five Prime, unless the Parties otherwise agree.

## ARTICLE 10 CONFIDENTIALITY; PUBLICATION

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

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

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(b) the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement; and

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

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

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

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

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

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

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

No combination of features or disclosures shall be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party, unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

**10.3 Authorized Disclosures.** Notwithstanding the obligations set forth in Sections 10.1 and 10.5, a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent such disclosure is reasonably necessary in the following situations:

\*\*\* = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(a) (i) the Patent Prosecution of Five Prime Patents as contemplated by this Agreement; (ii) regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Development or Commercialization of a Licensed Product; or (iii) subject to Section 10.6, complying with Applicable Laws, including regulations promulgated by securities exchanges;

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

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

(d) such disclosure is by Five Prime and is required to comply with its obligations to Third Party licensors, including Upstream Licensors; or

(e) disclosure pursuant to Section 10.5 and 10.6.

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

Nothing in Sections 10.1 or 10.3 shall limit either Party in any way from disclosing to any Third Party such Party's U.S. or foreign income Tax treatment and the U.S. or foreign income Tax structure of the transactions relating to such Party that are based on or derived from this Agreement, as well as all materials of any kind (including opinions or other Tax analyses) relating to such Tax treatment or Tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

**10.4 Publications.** Zai will not publicly present or publish any Clinical Trial data, non-clinical data or any associated results or conclusions generated by or on behalf of Zai pursuant to this Agreement (each such proposed presentation or publication, a "**Publication**"), except in accordance with Five Prime's global publication strategy with respect to Licensed Products, and subject to the additional limitations set forth in this Section 10.4. In the event Zai desires to publicly present or publish a Publication in accordance with the foregoing sentence, Zai shall provide Five Prime (including the Alliance Manager and all Five Prime members of the JSC) with a copy of such proposed Publication at least [\*\*\*] prior to the earlier of its presentation or

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intended submission for publication; provided that in the case of abstracts, this period shall be at least [\*\*\*] (such applicable period, the “**Review Period**”). Zai agrees that it will not submit or present any Publication (a) until Five Prime has provided written comments during such Review Period on the material in such Publication or (b) until the applicable Review Period has elapsed without written comments from Five Prime, in which case Zai may proceed and the Publication will be considered approved in its entirety. If Zai receives written comments from Five Prime during the applicable Review Period, it shall consider the comments of Five Prime in good faith, but will retain the sole authority to submit the manuscript for Publication; provided that Zai agrees to (i) delete any Confidential Information of Five Prime that Five Prime identifies for deletion in Five Prime’s written comments, (ii) delete any Clinical Trial data, results, conclusions or other related information, the publication of which Five Prime determines, in its sole discretion, would conflict with Five Prime’s global publication strategy with respect to such Licensed Product, and (iii) delay such Publication for a period of up to an additional [\*\*\*] after the end of the applicable Review Period to enable Five Prime to draft and file a Patent with respect to any subject matter to be made public in such Publication and to which Five Prime has the applicable intellectual property rights to file such Patent. Zai shall provide Five Prime a copy of the Publication at the time of the submission or presentation. Zai agrees to acknowledge the contributions of Five Prime, and the employees of Five Prime, in all Publications as scientifically appropriate. Zai shall require its Affiliates, sublicensees and contractors to comply with the obligations of this Section 10.4 as if they were Zai, and shall be liable for their non-compliance.

**10.5 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 10.5 shall be considered a Publication hereunder and shall be subject to Section 10.4.

**10.6 Publicity; Use of Names.**

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in Section 10.3 and this Section 10.6. The Parties have agreed on a joint press release announcing this Agreement, which is attached hereto as **Exhibit D**, to be issued by the Parties on such date and time as may be agreed by the Parties. No other disclosure of the existence or the terms of this Agreement may be made by either Party or its Affiliates except as provided in Section 10.3 and this Section 10.6. Zai shall not use the name, trademark, trade name or logo of Five Prime, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, except as provided in this Section 10.6 or with the prior express written permission of Five Prime, except as may be required by Applicable Laws. Zai shall use Five Prime’s corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases, and accompanied explanatory text such as “Licensed from Five Prime Therapeutics, Inc.”; provided that Zai will use Five Prime’s corporate name only in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of Five Prime shall not be impaired, and in a manner consistent with best practices used by Zai with respect to its other collaborators.

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(b) Notwithstanding Section 10.6(a), Five Prime 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 the FPA144-004 Study. 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.

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

(d) Each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with Governmental Authorities) of certain terms of or material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Applicable Laws, provided that the Party seeking such disclosure (i) receives advice from counsel that it is legally required to make such public disclosure and (ii) if practicable and permitted by Applicable Laws, first provides the other Party a copy of the proposed disclosure, and reasonably considers any comments thereto provided by the other Party within [\*\*\*] after the receipt of such proposed disclosure.

(e) Other than the press release set forth in **Exhibit D** and the public disclosures permitted by Section 10.6(b), the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain, shall first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld or delayed), except as required by Applicable Laws.

(f) The Parties agree that after a disclosure pursuant to Section 10.6(d) or issuance of a press release (including the initial press release) or other public announcement pursuant to Section 10.6(a) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party’s prior consent and approval.

(g) Each Party shall have the right to use the other Party’s name and logo in presentations, its website, collateral materials and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 10.6; provided that Zai will use Five Prime’s corporate name only in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of Five Prime shall not be impaired, and consistent with best practices used by Zai for its other collaborators.

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**10.7 Attorney-Client Privilege.** Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the Receiving Party and the Disclosing Party shall have the right to assert such protections and privileges. Notwithstanding the foregoing, nothing in this Section 10.7 shall apply with respect to a dispute between the Parties (including their respective Affiliates).

## **ARTICLE 11 REPRESENTATIONS, WARRANTIES, AND COVENANTS**

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

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

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

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

(a) subject to Section 2.3, it has the right under the Five Prime IP to grant the Licenses to Zai, and it has not granted any license or other right under the Five Prime IP that is inconsistent with the License;

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

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

(d) the Five Prime IP includes all Know-How owned or licensed by Five Prime or its Affiliates that is necessary or reasonably useful to Develop, manufacture and Commercialize Licensed Antibodies or Licensed Products in the Field in the Territory as such

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Development, manufacture and Commercialization is currently being conducted by Five Prime or contemplated to be conducted by the Parties hereunder, and all Patents in the Territory that are owned or licensed by Five Prime or its Affiliates that cover a Licensed Product (including composition of matter and methods of using, making or detecting Licensed Products).

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

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

(g) to Five Prime's knowledge, (i) the Upstream Licensors have obtained, or caused their Affiliates to obtain, assignments from the inventors of all rights and embodiments in the Five Prime IP that has been licensed to Five Prime under the Upstream License Agreements, (ii) all such assignments are valid and enforceable, and (iii) the inventorship of the Five Prime Patents licensed from the Upstream Licensors under the Upstream License Agreements is properly identified on each issued patent or patent application in the Five Prime Patents;

(h) Five Prime and its Affiliates are in compliance in all material respects with the Upstream Licenses and the [\*\*\*] Agreements; and

(i) Five Prime and its Affiliates have taken Commercially Reasonable Efforts consistent with industry practices to protect the secrecy, confidentiality and value of all Five Prime Know-How that constitutes trade secrets under Applicable Law.

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

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

(b) Zai and its Affiliates is not, and has not been, debarred or disqualified by any Regulatory Authority;

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

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

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**11.4 Covenants of Zai.** Zai covenants to Five Prime that:

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

(b) Zai will conduct its obligations with respect to the FPA144-004 Study under the Global Development Plan in strict adherence with the study design set forth in the protocol for the FPA144-004 Study and as set forth in the Global Development Plan, each as may be amended from time to time, and will comply with the statistical analysis plan implemented by Five Prime in connection therewith; and

(c) Zai will only engage Clinical Trial sites under the Territory Development Plan and the Global Development Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the CFDA.

**11.5 Covenants of Five Prime.** Five Prime covenants to Zai that during the Term:

(d) Five Prime shall comply with all Applicable Laws applicable to its Development and manufacture of Licensed Antibodies and Licensed Products pursuant to this Agreement;

(e) Five Prime and its Affiliates shall remain in compliance in all material respects with the Upstream Licenses and the [\*\*\*] Agreements;

(f) Five Prime will not, without Zai's prior written consent, amend any Upstream License or the [\*\*\*] Agreements in a manner that would materially adversely affect the rights granted to Zai hereunder (including, for the avoidance of doubt, an increase in any amounts owed or costs to be paid by Zai hereunder) or Five Prime's ability to fully perform its obligations hereunder; and

(g) Five Prime shall provide prompt notice to Zai of its receipt of any written notice that alleges material breach by Five Prime of, or requests a material amendment of, any Upstream License or the [\*\*\*] Agreements.

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

**11.7 Compliance with Anti-Corruption Laws.**

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

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

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(ii) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it will, no later than [\*\*\*] following the end of each Calendar Year, verify in writing that to the best of Zai's knowledge, there have been no violations of Anti-Corruption Laws by Zai, its Affiliates or sublicensees, or persons employed by or subcontractors used by Zai or its Affiliates or sublicensees in the performance of this Agreement, or shall provide details of any exception to the foregoing; and

(iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Agreement in order to document or verify compliance with the provisions of this **Section 11.7**, and upon request of Five Prime, up to once per year and upon reasonable advance notice, shall provide Five Prime or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 11.7.

(b) Zai represents and warrants that, to its knowledge, neither Zai nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of Zai or any of its Affiliates:

(i) has taken any action in violation of any applicable Anti-Corruption Laws; or

(ii) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in **Section 11.7(d)**), for the purposes of:

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

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

(3) securing any improper advantage; or

(4) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

(c) Zai further represents and warrants that, as of the Effective Date, none of the officers, directors or employees of Zai or of any of its Affiliates or agents acting on behalf of Zai or any of its Affiliates, in each case that are employed or reside outside the United States, is a Public Official.

(d) For purposes of this **Section 11.7**, "**Public Official**" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or

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representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

## ARTICLE 12 INDEMNIFICATION

**12.1 By Zai.** Zai shall indemnify and hold harmless Five Prime, [\*\*\*], its and their Affiliates, and their respective directors, officers, employees and agents (individually and collectively, the “**Five Prime Indemnitee(s)**”) from and against all losses, liabilities, damages and expenses (including reasonable attorneys’ fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party, including by the CFDA or any other Regulatory Authority with jurisdiction in the Territory, (individually and collectively, “**Losses**”) to the extent arising from (a) the Development, manufacture or Commercialization of the Licensed Antibody or Licensed Products by or on behalf of Zai or any of its Affiliates or sublicensees (including actions related to Zai’s role as the authorized regulatory agent of record for Five Prime pursuant to this Agreement), including product liability claims, (b) Zai’s actions (or omissions) in the performance of its obligations with respect to Regulatory Submissions and interactions with Regulatory Authorities, in each case, as an agent of Five Prime in the Territory, (c) the negligence or willful misconduct of Zai or its Affiliates or sublicensees, (d) Zai’s breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, or (e) failure of Zai or its Affiliates or sublicensees to abide by any Applicable Laws, in each case of clauses (a) through (e) above, except to the extent such Losses arise out of an Five Prime Indemnitee’s negligence or willful misconduct, breach of this Agreement, or material failure to abide by any Applicable Laws.

**12.2 By Five Prime.** Five Prime shall indemnify and hold harmless Zai, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the “**Zai Indemnitee(s)**”) from and against all Losses to the extent arising from (a) the Development, manufacture or Commercialization of the Licensed Antibody or Licensed Products by or on behalf of Five Prime or any of its Affiliates or sublicensees (not including Zai or its Affiliates or sublicensees), including product liability claims, in each case outside of the Territory, (b) the negligence or willful misconduct of Five Prime or its Affiliates, (c) Five Prime’s breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, or (d) failure of Five Prime or its Affiliates to abide by any Applicable Law, in each case of clauses (a) through (d) above, except to the extent such Losses arise out of any of a Zai Indemnitee’s negligence or willful misconduct, breach of this Agreement or material failure to abide by any Applicable Law.

**12.3 Indemnification Procedure.** If either Party is seeking indemnification under Sections 12.1 or 12.2 (the “**Indemnified Party**”), it shall inform the other Party (the “**Indemnifying Party**”) of the claim giving rise to the obligation to indemnify pursuant to such Section within [\*\*\*] after receiving written notice of the claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a claim shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall

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have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If the Parties cannot agree as to the application of Section 12.1 or 12.2 as to any claim, pending resolution of the dispute pursuant to Article 15, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 12.1 or 12.2 upon resolution of the underlying claim.

**12.4 Mitigation of Loss.** Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 12. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

**12.5 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 12.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 12.1 OR 12.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO CONFIDENTIALITY OR ZAI'S BREACH OF ITS OBLIGATIONS UNDER SECTION 2.8 OR 11.4(A).

**12.6 Insurance.** Zai shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold in the Territory. Zai shall provide Five Prime with evidence of such insurance upon request and shall provide Five Prime with written notice at least [\*\*\*] prior to the cancellation, non-renewal or material changes in such insurance. Such insurance shall not be construed to create a limit of Zai's liability with respect to its indemnification obligations under this Article 12.

## **ARTICLE 13 INTELLECTUAL PROPERTY**

### **13.1 Inventions.**

**(a) Ownership.** As between the Parties, (i) Five Prime shall solely own all Five Prime IP and FPA144 Collaboration IP, (ii) Zai shall solely own all Zai IP, and (iii) the ownership of any Collaboration IP shall be determined by inventorship. FPA144 Collaboration IP shall be included in the Five Prime IP and licensed to Zai in the Field in the Territory under Section 2.1.

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(b) **Disclosure.** Each Party shall promptly disclose to the other Party all Inventions within the FPA144 Collaboration IP and Collaboration IP (including the Zai Collaboration IP), including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto, and shall also promptly respond to reasonable requests from the other Party for additional information relating thereto.

(c) **Assignment; Jointly-owned IP.**

(i) Zai shall and hereby does assign to Five Prime all right, title and interest in and to all FPA144 Collaboration IP. Zai shall take (and cause its Affiliates, sublicensees and their employees, agents, and contractors to take) such further actions reasonably requested by Five Prime to evidence such assignment and to assist Five Prime in obtaining patent and other intellectual property rights protection for the FPA144 Collaboration IP. Zai shall obligate its Affiliates, sublicensees and contractors to assign all FPA144 Collaboration IP to Zai (or directly to Five Prime) so that Zai can comply with its obligations under this Section 13.1, and Zai shall promptly obtain such assignment.

(ii) Subject to the rights granted under and the restrictions set forth in this Agreement, it is understood that neither Party shall have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit any jointly-owned Collaboration IP (or any Patents claiming the same, "**Joint Patents**"), by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting.

**13.2 Patent Prosecution.**

(a) **Five Prime Patents.**

(i) Subject to Section 13.2(c), as between the Parties, Five Prime shall have the right to control the Patent Prosecution of all Five Prime Patents [\*\*\*].

(ii) Five Prime shall consult with Zai and keep Zai reasonably informed of the Patent Prosecution of the Five Prime Patents and shall provide Zai with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, Five Prime shall provide Zai with drafts of all proposed material filings and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the Five Prime Patents for Zai's review and comment prior to the submission of such proposed filings and correspondence. Further, Five Prime shall notify Zai of any decision to cease Patent Prosecution or maintenance of any Five Prime Patents in the Territory. Five Prime will consider Zai's comments on Patent Prosecution but will have final decision-making authority under this Section 13.2(a)(ii).

(b) **Zai Patents.** As between the Parties, Zai shall have the sole right to control the Patent Prosecution of all Zai Patents throughout the world, [\*\*\*].

(c) **Jointly-Owned Collaboration IP.** In the event that any jointly-owned Collaboration IP is created hereunder, at either Party's request, the Parties shall discuss a mutually acceptable filing and prosecution strategy for any Joint Patents, provided that absent such agreement, Five Prime shall control the Patent Prosecution of any Joint Patents, as set forth in this Agreement. Unless the Parties' agree in writing on an alternative arrangement, Five Prime shall be responsible for all costs of Patent Prosecution of Joint Patents.

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

### 13.3 Patent Enforcement.

(a) **Notice.** Each Party shall notify the other within [\*\*\*] of becoming aware of any alleged or threatened infringement by a Third Party of (i) any of the Five Prime Patents in the Territory or (ii) any of the Zai Patents in the Territory, which infringement of such Zai Patents adversely affects or is expected to adversely affect any Licensed Product in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any Five Prime Patents (collectively "**Product Infringement**"). Each Party shall also notify the other within [\*\*\*] of becoming aware of any alleged or threatened infringement by a Third Party of any Patent that claims Zai Collaboration IP that is solely owned by Zai ("**Zai Collaboration Patent**"), which infringement adversely affects or is expected to adversely affect any Licensed Product outside of the Territory, including any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent(s) (an "**Ex-Territory Infringement**"). For clarity, Product Infringement and Ex-Territory Infringement, in each case, exclude any adversarial Patent Prosecution proceedings.

#### (b) Enforcement Rights.

(i) Five Prime shall have the first right to bring and control any legal action to enforce Five Prime Patents (including Joint Patents) against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate, and Five Prime shall consider in good faith the interests of Zai in such enforcement of the Five Prime Patents. If Five Prime or its designee fails to abate such Product Infringement in the Territory or to file an action to abate such Product Infringement in the Territory within [\*\*\*] after a written request from Zai to do so, or if Five Prime discontinues the prosecution of any such action after filing without abating such infringement, then Zai shall have the right to enforce the Five Prime Patents against such Product Infringement in the Territory at its own expense as it reasonably determines appropriate provided that (A) Five Prime does not provide reasonable rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party) and (B) Zai shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Five Prime Patent without the prior written consent of Five Prime. Zai shall have the sole right to bring and control any legal action to enforce Zai Patents against any Product Infringement in the Territory at its own expense as it reasonably determines appropriate. Zai shall not have the right to enforce any Five Prime Patent outside of the Territory without the prior written consent of Five Prime.

(ii) Zai shall have the first right to bring and control any legal action to enforce any Zai Collaboration Patent against any Ex-Territory Infringement outside of the Territory at its own expense as it reasonably determines appropriate, and Zai shall consider in good faith the interests of Five Prime in such enforcement of the Zai Collaboration Patents. If Zai or its designee fails to abate such Ex-Territory Infringement outside of the Territory or to file an action to abate such Ex-Territory Infringement outside of the Territory within [\*\*\*] after a written request from Five Prime to do so, or if Zai discontinues the prosecution of any such

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action after filing without abating such infringement, then Five Prime shall have the right to enforce such Zai Collaboration Patents against such Ex-Territory Infringement outside the Territory at its own expense as it reasonably determines appropriate provided that (A) Zai does not provide reasonable rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party) and (B) Five Prime shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Zai Collaboration Patent without the prior written consent of Zai.

(c) **Cooperation.** At the request of the Party bringing an action related to Product Infringement or Ex-Territory Infringement, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action, at each such Party's sole cost and expense.

(d) **Recoveries.** Any recoveries resulting from an enforcement action relating to a claim of Product Infringement in the Territory or Ex-Territory Infringement outside of the Territory shall be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall be, (i) if Five Prime is the enforcing Party, [\*\*\*], or (ii) if Zai is the enforcing Party, [\*\*\*].

(e) **Continuing Infringement.** With respect to any continuing Product Infringement of the Five Prime Patents in a region in the Territory, if (i) Five Prime or its designee fails to abate such infringement or file an action to abate such infringement within [\*\*\*] after receiving Zai's written request pursuant to Section 13.3(b)(i)), or if Five Prime discontinues the prosecution of any such action after filing without abating such infringement, and (ii) Zai notifies Five Prime that it wishes to exercise its right to enforce the Five Prime Patents against such Product Infringement pursuant to Section 13.3(b)(i) and Five Prime provides notice to Zai that Five Prime has a reasonable rationale for denying such exercise in accordance with Section 13.3(b)(i)(A) (which notice must be provided to Zai within ten Business Days from the date of Zai's notice to Five Prime pursuant to Section 13.3(b)(i)), then, from the date of such notice from Five Prime pursuant to Section 13.3(b)(i)(A) until such time as such Product Infringement is abated, the royalty rate that would otherwise be owed under Section 9.3 for the applicable Licensed Product in such region during each applicable Calendar Quarter shall be reduced to [\*\*\*].

#### 13.4 Infringement of Third Party Rights.

(a) **Notice.** If any Licensed Product used or sold by Zai, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent or other rights in the Territory that are owned or controlled by such Third Party, Zai shall promptly notify Five Prime within [\*\*\*] after receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

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(b) **Defense.** Zai shall be solely responsible for the defense of any such infringement claims brought against Zai, at Zai's cost and expense; provided that Zai shall not agree to any settlement, consent to judgment or other voluntary final disposition in connection with such defense action without Five Prime's consent if such settlement, consent to judgment or other voluntary final disposition would (a) result in the admission of any liability or fault on behalf of Five Prime, (b) result in or impose any payment obligations upon Five Prime, or (c) subject Five Prime to an injunction or otherwise limit Five Prime's ability to take any actions or refrain from taking any actions under this Agreement or with respect to any Licensed Antibody or Licensed Product. Zai shall keep Five Prime informed on the status of such defense action, and Five Prime shall have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense.

**13.5 Patents Licensed From Third Parties.** Each Party's rights under this Article 13 with respect to the prosecution and enforcement of any Five Prime Patent that is licensed by Five Prime from a Third Party shall be subject to the rights of such Third Party to prosecute and enforce such Patent.

**13.6 Product Trademarks.** Subject to Section 8.4(c), Zai shall have the right to brand Licensed Products in the Territory using trademarks, logos, and trade names it determines appropriate for such Licensed Products, which may vary by region or within a region (the "**Product Marks**"); provided, however, that Zai shall provide Five Prime with a reasonable opportunity to review and provide comments on each proposed Product Mark, shall give due consideration to Five Prime's comments before selecting any Product Mark, and shall not use any trademarks or house marks of Five Prime (including Five Prime's corporate name) or any trademark confusingly similar thereto without Five Prime's prior written consent. Zai shall own all rights in the Product Marks in the Territory and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary, at Zai's cost and expense.

**13.7 Patent Marking.** Zai shall mark all Licensed Products in accordance with the applicable patent marking laws, and shall require all of its Affiliates and sublicensees to do the same. To the extent permitted by Applicable Laws, Zai shall indicate on the product packaging, advertisement and promotional materials that such Licensed Product is in-licensed from Five Prime.

## ARTICLE 14 TERMS AND TERMINATION

**14.1 Term.** This Agreement shall be effective as of the Effective Date, and shall continue, on a region-by-region basis, in effect until the expiration of and payment by Zai of all of Zai's royalty payment obligations set forth in Section 9.3 applicable to such Licensed Product and such region (the "**Term**"). On a region-by-region basis, upon the natural expiration of this Agreement as contemplated in this Section 14.1, the Exclusive License and Research License in such region shall become fully paid-up, perpetual, irrevocable and non-exclusive with respect to all activities, except for Commercialization of Licensed Products in the Field pursuant to the Exclusive License, which shall remain exclusive to Zai until the [\*\*\*] of the date of such natural expiration (the "**Exclusive Tail Expiration Date**"), at which time the Exclusive License shall become non-exclusive with respect to all activities. In addition, on a region-by-region basis, upon the natural expiration of this Agreement, Five Prime shall have, and Zai hereby grants to Five Prime, effective upon such expiration, a non-exclusive, fully-paid up, perpetual, irrevocable

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and sublicensable (through multiple tiers) license under the Zai IP and Zai Collaboration IP to develop, make, have made, distribute, use, sell, offer for sale, import and otherwise commercialize Licensed Products (i) outside the Territory, and (ii) in any region in the Territory in which the Agreement has naturally expired; provided, however, that Five Prime shall not sell, offer for sale or otherwise Commercialize Licensed Products in any such region before the Exclusive Tail Expiration Date for such region and, after such Exclusive Tail Expiration Date, Five Prime shall not sell, offer for sale or otherwise Commercialize Licensed Products in such region pursuant to any Regulatory Approval under which Zai was selling, offering for sale or otherwise Commercializing Licensed Products in the Territory during the Term. For the avoidance of doubt, Five Prime shall be permitted to sell, offer for sale or otherwise Commercialize Licensed Products in any region in the Territory after the Exclusive Tail Expiration Date in such region under a new Regulatory Approval obtained by or on behalf of Five Prime following the expiration of the Term.

## 14.2 Termination

**(a) Termination by Zai for Convenience.** At any time, Zai may terminate this Agreement by providing written notice of termination to Five Prime, which notice includes an effective date of termination at least [\*\*\*] after the date of the notice.

### **(b) Termination for Material Breach.**

**(i)** If either Party believes in good faith that the other is in material breach of its obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party stating the cause and proposed remedy. For all breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party shall have [\*\*\*] from such notice to dispute or cure such breach, provided that if such breach is not reasonably capable of cure within such [\*\*\*] period, but is capable of cure within [\*\*\*] from such notice, the breaching Party may submit, within [\*\*\*] of such notice, a reasonable cure plan to remedy such breach as soon as possible and in any event prior to the end of such [\*\*\*], and, upon such submission, the [\*\*\*] cure period shall be automatically extended for so long as the breaching Party continues to use diligent efforts to cure such breach in accordance with the cure plan, but for no more than [\*\*\*]. For any breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party shall have [\*\*\*] from the receipt of the notice to dispute or cure such breach. If the Party receiving notice of breach fails to cure, or fails to dispute, that breach within the applicable period set forth above, then the Party originally delivering the notice of breach may terminate this Agreement effective on written notice of termination to the other Party. If the allegedly breaching Party in good faith disputes such material breach and provides written notice of that dispute to the other Party within the applicable period set forth above, the matter shall be addressed under the dispute resolution provisions in Article 15, and the termination shall not become effective unless and until it has been determined under Article 15 that the allegedly breaching Party is in material breach of this Agreement. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. Section 14.2(b)(i) shall not apply to or encompass a breach (or alleged breach) of Zai's diligence obligations pursuant to Section 5.1 or Section 8.1, which shall be governed solely by Section 14.2(b)(ii).

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(ii) (1) Subject to the provisions of this Section 14.2(b)(ii), Five Prime shall have the right to terminate this Agreement in its entirety if Zai is in material breach of its diligence obligations pursuant to Section 5.1 and Five Prime shall have the right to terminate this Agreement on a region-by-region basis with respect to all Licensed Products in such region in the Territory if Zai is in material breach of its diligence obligations pursuant to Section 8.1 with respect to such region; provided, however, this Agreement shall not so terminate unless (A) Five Prime provides Zai with written notice of Five Prime's intent to terminate, stating the reasons and justification for such termination and recommending steps which Five Prime believes Zai should take to cure such alleged breach, and (B) Zai, or its Affiliates or sublicensee, has not (x) during the [\*\*\*] period following such notice, provided Five Prime with a plan for curing such breach and (y) during the [\*\*\*] period following such notice carried out such plan and cured such alleged breach (subject to extension as set forth in Section 14.2(b)(i) above).

(2) If Zai disputes in good faith the existence or materiality of an alleged breach specified in a notice provided by Five Prime pursuant to Section 14.2(b)(ii)(1), and if Zai provides notice to Five Prime of such dispute within the thirty [\*\*\*] following such notice provided by Five Prime, Five Prime shall not have the right to terminate this Agreement unless and until the existence of such material breach or failure by Zai has been determined in accordance with Article 15 and Zai fails to cure such breach within [\*\*\*] following such determination (subject to extension as set forth in Section 14.2(b)(i) above). It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(c) **Termination for Patent Challenge.** Except to the extent the following is unenforceable under the laws of a particular jurisdiction, Five Prime may immediately terminate this Agreement in its entirety if Zai or its Affiliates or sublicensees, individually or in association with any other Person, commences a legal action challenging the validity, enforceability or scope of any Five Prime Patents anywhere in the world (a "**Patent Challenge**"). For the avoidance of doubt, the foregoing right of termination shall not apply with respect to any Patent Challenge where the Patent Challenge is (i) based solely on the scope of a Five Prime Patent or whether a claim therein qualifies as a Valid Claim and made in defense of a breach claim first brought by Five Prime against Zai pursuant to this Agreement or (ii) brought by a sublicensee of Zai and Zai has terminated the applicable sublicense agreement following notice thereof. For clarity, if a Third Party that is not a sublicensee of Zai commences a legal action challenging the validity, enforceability or scope of any Five Prime Patents anywhere in the world, and Zai's sole involvement in such action is to respond to a subpoena or take another action that is otherwise compelled by Applicable Law, then such involvement shall not be deemed to be a Patent Challenge.

(d) **Termination for Insolvency.** Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [\*\*\*] of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

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

**14.3 Effect of Termination.** Upon the termination of this Agreement:

(a) **Licenses.** The Licenses and all other rights granted by Five Prime to Zai under the Five Prime IP shall terminate and all sublicenses granted by Zai shall also terminate. In addition, upon the termination of this Agreement Five Prime shall have, and Zai hereby grants to Five Prime, effective upon such termination, (i) a worldwide, non-exclusive, fully-paid up, perpetual, irrevocable and sublicensable (through multiple tiers) license under the Zai IP to develop, make, have made, distribute, use, sell, offer for sale, import and otherwise commercialize Licensed Products, and (ii) an exclusive, fully-paid, royalty-free, perpetual, irrevocable and sublicenseable (through multiple tiers) license under the Zai Collaboration IP to develop, make, have made, distribute, use, sell, offer for sale, import and otherwise commercialize Licensed Products.

(b) **Regulatory Submissions.** Upon Five Prime's written request, Zai shall provide Five Prime with copies of all Regulatory Submissions for Licensed Products. Zai shall either assign to Five Prime or provide Five Prime with a right of reference with respect to such Regulatory Submissions, as Five Prime determines at its reasonable discretion, at Zai's cost and expense. In addition, upon Five Prime's written request, Zai shall, at its cost and expense, provide to Five Prime copies of all material related documentation, including material non-clinical, preclinical and clinical data that are held by or reasonably available to Zai, its Affiliates or sublicensees. The Parties shall discuss and establish appropriate arrangements with respect to safety data exchange, provided that Five Prime will assume all safety and safety database activities no later than [\*\*\*] after termination.

(c) **Trademarks.** Zai shall transfer and assign, and shall ensure that its Affiliates transfer and assign, to Five Prime, at no cost to Five Prime, all Product Marks relating to any Licensed Product and any applications therefor (excluding any such marks that include, in whole or part, any corporate name or logos of Zai or its Affiliates or sublicensees). Five Prime and its Affiliates and licensees shall have the right to use other identifiers specific to any Licensed Product (e.g., Zai compound identifiers). Zai shall also transfer to Five Prime any in-process applications for generic names for any Licensed Product.

(d) **Inventory.** At Five Prime's election and request, Zai shall transfer to Five Prime or its designee some or all inventory of Licensed Antibody and 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 Zai, its Affiliates or sublicensees; provided that Five Prime shall pay Zai a price equal to Zai's fully burdened manufacturing cost of such transferred Licensed Antibody and Licensed Products.

(e) **Wind Down and Transition.** Zai shall be responsible, at its own cost and expense, for the wind-down of Zai's, its Affiliates' and its sublicensees' Development, manufacture and Commercialization activities for Licensed Products. Zai shall, and shall cause

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

its Affiliates and sublicensees to, reasonably cooperate with Five Prime to facilitate orderly transition of the Development, manufacture and Commercialization of Licensed Products to Five Prime or its designee, including (i) assigning or amending as appropriate, upon request of Five Prime, any agreements or arrangements with Third Party vendors (including distributors) to Develop, manufacture, promote, distribute, sell or otherwise Commercialize Licensed Products or, to the extent any such Third Party agreement or arrangement is not assignable to Five Prime, reasonably cooperating with Five Prime to arrange to continue to provide such services for a reasonable time after termination; and (ii) to the extent that Zai or its Affiliate is performing any activities described above in (i), reasonably cooperating with Five Prime to transfer such activities to Five Prime or its designee and continuing to perform such activities on Five Prime's behalf for a reasonable time after termination until such transfer is completed.

**(f) Ongoing Clinical Trial.** If, at the time of such termination, Zai or its Affiliates are conducting any Clinical Trials, then, at Five Prime's election on a Clinical Trial-by-Clinical Trial basis: (i) Zai shall fully cooperate, and shall ensure that its Affiliates fully cooperate, with Five Prime to transfer the conduct of such Clinical Trial to Five Prime or its designees effective as of [\*\*\*] after the termination effective date, and Five Prime shall assume any and all liability for the conduct of such transferred Clinical Trial after the effective date of such transfer (except to the extent arising prior to the transfer date or from any willful misconduct or negligent act or omission by Zai, its Affiliates or their respective employees, agents and contractors); and (ii) Zai shall, [\*\*\*], orderly wind-down the conduct of any such Clinical Trial that is not assumed by Five Prime under clause (i) above.

**(g) Return of Confidential Information.** At Five Prime's election, Zai shall return (at Five Prime's expense) or destroy all tangible materials comprising, bearing or containing any Confidential Information of Five Prime that are in Zai's or its Affiliates' or sublicensees' possession or control and provide written certification of such destruction; provided that Zai may retain one copy of such Confidential Information for its legal archives, and provided further, that Zai shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

**14.4 Alternative Remedy for Termination.** If Zai has the right to terminate this Agreement pursuant to Section 14.2(b) on account of Five Prime's uncured material breach, then Zai may elect by written notice to Five Prime within [\*\*\*] following the expiration of all applicable cure periods, to exercise its rights under this Section 14.4 as a sole and exclusive remedy in lieu of exercising its right under Section 14.2(b). For clarity, if Five Prime disputes Zai's right to terminate pursuant to Section 14.2(b) following Zai's election under this Section 14.4, the Parties shall resolve any such dispute under Section 15.3. Upon a final determination by an arbitrator pursuant to Section 15.3 of an uncured material breach of this Agreement by Five Prime, or, if dispute resolution procedures were not initiated by Five Prime within [\*\*\*] after Zai's written notice of election under this Section 14.4, then this Agreement will remain in full force and effect, provided that Zai may thereafter reduce any [\*\*\*] payments that accrue after the date of Zai's notice of election under this Section 14.4 by [\*\*\*], for the remainder of the Term, subject in all cases to Section 9.3(c)(iii).

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**14.5 Termination Press Releases.** In the event of termination of this Agreement for any reason and subject to the provisions of Section 10.3, the Parties shall cooperate in good faith to coordinate public disclosure of such termination and the reasons therefor, and shall not, except to the extent required by Applicable Laws, disclose such information without the prior approval of the other Party. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Laws and regulatory guidance documents, and reasonable sensitivity to potential negative investor reaction to such news.

**14.6 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of [\*\*\*] shall survive the expiration or termination of this Agreement.

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

## ARTICLE 15 DISPUTE RESOLUTION

**15.1 General.** The Parties recognize that a dispute may arise relating to this Agreement (a “*Dispute*”). Any Dispute, including Disputes that may involve the Affiliates of any Party, shall be resolved in accordance with this article 15.

**15.2 Negotiation; Escalation.** The Parties shall negotiate in good faith and use reasonable efforts to settle any Dispute under this Agreement. Any Dispute as to the breach, enforcement, interpretation or validity of this Agreement shall be referred to the Executive Officers for attempted resolution. In the event the Executive Officers are unable to resolve such Dispute within [\*\*\*] of such Dispute being referred to them, then, upon the written request of either Party to the other Party, the Dispute shall be subject to arbitration in accordance with Section 15.3.

### **15.3 Arbitration.**

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

**(b)** Upon receipt of an Arbitration Notice by a Party, the applicable dispute shall be resolved by final and binding arbitration before a panel of three arbitrators (the “*Arbitrators*”), with each arbitrator having not less than [\*\*\*] of experience in the biotechnology or pharmaceutical industry and subject matter expertise with respect to the matter subject to arbitration. Any Arbitrator chosen hereunder shall have educational training and industry

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experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the particular dispute. Each Party shall promptly select one Arbitrator each, which selections shall in no event be made later than [\*\*\*] after receipt of the Arbitration Notice. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrators chosen by the Parties, but in no event later than [\*\*\*] after the date that the last of such Arbitrators was appointed.

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

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

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

(f) Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, (A) the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding; and (B) in the event that the subject of the dispute relates to the exercise by a Party of a termination right hereunder, including in the case of a material breach of this Agreement, the effectiveness of such termination shall be stayed until the conclusion of the proceedings under this Section 15.3.

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

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

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**ARTICLE 16**  
**MISCELLANEOUS**

**16.1 Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances (except for a strike, lockout or labor disturbance with respect to the non-performing Party's respective employees or agents), fire, floods, earthquakes or other acts of God, or any generally applicable action or inaction by any governmental authority (but excluding any government action or inaction that is specific to such Party, its Affiliates or sublicensees, such as revocation or non-renewal of such Party's license to conduct business), or omissions or delays in acting by the other Party. The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations despite the ongoing circumstances

**16.2 Assignment.** This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, Five Prime may assign its rights to receive payments under this Agreement to one or more Entities without consent of Zai, and either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder (a) in whole or in part to an Affiliate of such Party, or (b) in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets, whether in a merger, acquisition, or similar transaction. Any attempted assignment not in accordance with this Section 16.2 shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

**16.3 Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) that, insofar as practical, implement the purposes of this Agreement.

\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



**16.4 Notices.** All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile or electronic mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Five Prime:

Five Prime Therapeutics, Inc.  
111 Oyster Point Boulevard  
South San Francisco  
California 94080  
USA  
[\*\*\*]  
[\*\*\*]

with a copy to:

Five Prime Therapeutics, Inc.  
111 Oyster Point Boulevard  
South San Francisco  
California 94080  
USA  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

and a copy to (which shall not constitute notice):

Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304-1130  
USA  
[\*\*\*]  
[\*\*\*]

If to Zai:

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

with a copy to:

Ropes & Gray LLP  
800 Boylston Street

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Boston, MA 02199-3600

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\*\*\*]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by electronic mail or facsimile on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth Business Day following the date of mailing if sent by mail.

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

**16.6 Entire Agreement; Amendments.** This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties. The Parties agree that, effective as of the Effective Date, that certain Mutual Non-Disclosure Agreement between Zai and Five Prime dated as of July 9, 2017 (the “**Confidentiality Agreement**”) shall be superseded by this Agreement, and that disclosures made prior to the Effective Date pursuant to the Confidentiality Agreement shall be subject to the confidentiality and non-use provisions of this Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party’s or its Affiliate’s obligations pursuant to the Confidentiality Agreement.

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

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

**16.9 Waiver.** Any waiver of any provision of this Agreement shall be effective only if in writing and signed by Five Prime and Zai. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or

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delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

**16.10 Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

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

**16.12 Business Day Requirements.** In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

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

**16.14 Non-Solicitation of Employees.** After the Effective Date and during the Term, each Party agrees that neither it nor any of its Affiliates shall recruit, solicit or induce any employee of the other Party that such Party knew was directly and substantially involved in the Development or Commercialization activities under this Agreement to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (a) circumstances where an employee of a Party (i) initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (ii) responds to general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements or postings, and (b) discussions, interviews, negotiations, offers or acceptances of employment or similar activities that arise as a result of circumstances described in (a).

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**16.15 Construction.** Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.”

**16.16 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties.

**16.17 Language.** This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

*{Signature Page Follows}*

[\*\*\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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

**FIVE PRIME THERAPEUTICS, INC.**

**ZAI LAB (SHANGHAI) Co., LTD.**

By: /s/ Lewis T. Williams  
Name: Lewis T. Williams  
Title: President & CEO

By: /s/ Samantha Du  
Name: Samantha Du  
Title: CEO

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## List of Exhibits

<b>Schedule 2.3:</b>	<b>[***]</b>
<b>Exhibit A:</b>	<b>Five Prime Patents</b>
<b>Exhibit B:</b>	<b>Structure of FPA144</b>
<b>Exhibit C:</b>	<b>Allocation of Global Costs</b>
<b>Exhibit D:</b>	<b>Joint Press Release</b>

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**Schedule 2.3**

**[\*\*\*]**

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**Exhibit A**  
**Five Prime Patents**

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**Exhibit B**  
**Structure of FPA144**

[\*\*\*]

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## Exhibit C

### Allocation of Global FPA144-004 Study Costs

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**Exhibit D**  
**Joint Press Release**

**Five Prime Therapeutics and Zai Lab Announce Exclusive License Agreement for FPA144 Anti-FGFR2b Antibody in Greater China and Global Strategic Development Collaboration**

*Planned global Phase 3 FIGHT trial in front-line gastric and gastro-esophageal junction cancers to include sites in China where disease incidence is the highest in the world*

SOUTH SAN FRANCISCO, Calif. and SHANGHAI, China, Dec. XX, 2017 -- [Five Prime Therapeutics, Inc.](#) (NASDAQ: FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, and [Zai Lab Limited](#) (NASDAQ: ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced an exclusive license agreement for FPA144 in Greater China and global strategic development collaboration. Five Prime's FPA144 is a first-in-class isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastro-esophageal junction cancer. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually.<sup>1,2</sup> The randomized, controlled Phase 3 portion of the FIGHT trial evaluating FPA144 plus chemotherapy is expected to start in the second half of 2018 and would serve as a global registrational study for the treatment of front-line gastric and gastro-esophageal junction cancers. Zai Lab will manage the Phase 3 portion of the trial in China.

"We believe Zai Lab is the right partner for FPA144 in Greater China for this innovative product," said Aron Knickerbocker, Chief Operating Officer of Five Prime and incoming Chief Executive Officer (effective January 1, 2018). "China accounts for more than 40% of new gastric cancer cases globally<sup>2</sup>, so it is critical to align strategically with a strong collaborator with the infrastructure, relationships and resources to help us advance FPA144 global development expeditiously. Zai Lab is ideally positioned given their experienced leadership team, focus on innovative drugs, and established expertise and network within oncology. We look forward to working with Zai Lab to carry out our worldwide development program for FPA144 and accelerate enrollment in the global Phase 3 portion of the FIGHT trial."

"Five Prime has pioneered the development of some very exciting and highly-targeted antibodies, including FPA144, which we believe holds tremendous promise for cancer patients in Greater China. We are committed to working with Five Prime to accelerate the global development timelines for this important investigational therapy," stated Samantha Du, Chairman and CEO of Zai Lab. "This strategic collaboration highlights the strength of our team and business model as the partner of choice in China and in delivering innovative therapies to patients in China and beyond."

Under the terms of the agreement, Five Prime has granted Zai Lab an exclusive license to develop and commercialize FPA144 in the Greater China territory: China, Hong Kong, Macau, and Taiwan. Zai Lab will be responsible for conducting the Phase 3 FIGHT trial in Greater China, including screening, enrollment and treatment of patients, and for commercialization of FPA144 in the Greater China territory. Five Prime will manufacture and supply FPA144 for the study. A Joint Steering Committee will be formed between the companies to oversee development, regulatory and commercialization activities in greater China. Five Prime will

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receive a \$5 million upfront payment and is eligible to receive up to \$39 million in development and regulatory milestone payments. Five Prime is also eligible to receive from Zai Lab a royalty percentage on net sales of FPA144 in Greater China ranging from the high teens to the low twenties. Given the strategic importance of China to the development and commercialization of FPA144 and to align the interests of the two companies globally, Zai Lab is also eligible to receive a low single-digit royalty from Five Prime on net sales of FPA144 outside of Greater China.

“Gastric cancer is the fifth most common cancer in the world and the second most common in China. Patients whose tumors overexpress FGFR2b or have *FGFR2* gene amplification have an especially poor prognosis,” said Dr. Shukui Qin, the Executive Member of the Asian Clinical Oncology Society, Senior Vice President of Chinese Society of Clinical Oncology and the Director of Cancer Center of People’s Liberation Army. “I am encouraged that we may be able to identify those patients with companion diagnostics and potentially treat them more effectively with a highly targeted therapy like FPA144. There is a critical need for more effective and safe therapies for gastric cancer patients here, so I am pleased that I and my fellow oncologists throughout China can play an important role in the FIGHT trial.”

#### **About FPA144**

FPA144 is an isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family. FPA144 has also been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells.

FPA144 is being evaluated as a potential treatment for gastric cancer and bladder cancer. In a Phase 1 trial, FPA144 demonstrated monotherapy activity in heavily pre-treated patients with FGFR2b-positive gastric cancer and did not exhibit certain toxicities that have been seen with less selective FGFR2 small molecule therapeutics. An estimated 10% patients with gastric cancer have tumors that overexpress FGFR2b or have FGFR2 gene amplification, which is associated with poor prognosis.

#### **About Five Prime**

Five Prime Therapeutics, Inc. (NASDAQ:FPRX) discovers and develops innovative therapeutics to improve the lives of patients with serious diseases. Five Prime's comprehensive discovery platform, which encompasses virtually every medically relevant extracellular protein, positions it to explore pathways in cancer, inflammation and their intersection in immuno-oncology, an area with significant therapeutic potential and a growing focus of the company's R&D activities. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and late preclinical development. For more information, please visit [www.fiveprime.com](http://www.fiveprime.com).

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## About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and global unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

## Five Prime Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Five Prime's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements about (i) the timing of the initiation, progress and scope of the FIGHT clinical trial; (ii) the potential use of FPA144 to treat patients with gastric and gastro-esophageal junction cancer; (iii) the extent of *FGFR2* gene amplification and FGFR2b protein overexpression in patients with gastric and gastro-esophageal junction cancer; and (iv) Five Prime's potential receipt of milestone payments and royalties. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Five Prime's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as required by law, Five Prime assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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## **Zai Lab Forward-Looking Statements**

This press release includes certain disclosures which contain “forward-looking statements,” including, without limitation, statements regarding the timing of the initiation, progress and scope of the FIGHT clinical trial, the potential use of FPA144 to treat patients with gastric and gastro-esophageal junction cancer, Five Prime's potential receipt of milestone payments and royalties from Zai Lab and Zai Lab's potential receipt of royalties from Five Prime. You can identify forward-looking statements because they contain words such as “believes” and “expects.” Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's filings with the Securities and Exchange Commission. Zai Lab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

## **REFERENCES:**

1 Translational Gastrointestinal Cancer, Vol 2, Supplement 1 (June 2013); *A current view of gastric cancer in China*, Zhaode Bu, Jiafu Ji

2 CA: A Cancer Journal for Clinicians, 25 January 2016; *Cancer statistics in China, 2015*, Wanqing Chen et al

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**THIRD AMENDED AND RESTATED FOUNDER EMPLOYMENT AGREEMENT**

THIS THIRD AMENDED AND RESTATED FOUNDER EMPLOYMENT AGREEMENT (“**Agreement**”) is made and entered into as of November 10, 2017 (the “**Effective Date**”), by and between Zai Lab Limited, a limited company incorporated under the laws of the Cayman Islands (the “**Company**”), and Samantha (Ying) Du, an individual (the “**Founder**”).

**WHEREAS**, the Company and the Founder previously entered into that certain Second Amended and Restated Founder Employment Agreement dated as of February 3, 2017 (the “**Existing Agreement**”); and

**WHEREAS**, the Company and the Founder desire to amend and replace the Existing Agreement in its entirety with the terms and conditions set forth in this Agreement.

**NOW, THEREFORE**, in consideration of the mutual covenants and obligations hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. **Employment.** The Founder’s employment under the terms of this Agreement will commence as of the Effective Date and will continue until terminated in accordance with Section 4 (the “**Employment Period**”).

1.1. Duties and Responsibilities. The Company agrees to employ the Founder as the Chairperson and Chief Executive Officer of the Company, to render such services and to perform such duties and responsibilities as are normally associated with and inherent in the aforementioned role and the capacity in which the Founder is employed, as well as such other duties and responsibilities as shall from time to time be assigned to the Founder by the Board of Directors of the Company (the “**Board**”).

1.2. Acceptance of Employment. The Founder accepts such employment set out in Section 1.1 and agrees to faithfully perform and render the services required of the Founder under this Agreement. Except for reasonable vacations, absences due to temporary illness, and activities that may be mutually agreed to by the parties, the Founder shall devote substantially all of her time, attention and energies during normal business hours and such evenings and weekends as may be reasonably required for the discharge of her duties to the Company and the performance of the Founder’s duties and responsibilities under this Agreement.

1.3. Positions with Subsidiaries/Affiliates. If requested by the Board and agreed upon by the Founder, the Founder agrees to serve without additional compensation if elected, nominated or appointed as an officer and/or director of the Company and any of the subsidiaries or affiliates of the Company and in one or more executive offices of any of the subsidiaries or affiliates of the Company, provided that the Founder is indemnified for serving in any and all such capacities pursuant to the indemnification provisions set forth in the bylaws of such subsidiaries and/or affiliates.

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1.4. **Conflicts of Interest.** The Founder has reviewed with the Board the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Founder or her associate(s) in all such business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Founder agrees to review with the Board any potential directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles with business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Founder or her associate(s) is precluded from owning an interest (legal and beneficial, direct and indirect) in another company or serving as an employee, director, consultant, advisor or member of such other company that may be directly competitive or directly in conflict with the Company until such interest is presented to the Board and the Board consents to such interest or employment. The Company further acknowledges and agrees that, subject to the prior written approval by a majority of the Board (which majority shall exclude the Founder if the Founder is a then-current member of the Board) and consistent with the terms of the Compliance Agreement (as defined below), the Founder may serve on the boards of directors and advisory boards of other companies which are not in direct competition or not in direct conflict with the Company and its subsidiaries and affiliates, provided that such service does not interfere with the performance of the Founder's duties hereunder. Notwithstanding any of the foregoing, the Founder's interest in, and affiliation with, Quan Venture Fund I, LP, and its affiliates is not deemed to conflict with her responsibilities to the Company or interfere with her performance of her duties hereunder.

2. **Reserved.**

3. **Compensation, Benefits and Expense Reimbursements.**

3.1. **Base Salary.** In consideration for the agreement of the Founder to be employed under this Agreement, during the Employment Term, the Founder shall receive from the Company an annual base salary (as it may be adjusted from time to time, the "**Base Salary**") of US\$620,000, with the understanding that, at the sole discretion of the Company, up to an aggregate of (a) fifty percent (50%) of the Base Salary may be paid by the Company or one or more subsidiaries of the Company domiciled in the Cayman Islands (each such subsidiary, a "**Cayman Subsidiary**"), (b) thirty percent (30%) of the Base Salary may be paid by one or more subsidiaries of the Company domiciled in the People's Republic of China (each, a "**PRC Subsidiary**"), and (c) twenty percent (20%) of the Base Salary may be paid by one or more subsidiaries of the Company domiciled in the United States (each, a "**U.S. Subsidiary**"), in each case, pursuant to a short-form labor contract between the Founder and such Cayman Subsidiary, PRC Subsidiary, or U.S. Subsidiary, as applicable, identified by the Company, to the extent required by or desirable under applicable laws. The Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service or similar organization. The Company shall pay such Base Salary in arrears on the last working day (Monday to Friday) of each month in accordance with the standard payroll procedures of the Company (as they may be modified from time to time). The Base Salary will be subject to review by the Board or the Compensation Committee of the Board (the "**Compensation Committee**") and adjustments will be made by the Board or the Compensation Committee based upon its respective normal performance review practices.



3.2. Stock Options. During the Employment Period, the Founder may, from time to time, be entitled to receive options to purchase ordinary shares of the Company or its affiliates and other equity-based incentives as and when determined by the Board or the Compensation Committee, in its respective sole and exclusive discretion.

3.3. Bonus. During the Employment Period, the Founder may be entitled to receive an annual bonus with a target equal to 70% of the Base Salary (the “**Target Bonus**”), the actual amount of which shall be determined by the Board or the Compensation Committee in its respective discretion. Any annual bonus earned hereunder shall be paid not later than March 15<sup>th</sup> following the end of the calendar year to which it relates and otherwise in accordance with the Company’s bonus plan as in effect from time to time. The Company’s current practice, which is subject to change, is to pay annual bonuses to employees in January of the calendar year following the calendar year to which the annual bonus relates.

3.4. Fringe Benefits. During the Employment Period, the Founder will be entitled to the fringe benefits that are made available to employees of the Company and such other benefits as are determined by the Board or the Compensation Committee, in its respective sole and exclusive discretion, it being understood that the Founder shall continue to receive the fringe benefits provided under the Existing Agreement.

3.5. Reimbursements. During the Employment Period, the Founder will be reimbursed, in accordance with the practice applicable to employees of the Company from time to time, for all reasonable traveling expenses and other disbursements incurred by her for or on behalf of the Company in the performance of her duties hereunder upon presentation by the Founder of appropriate documentation.

3.6. Deductions. Recognizing that the Founder is an employee for all purposes, the Company or a subsidiary of the Company shall deduct from any compensation payable to the Founder the sums which the Company or such subsidiary is required by law to deduct, including, but not limited to, government state withholding taxes, social security taxes and state disability insurance and mandatory provident funds, and the Company or such subsidiary shall pay any amounts so deducted to the applicable governmental entities and agents entitled to receive such payments.

#### 4. Termination of Employment.

4.1. Death or Disability. If the Founder dies during the Employment Period, the Founder’s employment by the Company hereunder shall automatically terminate on the date of the Founder’s death. If, during the Employment Period, the Founder is incapacitated or disabled by accident, sickness or otherwise so as to render her mentally or physically incapable of performing the services required to be performed by her under this Agreement for a period of ninety (90) consecutive days or longer, or for ninety (90) days during any six- (6-) month period (such condition being herein referred to as “**Disability**”), the Company, at its option, may terminate the Founder’s employment under this Agreement immediately upon giving her notice to that effect. In the case of a Disability, until the Founder becomes eligible for disability income under the Company’s disability income insurance (if any) or until the Company terminates the Founder’s employment in accordance with the foregoing, whichever occurs first, the Founder

will be entitled to receive compensation, at the rate and in the manner provided in Section 3.1, notwithstanding any such physical or mental disability. Termination pursuant to this Section 4.1 is referred to in this Agreement as a “**Death/Disability Termination**”.

(a) Substitution. The Board may designate another employee to act in the Founder’s place during any period of Disability suffered by the Founder during the Employment Period. Notwithstanding any such designation, the Founder shall continue to receive the Base Salary and benefits in accordance with Section 3 of this Agreement until the Founder becomes eligible for disability income under the Company’s disability income insurance (if any) or until the termination of the Founder’s employment, whichever occurs first.

(b) Disability Income Payments. While receiving disability income payments under the Company’s disability income insurance, if any (the “Disability Payments”), the Founder shall remain entitled to receive the Base Salary under Section 3.1, which shall be reduced by any Disability Payments received by the Founder, and shall continue to participate in all other compensation and benefits in accordance with Sections 3.2, 3.3 and 3.4 until the date of the Founder’s termination of employment.

(c) Verification of Disability. If any question arises as to whether during any period the Founder is disabled through any illness, injury, accident or condition of either a physical or psychological nature so as to be unable to perform substantially all of the Founder’s duties and responsibilities hereunder, the Founder may, and at the request of the Company shall, submit to a medical examination by a physician selected by the Company to whom the Founder or the Founder’s guardian has no reasonable objection to determine whether the Founder is so disabled and such determination shall for the purposes of this Agreement be conclusive of the issue. If such question arises and the Founder fails to submit to such medical examination, the Company’s determination of the issue shall be binding on the Founder.

4.2. Termination by the Company for Cause. The Company, on recommendation from the Board (excluding the Founder if the Founder is a then current member of the Board), may terminate the employment of the Founder hereunder at any time during the Employment Period for Cause (as defined below) (such termination being referred to in this Agreement as a “**Termination for Cause**”) by giving the Founder notice of such termination, upon the giving of which such termination shall take effect immediately. For the purpose of this Agreement, “**Cause**” means any one of the following grounds:

(a) repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the Founder’s obligations and duties to or for the Company;

(b) the Founder’s conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws;

(c) gross mismanagement by the Founder of the business and affairs of the Company or any subsidiary or affiliate of the Company which directly results in a material loss to the Company and for which the Company has reasonable proof was committed by the Founder;

(d) material violation of any material terms of this Agreement or the Compliance Agreement (as defined below); or

(e) a conclusive finding by an independent fact finder appointed by the Board of any willful misconduct, dishonesty or acts of moral turpitude by the Founder which is materially detrimental to the interests and well-being of the Company and its subsidiaries and affiliates, including, without limitation, harm to its business or reputation.

4.3. Termination by the Company without Cause. The Company, on recommendation from the Board (excluding the Founder if the Founder is a then-current member of the Board), may terminate the employment of the Founder hereunder other than for Cause at any time upon thirty (30) days advance written notice to the Founder (such termination being referred to in this Agreement as a “**Termination without Cause**”).

4.4. Termination by the Founder for Good Reason. The Founder may terminate her employment hereunder at any time for Good Reason (as defined below) by giving the Company written notice of such termination, provided that such notice specifies: (a) the basis for termination and (b) the effective date of termination (such termination being referred to in this Agreement as a “**Termination for Good Reason**”). For purposes of this Agreement, the term “**Good Reason**” shall mean (i) any material diminution of the Founder’s duties or responsibilities hereunder (except in each case in connection with the Termination for Cause or pursuant to Section 4.1) or the assignment to the Founder of duties or responsibilities that are materially inconsistent with the Founder’s then current position; (ii) any material breach of this Agreement by the Company which is not cured within ten (10) business day days after written notice thereof is given to the Company; or (iii) a relocation of the Founder (other than any relocation requested by the Founder) from the place of assignment of the Founder by the Company as of the Effective Date to a location more than thirty (30) kilometers from such location, other than on a temporary basis not to exceed a period equal to six (6) consecutive calendar months.

4.5. Termination by the Founder without Good Reason. The Founder may terminate her employment hereunder without Good Reason at any time upon reasonable notice by the Founder to the Board of no fewer than thirty (30) calendar days (such termination being referred to in this Agreement as a “**Termination without Good Reason**”).

## 5. Effect of Termination.

### 5.1. Termination for Cause or without Good Reason.

(a) Upon the termination of the Founder’s employment hereunder pursuant to a Termination for Cause or a Termination without Good Reason, neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the “**Final Compensation**”):

- (i) the unpaid portion of the Base Salary provided for in Section 3.1, computed on a pro rata basis up to (and including) the effective date of such termination;

(ii) reimbursement for any expenses for which the Founder has not been reimbursed as provided in Section 3.5, provided that that the Founder submits all such expenses and required supporting documentation within sixty (60) days of the effective date of such termination; and

(iii) any additional compensation as may be expressly required under applicable law.

(b) Final Compensation (other than any expense reimbursement, which shall be paid within thirty (30) days after such reimbursement is submitted in accordance with subsection (ii) above) will be paid to the Founder within thirty (30) days following the date of termination (or such shorter period required by law).

5.2. Termination upon Death or Disability.

(a) Upon the termination of the Founder's employment hereunder pursuant to a Death/Disability Termination, neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following:

(i) Final Compensation in accordance with Section 5.1; and

(ii) an aggregate amount equal to one (1) months' Base Salary plus an amount equal to one month of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder, payable in accordance with the Company's normal payroll practices, subject to Sections 5.5 and 14.3.

(b) Notwithstanding anything to the contrary in any agreement between the Founder and the Company, upon a Death/Disability Termination, the Founder, or her beneficiaries or estate (as applicable), will be entitled to one hundred percent (100%) accelerated vesting of any then-outstanding unvested stock options, restricted stock or other equity awards granted to the Founder by the Company, subject to Sections 5.5 (in the case of a termination by the Company due to Disability) and 14.3.

5.3. Termination without Cause or for Good Reason.

(a) Upon the termination of the Founder's employment hereunder pursuant to a Termination without Cause or a Termination for Good Reason, neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to eighteen (18) months' Base Salary; and

(iii) an aggregate payment equal to eighteen (18) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder.

(b) Subject to Sections 5.5 and 14.3, Severance Payments (other than Final Compensation) will be provided in the form of salary continuation, payable in equal installments in accordance with the Company's normal payroll practices during the eighteen- (18) month period following the effective date of the termination of the Founder's employment, provided that the first such payment will be made on the next regular pay day following the date on which the Release of Claims (as defined below) becomes effective and irrevocable and will be retroactive to effective date of the termination of the Founder's employment.

(c) Notwithstanding anything to the contrary in any agreement between the Founder and the Company, upon a Termination without Cause or a Termination for Good Reason, the Founder will be entitled to one hundred percent (100%) accelerated vesting of any then-outstanding invested stock options, restricted stock or other equity awards granted to the Founder by the Company, subject to Sections 5.5 and 14.3.

#### 5.4. Change in Control Termination.

(a) Upon the termination of the Founder's employment hereunder pursuant to a Termination without Cause or a Termination for Good Reason within twelve (12) months following a Change in Control (such termination being referred to in this Agreement as a "**Change in Control Termination**"), neither the Founder nor her beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive the following (in the aggregate, the "**Enhanced Severance Payments**"):

(i) Final Compensation in accordance with Section 5.1;

(ii) an aggregate payment equal to eighteen (18) months' Base Salary;

(iii) an aggregate payment equal to eighteen (18) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder; and

(iv) a payment equal to the sum of (x) six (6) months' Base Salary, (y) two times the Target Bonus and (z) six (6) months of the Company's portion of monthly premiums payable immediately prior to the effective date of such termination with respect to health, dental, and vision insurance coverage for the Founder.

(b) Subject to Sections 5.5 and 14.3, other than Final Compensation, Enhanced Severance Payments will be paid as follows: (i) the amounts under Section 5.4(a)(ii) and Section 5.4(a)(iii) will be provided in the form of salary continuation, payable in equal installments in accordance with the Company's normal payroll practices during the eighteen- (18-) month period following the effective date of the termination of the Founder's employment, provided that the first such payment will be made on the next regular pay day following the date on which the Release of Claims (as defined below) becomes effective and irrevocable and will be retroactive to effective date of the termination of the Founder's employment, and (ii) the amount under Section 5.4(a)(iv) will be paid in a lump sum on the next regular pay day following the date on which the Release of Claims (as defined below) becomes effective and irrevocable.

(c) Notwithstanding anything to the contrary in any agreement between the Founder and the Company, upon a Change in Control Termination, the Founder will be entitled to one hundred percent (100%) accelerated vesting of any then-outstanding unvested stock options, restricted stock or other equity awards granted to the Founder by the Company, subject to Sections 5.5 and 14.3.

(d) For purposes of this Agreement, "**Change in Control**" means the occurrence of any of the following:

(i) any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than 50% of the total voting power of the stock of the Company, except that any change in the ownership of the stock of the Company as a result of a private financing of the Company that is approved by the Board will not be considered a Change in Control;

(ii) a majority of members of the Board is replaced during any twelve- (12-) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election; or

(iii) any Person acquires (or has acquired during the twelve- (12-) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 50% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions. For purposes of this subsection (iii), gross fair market value means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company. Further and for the avoidance of doubt, a transaction will not constitute a Change in Control if: (i) its sole purpose is to re-domicile the Company in a jurisdiction other than its original jurisdiction of incorporation, or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. With regard to any payment considered to be nonqualified deferred compensation under Section 409A (as defined below), to the extent applicable, that is payable upon a Change in Control, to avoid the imposition of an additional tax, interest or penalty under Section 409A (as defined below), no amount will be payable unless such change in control constitutes a "change in control event" within the meaning of Section 1.409A-3(i)(5) of the Treasury Regulations.

5.5. **Conditions to Receipt of Severance.** The receipt of any payments and benefits pursuant to Sections 5.2 – 5.4 (other than Final Compensation) is conditioned on the Founder signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release of Claims**"), provided that such separation agreement and release of claims becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the "**Release Deadline**"). If the Release of Claims does not become effective by the Release Deadline, the Founder will forfeit any rights to severance or benefits (other than Final Compensation) under this Agreement. In no event will severance payments or benefits (other than Final Compensation) be paid or provided under this Agreement until such Release of Claims becomes effective and irrevocable. If the sixty- (60-) day period following termination referred to herein extends through two (2) taxable years, to the extent required to comply with Section 409A, such amount will be paid in the second taxable year (but within the sixty- (60-) day period) following the Founder's termination.

6. **Compliance Agreement.** The Founder agrees that the Agreement Regarding Confidentiality, Trade Secrets, Intellectual Property and Competitive Activities previously executed by the Founder (the "**Compliance Agreement**") remains in full force and effect.

7. **Standards of Conduct.** The Founder will conduct herself in an ethical and professional manner at all times and in accordance with any employee policies or guidelines which the Company may issue from time to time.

8. **Indemnification.**

8.1. **Indemnification.** In the event that (a) the Founder was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Founder's Corporate Status (as defined below) or (b) the Founder was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Founder's Corporate Status, the Founder shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by the Founder in connection with such Proceeding to the maximum extent permitted by applicable law (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution

process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitral or investigative, whether formal or informal, (ii) “**Corporate Status**” means the status of the Founder as an employee and/or director of the Company, as applicable, (iii) “**Expenses**” means all fees, costs and expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys’ fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants, counsels and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) “**Liabilities**” means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

8.2. **Advancement of Expenses.** The Company agrees that the Company shall pay to the Founder all Indemnifiable Amounts incurred by the Founder in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Founder provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Founder is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

8.3. **Limitation on Indemnification.** The Founder shall not be entitled to any indemnification under this **Section 8** if the Founder knowingly violated any duty, responsibility or obligation imposed under this Agreement, the Compliance Agreement or any Company policy.

8.4. **Change in Law.** To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Founder shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

9. **Representations and Warranties of the Company.** The Company represents and warrants to the Founder that the execution of this Agreement by the Company has been duly authorized by resolution of the Board.

10. **Representations and Warranties of the Founder.** The Founder represents and warrants to the Company that: (i) the Founder has the proper skill, training and background so as to be able to perform under the terms of this Agreement in a competent and professional manner; (ii) the Founder will not infringe any intellectual property rights including patent, copyright, trademark, trade secret or other proprietary right of any person; and (iii) the Founder will not use any trade secrets or confidential information for purposes other than for the furtherance of the business of the Company and will not use any trade secrets or confidential information owned by any third party.

11. **Enforcement.** It is the desire and intent of the parties hereto that the provisions of this Agreement will be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, to the extent



that a restriction contained in this Agreement is more restrictive than permitted by the laws of any jurisdiction whose law may be deemed to govern the review and interpretation of this Agreement, the terms of such restriction, for the purpose only of the operation of such restriction in such jurisdiction, will be the maximum restriction allowed by the laws of such jurisdiction and such restriction will be deemed to have been revised accordingly herein. A court having jurisdiction over an action arising out of or seeking enforcement of any restriction contained in this Agreement may modify the terms of such restriction in accordance with this Section 11.

12. **Dispute Resolution.** In the event the parties hereto are unable to settle a dispute between them regarding this Agreement through friendly consultation, such dispute shall be referred to and finally settled by arbitration administered by JAMS in accordance its Employment Arbitration Rules & Procedures (the “**Arbitration Rules**”) in effect, which rules are deemed to be incorporated by reference into this Section 12 applying the laws of the State of New York, without regard to any principles of conflicts of laws that would result in the application of the laws of another jurisdiction. The arbitration tribunal shall consist of three (3) arbitrators to be appointed according to the Arbitration Rules (the “**Arbitration Board**”). The Arbitration Board shall decide any such dispute or claim strictly in accordance with the governing law specified in Section 14.6. Judgment upon any arbitral award rendered hereunder may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The costs and expenses of the arbitration, including the fees of the Arbitration Board, shall be borne equally by each party to the dispute or claim, and each party shall pay its own fees, disbursements and other charges of its counsel; provided that the Arbitration Board shall have the right to allocate the costs and expenses between each party as the Arbitration Board deems equitable. Any award made by the Arbitration Board shall be final and binding on each of the parties that were parties to the dispute. The parties expressly agree to waive the applicability of any laws and regulations that would otherwise give the right to appeal the decisions of the Arbitration Board so that there shall be no appeal to any court of law for the award of the Arbitration Board, and a party shall not challenge or resist the enforcement action taken by any other party in whose favor an award of the Arbitration Board was given. Notwithstanding this agreement to arbitrate, the parties agree that either party may seek provision remedies such as a temporary restraining order or a preliminary injunction from a court of competent jurisdiction in aid of arbitration. As a material part of this agreement to arbitrate claims, the parties expressly waive all rights to a jury trial in court on all statutory or other claims. The parties acknowledge and agree that no claims will be arbitrated on a class action or collective action basis.

13. **Covenant Against Assignment.** The Founder may not assign any rights or delegate any of the duties of the Founder under this Agreement. As used in this provision, “assignment” and “delegation” shall mean any sale, gift, pledge, hypothecation, encumbrance, or other transfer of all or any portion of the rights, obligations, or liabilities in or arising from this Agreement to any person or entity, whether by operation of law or otherwise, and regardless of the legal form of the transaction in which the attempted transfer occurs.

14. **Miscellaneous.**

14.1. **Notices.** Any notice, request, demand or other communication required or permitted to be given to a party pursuant to the provisions of this Agreement will be in writing and will be effective and deemed given under this Agreement on the earliest of: (i) the date of personal delivery, (ii) the date of transmission by facsimile or e-mail, with confirmed

transmission and receipt, (iii) two (2) days after deposit with an internationally-recognized courier or overnight service such as Federal Express or DHL, or (iv) five (5) days after mailing via certified mail, return receipt requested. All notices not delivered personally or by facsimile will be sent with postage and other charges prepaid and properly addressed to the party to be notified at the address set forth on the signature pages hereto.

14.2. Time. Time is of the essence in performance of the rights and obligations under this Agreement.

14.3. Section 409A. Notwithstanding anything to the contrary in this Agreement, if at the time the Founder's employment terminates, the Founder is a "specified employee," as defined below, any and all amounts payable under this Agreement on account of such separation from service that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next business day following the expiration of such six- (6-) month period or, if earlier, upon the Founder's death; except (a) to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury regulation Section 1.409A-1(b) (including without limitation by reason of the safe harbor set forth in Section 1.409A-1(b)(9)(iii), as determined by the Company in its reasonable good faith discretion); (b) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (c) other amounts or benefits that are not subject to the requirements of Section 409A of the Internal Revenue Code of 1986, as amended ("**Section 409A**"). For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a "separation from service" (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term "specified employee" means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

14.4. Survival. The provisions set forth in Sections 5, 6, 8, 11, 12 and 14 of this Agreement (and any other provisions necessary to give effect to such provisions) shall survive the termination of this Agreement.

14.5. Binding Agreement; Benefit. The provisions of this Agreement will be binding upon and will inure to the benefit of the respective heirs, legal representatives and successors of the parties hereto.

14.6. Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the State of New York, without giving effect to its principles or rules of conflict laws to the extent such principles or rules would require or permit the application of the laws of another jurisdiction.

14.7. Waiver of Breach. The waiver by either party of a breach of any provision of this Agreement by the other party must be in writing and will not operate or be construed as a waiver of any subsequent breach by such other party.

14.8. Entire Agreement; Amendments. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements or understanding among the parties with respect thereto, including, without limitation, the Existing Agreement. This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

14.9. Headings. The Section headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

14.10. Severability. Subject to the provisions of Section 11 above, any provision of this Agreement that is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction.

14.11. Assignment. This Agreement is personal in its nature and the parties hereto shall not, without the consent of the other party hereto, assign or transfer this Agreement or any rights or obligations hereunder; provided, however, that the rights and obligations of the Company hereunder shall be assignable and delegable in connection with any subsequent merger, consolidation, sale of all or substantially all of the assets or shares of the Company or similar transaction involving the Company or a successor corporation.

14.12. Further Assurances. The Founder agrees to execute, acknowledge, seal and deliver such further assurances, documents, applications, agreements and instruments, and to take such further actions, as the Company may reasonably request in order to accomplish the purposes of this Agreement.

14.13. Costs. Each of the parties shall pay all costs and expenses incurred or to be incurred by such party in negotiating and preparing this Agreement and in closing and carrying out the transactions contemplated by this Agreement.

14.14. Interpretation of Agreement. This Agreement has been negotiated at arm's length between persons knowledgeable in the matters dealt with in this Agreement. In addition, each party has been represented by experienced and knowledgeable legal counsel. Accordingly, any rule of law, or any legal decision that would require interpretation of any ambiguities in this Agreement against the party that has drafted it, is of no application and is waived.

14.15. Counterparts. The parties may execute this Agreement in any number of counterparts and, as so delivered, the counterparts shall together constitute one and the same document. The parties agree that each such counterpart is an original and shall be binding upon all of the parties, even though all of the parties are not signatories to the same counterpart.

14.16. No Third-Party Rights. Nothing in this Agreement is intended to grant to any third party (other than the parties' respective successors in title and permitted assigns) any right to enforce any term of this Agreement or to confer on any third party (other than the parties' respective successors in title and permitted assigns) any benefits under this Agreement. No person who is not a party to this Agreement shall have any right to enforce any term of this Agreement.



IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

ZAI LAB LIMITED

FOUNDER:

By: /s/ Peter Wirth  
Peter Wirth  
Title: Chairman, Compensation Committee

By: /s/ Samantha Du  
Samantha (Ying) Du

Address:  
4560 Jinke Road, Bldg. 1, 4F  
Pudong, Shanghai, 201210, China

Address:  
On File with the Company

December 11, 2017

Samantha (Ying) Du c/o Zai Lab  
Limited 4560 jinke Road, Bldg. 1,4F  
Pudong, Shanghai, 201210, China

Dear Samantha:

This letter agreement (the “Agreement”) shall serve to supplement the terms and conditions of that certain Third Amended and Restated Founder Employment Agreement between you and Zai Lab Limited (the “Company”) dated November 10, 2017 (the “Founder Agreement”).

Section 3.1 of the Founder Agreement provides that up to 20% of your Base Salary (as defined in the Founder Agreement) may be paid to you by one or more subsidiaries of the Company domiciled in the United States. Subject to the terms and conditions prescribed herein, this Agreement confirms that, should you provide services to Zai Lab (US) LLC, a Delaware limited liability company and a subsidiary of the Company (the “U.S. Subsidiary”) during the Employment Period (as defined in the Founder Agreement), the U.S. Subsidiary shall be responsible for and shall pay that portion of your Base Salary, not to exceed 20% of your Base Salary, that reflects the time, attention and energies that you spend in providing such services to the U.S. Subsidiary, as determined by the Company in its sole discretion (the “U.S. Salary”).

The U.S. Salary paid by the U.S. Subsidiary under this Agreement shall be reduced by any tax or other amounts required to be withheld by the U.S. Subsidiary under applicable law. In addition and for the avoidance of doubt, any U.S. Salary paid pursuant to this Agreement in any year during the Employment Period shall serve to reduce the Base Salary to which you are otherwise entitled under the Founder Agreement for such year so that you shall receive no more than the Base Salary for any year of the Employment Period.

Except as provided herein, this Agreement shall not otherwise serve to alter the terms and conditions of the Founder Agreement, which shall continue to apply in full force and effect.

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If the foregoing is acceptable to you, please sign this Agreement in the space provided and return it to the Company no later than December 15, 2017.

Sincerely yours,

Zai Lab Limited

Zai Lab (US) LLC

By: /s/ Peter Wirth

By: /s/ Mandy Li

Peter Wirth

Mandy Li

Chairman, Compensation Committee

Authorized Signatory

Accepted and Agreed:

/s/ Samantha Du

Samantha (Ying) Du

**EMPLOYMENT AGREEMENT**

William Ki Chul Cho

THIS EMPLOYMENT AGREEMENT (“**Agreement**”) is made and entered into on March 2, 2018 (the “**Effective Date**”), by and between Zai Lab (Hong Kong) Ltd., a limited company incorporated under the laws of Hong Kong whose registered office is at Room 1902, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong (the “**Company**”), and William Ki Chul Cho, an individual (the “**Employee**”) whose correspondence address is XXX and whose US passport number is XXX.

**RECITALS**

The Company is engaged in the business of researching, developing, manufacturing, commercialization of drug products in the pharmaceutical industry, including and without limitation to sales and marketing of both small molecule and large molecule therapeutics (the “**Business Of The Company**”), and the Employee is qualified to engage in providing such services contemplated under this Agreement.

**AGREEMENT**

NOW, THEREFORE, in consideration of the promises and the respective covenants and agreements of the parties, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **EMPLOYMENT.** From the Effective Date and throughout the time for which the Employee’s employment under this Agreement is not terminated, the Company agrees to continue the employment of the Employee and the Employee agrees to continue employment with the Company.

1.1. **Employment by Company.** The Company agrees to employ the Employee as the Chief Financial Officer of the Company, to render such services and to perform such duties and responsibilities as are normally associated with and inherent in the aforementioned role and the capacity in which the Employee is employed, as well as such other duties and responsibilities as shall from time to time be assigned to the Employee by the Chief Executive Officer of the Company. The Employee shall report directly to the Chief Executive Officer of the Company or such other senior executive officer of the Company as designated by the Chief Executive Officer or the Board of Directors of the Company.

1.2. **Acceptance of Employment.** The Employee accepts such employment set out in Section 1.1 and agrees to faithfully perform and render the services required of the Employee under this Agreement. Except for activities that may be mutually agreed to by the parties and other absences consistent with the policies of the Company then in effect, the Employee shall devote his entire business time, attention and energies as may be reasonably required for the discharge of his duties to the Business Of The Company and the performance of the Employee’s duties and responsibilities under this Agreement.

1.3. **Positions with Subsidiaries.** If requested by the Company and agreed upon by the Employee, the Employee agrees to serve without additional compensation if elected, nominated or appointed as an officer and/or director of the Company and any of the subsidiaries or affiliates of the Company and in one or more executive offices of any of the subsidiaries of the Company, provided that the Employee is indemnified for serving in any and all such capacities pursuant to the indemnity provisions set forth in the bylaws of such subsidiaries and/or affiliates.

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1.4. Conflicts of Interest. The Employee has reviewed with the board of directors of the Company (the “**Board**”) the present directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles held by the Employee or his associate(s) in all such business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Employee agrees to review with the Board any potential directorships, ownership (legal and beneficial, direct and indirect) interests and other positions or roles with business organizations or arrangements which may be directly competitive or directly in conflict with the Company. The Employee or his associate(s) is precluded from owning an interest (legal and beneficial, direct and indirect) in another company or serving as an employee, director, consultant, advisor or member of such another company that may be directly competitive or directly in conflict with the Company until such interest is presented to the Board and the Board consents to such interest or employment. The Company further acknowledges and agrees that, subject to the prior written approval by a majority of the Board (which majority shall exclude the Employee if the Employee is a then current member of the Board) and consistent with the terms of the Compliance Agreement (as defined below), the Employee may serve on the boards of directors and advisory boards of other companies which is not in direct competition or not in direct conflict with the Company provided that such service does not interfere with the performance of the Employee’s duties hereunder.

2. **PLACE OF PERFORMANCE**. The Employee shall discharge his responsibilities at such corporate locations of the Parent Company as is reasonably determined by the Chief Executive Officer, with the understanding that during the 2018 calendar year the Employee shall divide his business time between the global corporate headquarters of the Parent Company in Shanghai, China , and the Company’s Hong Kong office, with the understanding that the Employee will try to relocate to Shanghai, China, no later than January 1, 2019. The Company may require that the Employee travel in furtherance of the Business Of The Company to the extent necessary and/or substantially consistent with the then present business travel obligations of employees at substantially the same service level as the Employee.

3. **COMPENSATION BENEFITS AND EXPENSE REIMBURSEMENTS**.

3.1 Base Salary. In consideration for the agreement of the Employee to be employed under this Agreement, the Employee shall receive from the Company an annual base salary (“**Base Salary**”) of US\$400,000. This Base Salary, and all other compensation and reimbursement under the Agreement, may be provided through a human resources service organization, and will be payable in such installments as are applicable to employees of the Company at substantially the same service level as the Employee. The Base Salary to be paid to the Employee will be subject to reduction for payroll tax withholdings legally required (if any) or such other reductions properly and reasonably requested by the Employee. The Company shall pay such Base Salary in arrears on the last working day (Monday to Friday) of each month in accordance with the standard payroll procedures of the Company. The Employee’s Base Salary will be subject to review and adjustments will be made based upon the Company’s normal performance review practices.

3.2 Equity Incentives.

3.2.1 Stock Option. Subject to the approval of the Board, the Employee shall, as soon as practicable following the Employee’s commencement of employment with the Company (and following his execution of the Option Agreement (as defined below)), be granted an option to purchase 400,000 American Depositary Shares (“**ADSs**”) representing ordinary shares of the Parent Company ordinary shares (the “**Option**”) at an exercise price equal to the fair market value of the ADSs on the date of grant in accordance with the Zai Lab Limited 2017 Equity Incentive Plan (the “**Plan**”). The Option so granted shall vest in accordance with the standard

vesting schedule as set out in the Plan, subject to the Employee continuing to provide services to the Company under this Agreement through each applicable date and no notice of termination of employment has been tendered through each applicable date. The Option will be subject to the terms, definitions and provisions of the Plan and the stock option agreement to be entered into by and between the Employee and the Parent Company (the “**Option Agreement**”), both of which documents are incorporated herein by reference.

3.2.2 Restricted Stock. Subject to the approval of the Board, the Employee shall, as soon as practicable following the Employee’s commencement of employment with the Company (and following his execution of the Restricted Stock Agreement (as defined below)), be granted 100,000 American Depositary Shares (“**ADSs**”) representing ordinary shares of the Parent Company (the “**Restricted Stock Grant**”), with the understanding that such Restricted Stock Grant will be made in accordance with the provisions of the Plan and that such Restricted Stock Grant will be subject to vesting requirements as set out in the Plan. The Restricted Stock Grant will be subject to the terms, definitions and provisions of the Plan and the restricted stock agreement to be entered by and between the Employee and the Parent Company (the “**Restricted Stock Agreement**”), both of which documents are incorporated herein by reference.

### 3.3 Bonuses.

3.3.1 Annual Bonus. During the Employment Period, the Employee may be entitled to receive an annual bonus with a target equal to 40% of the Base Salary (the “**Target Bonus**”), the actual amount of which shall be determined by the Board or the Compensation Committee in its respective discretion. Any annual bonus earned hereunder shall be paid not later than March 15th following the end of the calendar year to which it relates and otherwise in accordance with the Company’s bonus plan as in effect from time to time.

3.3.2 Sign-on Bonus. The Employee will be entitled to receive a cash payment of US\$300,000 (the “**Sign-On Bonus**”) on the seven-month anniversary of his continuous employment with the Company, provided that the Employee remains employed with the Company on the date of such anniversary. The Company will withhold all applicable income taxes on such amount, and will pay the net amount to the Employee with the regularly scheduled payroll for such month of payment. In the event that the employee’s employment is terminated by the Company for cause within the three (3) year period following the Effective Date, the Employee will repay to the Company the full amount of the Sign-On Bonus within thirty (30) days following the date of termination. In the event that the Employee resigns from the Company prior to the third anniversary of the Effective Date, he/she will repay to the Company a prorated portion of the Sign-On Bonus based on the number of full and partial months remaining in such three (3) year period as of the date of such termination of employment, with such repayment being made on or prior to the employee’s last working day with the Company.

3.4 Fringe Benefits. During the Employment Period, the Employee will be entitled to the fringe benefits that are made available to employees of the Company and such other benefits as are determined by the Board, in its sole and exclusive discretion.

3.5 Reimbursements. During the Employment Period, the Employee will be reimbursed, in accordance with the practice applicable to employees of the Company from time to time, for all reasonable traveling expenses and other disbursements incurred by him for or on behalf of the Company in the performance of his duties hereunder upon presentation by the Employee of appropriate vouchers.

3.6 Deductions. Recognizing that the Employee is an employee for all purposes, the Company shall deduct from any compensation payable to the Employee the sums which the Company is required by law to deduct, including, but not limited to, government state withholding taxes, social security taxes and state disability insurance and mandatory provident funds, and the Company shall pay any amounts so deducted to the applicable governmental entities and agents entitled to receive such payments.

#### 4. INVOLUNTARY TERMINATION.

4.1 Disability. If the Employee dies, then the Employee's employment by the Company hereunder shall automatically terminate on the date of the Employee's death. If the Employee is incapacitated or disabled by accident, sickness or otherwise so as to render him mentally or physically incapable of performing the services required to be performed by him under this Agreement for a period of ninety (90) consecutive days or longer, or for ninety (90) days during any six (6) month period (such condition being herein referred to as "**Disability**"), the Company, at its option, may terminate the Employee's employment under this Agreement immediately upon giving him notice to that effect. In the case of a Disability, until the Employee becomes eligible for disability income under the Company's disability income insurance (if any) or until the Company shall have terminated the Employee's service in accordance with the foregoing, whichever shall first occur, the Employee will be entitled to receive compensation, at the rate and in the manner provided in Section 3, notwithstanding any such physical or mental disability. Termination pursuant to this Section 4 is hereinafter referred to as an "**Involuntary Termination**".

4.2 Substitution. The Board may designate another employee to act in the Employee's place during any period of Disability suffered by the Employee during the Employment Period. Notwithstanding any such designation, the Employee shall continue to receive the Employee's Base Salary and benefits in accordance with Section 3 of this Agreement until the Employee becomes eligible for disability income under the Company's disability income insurance (if any) or until the termination of the Employee's employment, whichever shall first occur.

4.3 Disability Income Payments. While receiving disability income payments under the Company's disability income insurance (if any), the Employee shall not be entitled to receive any Base Salary under Section 3.1, but shall continue to participate in all other compensation and benefits in accordance with Sections 3.3 until the date of the Employee's termination of employment.

4.4 Verification of Disability. If any question shall arise as to whether during any period the Employee is disabled through any illness, injury, accident or condition of either a physical or psychological nature so as to be unable to perform substantially all of the Employee's duties and responsibilities hereunder, the Employee may, and at the request of the Company shall, submit to a medical examination by a physician selected by the Company to whom the Employee or the Employee's guardian has no reasonable objection to determine whether the Employee is so disabled and such determination shall for the purposes of this Agreement be conclusive of the issue. If such question shall arise and the Employee shall fail to submit to such medical examination, the Company's determination of the issue shall be binding on the Employee.

5. **TERMINATION FOR CAUSE BY THE COMPANY.** The Company, on recommendation from the Board, may terminate the employment of the Employee hereunder at any time during the Employment Period for “Cause” (such termination being hereinafter referred to as a “**Termination for Cause**”) by giving the Employee notice of such termination, upon the giving of which such termination shall take effect immediately. For the purpose of this Section 5, “Cause” means any one of the following grounds:

- (i) repeated drunkenness or use of illegal drugs which adversely interferes with the performance of the Employee’s obligations and duties in the Company;
- (ii) the Employee’s conviction of a felony, or any crime involving fraud or misrepresentation or violation of applicable securities laws;
- (iii) gross mismanagement by the Employee of the business and affairs of the Company or any subsidiary of the Company which directly results in a material loss to the Company and for which the Company has reasonable proof was committed by the Employee;
- (iv) material violation of any material terms of this Agreement or the Compliance Agreement (as defined below); or
- (v) a conclusive finding by an independent fact finder appointed by the Board for any willful misconduct, dishonesty or acts of moral turpitude by the Employee which is materially detrimental to the interests and well-being of the Company and its subsidiaries, including, without limitation, harm to its business or reputation.

6. **TERMINATION WITHOUT CAUSE BY THE COMPANY.** The Company, on recommendation from the Board, may terminate the employment of the Employee hereunder at any time during the Employment Period without “Cause” (such termination being hereinafter called a “**Termination Without Cause**”) by giving the Employee notice of such termination. The termination of service under this Section 6 will take effect upon the giving of reasonable advance notice of not less than thirty (30) calendar days.

7. **TERMINATION BY THE EMPLOYEE.**

7.1 Without Good Reason. Any termination of the employment of the Employee hereunder other than as a result of an Involuntary Termination, a Termination For Cause, a Termination Without Cause or a Termination for Good Reason will be referred to hereinafter as a “**Voluntary Termination**”. A Voluntary Termination will be deemed to be effective following reasonable notice by the Employee of not less than thirty (30) calendar days.

7.2 With Good Reason. The Employee may terminate his/ services hereunder at any time for Good Reason (as defined below) by giving the Company written notice of such termination, provided that such notice specifies: (i) the basis for termination and (ii) the effective date of termination (such termination being hereinafter referred to as a “**Termination for Good Reason**”). For purposes of this Agreement, the term “**Good Reason**” shall mean (a) any material diminution of the Employee’s duties or responsibilities hereunder (except in each case in connection with the Termination for Cause or pursuant to Section 4.1) or the assignment to the Employee of duties or responsibilities that are materially inconsistent with the Employee’s then current position; (b) any material breach of the Agreement by the Company which is not cured within ten (10) business day days after written notice thereof is given to the Company; or (c) a relocation of the Employee (other than any relocation requested by the Employee) from the place of initial assignment of the Employee by the Company to a location more than thirty (30) kilometers from such location, other than on a temporary basis not to exceed a period equal to six (6) consecutive calendar months.

8. **EFFECT OF TERMINATION ON SERVICES.**

8.1 Voluntary Termination or a Termination for Cause. Upon the termination of the Employee's employment hereunder pursuant to a Voluntary Termination or a Termination for Cause, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, its affiliates, or its subsidiaries under this Agreement except to receive:

- (i) the unpaid portion of the Base Salary provided for in Section 3.1, computed on a *pro rata* basis up to (and including) the effective date of such termination; and
- (ii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 3.5.

8.2 Involuntary Termination. Upon the termination of the Employee's employment hereunder pursuant to an Involuntary Termination, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive:

- (i) a termination payment equal to that provided for in Section 8.1(i) hereto;
- (ii) an aggregate amount equal to the Base Salary and fringe benefits for one (1) month, payable from the effective date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 3.1 and 3.4 hereof, plus any additional compensation as may be expressly required under applicable law; and
- (iii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 3.5.

8.3 Other Terminations. Upon the termination of the Employee's employment hereunder pursuant to a Termination Without Cause or a Termination for Good Reason, neither the Employee nor his beneficiary or estate will have any further rights or claims against the Company, its affiliates or its subsidiaries under this Agreement except to receive:

- (i) a termination payment equal to that provided for in Section 8.1(i) hereto;
- (ii) an aggregate amount equal to the Base Salary and fringe benefits (i) for six (6) months if such termination occurs prior to the third (3<sup>rd</sup>) anniversary of the Effective Date, or (ii) for twelve (12) months if such termination occurs on or following the third (3<sup>rd</sup>) anniversary of the Effective Date, (in either case, such six (6) months or twelve (12) months, the "**Severance Period**"), payable from the effective date of such termination in accordance with the Company's normal payroll policies and at the same rate and in the same manner as set forth in Sections 3.1 and 3.4 hereof, plus any additional compensation as may be expressly required under applicable law; and
- (iii) reimbursement for any expenses for which the Employee shall not have theretofore been reimbursed as provided in Section 3.5.

8.4 Release. The parties acknowledge and agree that damages which will result to the Employee for termination by the Company without Cause or other breach of this Agreement by the Company shall be extremely difficult or impossible to establish or prove, and agree that the payments made to the Employee during the Severance Period shall constitute liquidated damages for any breach of this Agreement by the Company through the date of termination. The Employee agrees that, except for such other payments and benefits to which the Employee may be entitled as expressly provided by the terms of this Agreement or any applicable benefit plan, such liquidated damages shall be in lieu of all other claims that the Employee may make by reason of termination of her/his employment or any such breach of this Agreement and that, as a condition to receiving payments during the Severance Period, the Employee will execute a release of claims in a form reasonably satisfactory to the Company.

8.5 Conditions to Receipt of Severance. The receipt of any severance pursuant to Section 8.3 will be subject to the Employee signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company and provided that such separation agreement and release of claims becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the “**Release Deadline**”). If the release of claims does not become effective by the Release Deadline, the Employee will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the release of claims becomes effective and irrevocable.

## 9. **CONFIDENTIAL INFORMATION.**

9.1 Ownership of Information. The Employee acknowledges and agrees that the Company has expended and plans to continue to expend substantial sums in the development, acquisition and use of the following information, and the following information, whether in oral, written, graphic or machine-readable form, is conclusively a trade secret owned by the Company: (i) the work product resulting from or related to the services performed under this Agreement; (ii) the computer software of the Company, including documentation; (iii) the buying habits and practices of the purchasing agents and customers of the Company; (iv) the details of the contractual relationship between the Company and employees, suppliers and customers of the Company; (v) the marketing methods and related data of the Company; (vi) the identity of the vendors and suppliers of the Company; (vii) the costs of the labor and materials used by the Company; (viii) the compensation paid to and other terms of employment of the employees, agents and independent contractors of the Company; (ix) the operational methods and procedures of the Company; (x) the routing lists of the Company; (xi) the financial statements and records of the Company; and (xii) the type, nature and amount purchased from the Company by customers of the Company (collectively, the “**Trade Secrets**”). The Employee agrees that all information, knowledge, including any source code, object code, enhancements and modifications, all files, including input and output materials, all documentation related to such programs and files, all media upon which any such computer programs, files and documentation are located (including tapes, disks, and other storage media), records, customer lists, know-how, Trade Secrets, trademarks and other proprietary information related to the Company is and shall be the property of the Company and, as such, is confidential and proprietary to the Company (collectively, the “**Confidential Information**”).

9.2 Protection of Information. The Employee agrees: (i) without limiting the other provisions of this Section 9.2, to use at least the same degree of care with the Confidential Information as the Employee uses with respect to similar confidential information owned by the Employee; (ii) to exercise diligence in maintaining in strict confidence and not disclosing, releasing or permitting the disclosure of the Confidential Information; (iii) not to use such Confidential Information, regardless of how it is obtained by the Employee, for the benefit of the Employee or other than for the performance of the obligations of the Employee under this

Agreement; (iv) not to remove any copyright or proprietary rights notice attached to or included in any Confidential Information; (v) to advise the Company in writing if the Employee learns of any use or disclosure of Confidential Information by any current or former employee or consultant; and (vi) that the unauthorized disclosure or misuse of such Confidential Information could irreparably damage the Company and/or third parties dealing with the Company.

9.3 Limitations of Confidentiality. Notwithstanding anything in this Agreement to the contrary, the Employee shall have no liability or obligation with regard to any Confidential Information which: (i) was publicly known and generally available in the public domain at the time it was disclosed to a third party or becomes publicly known and generally available in the public domain through no fault of the Employee; (ii) is disclosed to a third party with the prior written approval of the Company; (iii) becomes known to the Employee through a source other than the Company without breach of this Agreement by the Employee and is otherwise not in violation of the rights of the Company and such other source is not disclosing the Confidential Information in breach of any similar obligations to the Company; (iv) is disclosed to a third party by the Company without restrictions similar to those contained in this Agreement; or (v) is disclosed to a third party pursuant to the order or requirement of a court, administrative agency or other governmental body provided that (A) the Employee will, prior to the disclosure, provide the Company with prompt written notice of such order or requirement, if legally permissible, and will use its best efforts to assist the Company in seeking a protective order or another appropriate remedy, (B) if the Company waives the Employee's compliance with this Agreement or fails to obtain a protective order or other appropriate remedy, the Employee will furnish only that portion of the Confidential Information that is legally required to be disclosed and (C) any Confidential Information so disclosed shall maintain its confidentiality protection for all purposes other than in respect of such legally compelled disclosure.

10. **COMPLIANCE AGREEMENT.** As a pre-condition to the effectiveness of this Agreement, the Employee agrees to execute and deliver the Agreement Regarding Confidentiality, Trade Secrets, Intellectual Property and Competitive Activities attached hereto as Exhibit A (the "**Compliance Agreement**"), the terms and conditions of which are specifically incorporated herein by reference. The obligation of the Company to make payments to or on behalf of the Employee under Section 8.2(ii) or Section 8.3(ii) above is expressly conditioned upon the Employee's continued performance of the Employee's obligations under the Compliance Agreement.

11. **STANDARDS OF CONDUCT.** The Employee will conduct himself/herself in an ethical and professional manner at all times and in accordance with any Employee policies or guidelines which the Company may issue from time to time.

12. **INDEMNIFICATION.**

12.1 Indemnification. In the event that (a) the Employee was or is a party or is threatened to be made a party to any Proceeding (as defined below) by reason of the Employee's Corporate Status (as defined below) or (b) the Employee was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company to procure a judgment in its favor by reason of the Employee's Corporate Status, the Employee shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by the Employee in connection with such Proceeding (referred to herein as "**Indemnifiable Amounts**"). For purposes hereof, the terms (i) "**Proceeding**" means any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitral or investigative, whether formal or informal, (ii) "**Corporate Status**" means the status of the Employee as an employee and/or director of the Company, as applicable, (iii) "**Expenses**" means all fees, costs and

expenses incurred in connection with any Proceeding, including, without limitation, reasonable attorneys' fees, disbursements and retainers, fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants, counsels and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services and other disbursements and expenses and (iv) "**Liabilities**" means judgments, damages, liabilities, losses, penalties, excise taxes, and fines.

12.2 **Advancement of Expenses.** The Company agrees that the Company shall pay to the Employee all Indemnifiable Amounts incurred by the Employee in connection with any Proceeding, including a Proceeding by the right of the Company, in advance of the final disposition of such Proceeding, as the same are incurred, provided that the Employee provides the Company with a written undertaking to repay the amount of Indemnifiable Amounts if it is finally determined by a court of competent jurisdiction that the Employee is not entitled under this Agreement to indemnification with respect to such Indemnifiable Amounts.

12.3 **Limitation on Indemnification.** The Employee shall not be entitled to any indemnification under this Section 12 if the Employee knowingly violated any duty, responsibility or obligation imposed under this Agreement, the Compliance Agreement or any Company policy.

12.4 **Change in Law.** To the extent that a change in applicable law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under this Agreement, the Employee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent.

13. **COVENANT NOT TO COMPETE; NON-SOLICITATION.** The Employee covenants and agrees that for twelve (12) months after the termination date of the Employee, the Employee will not directly or indirectly or by action in concert with others:

13.1 Contact, induce or influence or seek to induce or influence any person who is an employee, agent, independent contractor, supplier, customer, officer or shareholder of the Company to terminate the employment of such person or ownership in or relationship with the Company by such person without regard to whether such person would subsequently then be engaged in a business or own an interest in a business competitive with the Business Of The Company;

13.2 Advance or lend funds to, or acquire an interest in excess of one percent (1.0%) in, any organization whether being a corporation, partnership, joint venture, trust, sole proprietorship or any individual which is currently competitive with the Company or which places the Employee in a position competitive with the Company; and

13.3 Serve as an employee, officer, agent, director, or independent contractor or promote or participate or in any way engage in a business or business activity which is or may be competitive with the Business Of The Company or which might place the Employee in a position competitive with the Business Of The Company.

13.4 The covenants contained in this Section 13 shall be construed as a series of separate covenants, one for each country, province, state, city or other political subdivision in which the Company currently engages in its business or, during the Employment Period, becomes engaged in its business. Except for geographic coverage, each such separate covenant shall be deemed identical in terms to the covenant contained in this Section 13. If, in any judicial proceeding, a court refuses to enforce any of such separate covenants (or any part thereof), then



such unenforceable covenant (or such part) shall be eliminated from this Agreement to the extent necessary to permit the remaining separate covenants (or portions thereof) to be enforced. In the event that the provisions of this Section 13 are deemed to exceed the time, geographic or scope limitations permitted by applicable law, then such provisions shall be reformed to the maximum time, geographic or scope limitations, as the case may be, permitted by applicable law.

14. **REPRESENTATIONS AND WARRANTIES OF THE COMPANY.** The Company represents and warrants to the Employee that the execution of this Agreement by the Company has been duly authorized by resolution of the Board.

15. **REPRESENTATIONS AND WARRANTIES OF THE EMPLOYEE.** The Employee represents and warrants to the Company that: (i) the Employee has the proper skill, training and background so as to be able to perform under the terms of this Agreement in a competent and professional manner; (ii) the Employee will not infringe any intellectual property rights including patent, copyright, trademark, trade secret or other proprietary right of any person; and (iii) the Employee will not use any Trade Secrets or Confidential Information for purposes other than for the furtherance of the Business Of The Company and will not use any trade secrets or confidential information owned by any third party.

16. **ENFORCEMENT.** It is the desire and intent of the parties hereto that the provisions of this Agreement will be enforced to the fullest extent permissible under the laws and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, to the extent that a restriction contained in this Agreement is more restrictive than permitted by the laws of any jurisdiction whose law may be deemed to govern the review and interpretation of this Agreement, the terms of such restriction, for the purpose only of the operation of such restriction in such jurisdiction, will be the maximum restriction allowed by the laws of such jurisdiction and such restriction will be deemed to have been revised accordingly herein. A court having jurisdiction over an action arising out of or seeking enforcement of any restriction contained in this Agreement may modify the terms of such restriction in accordance with this Section 16.

17. **DISPUTE RESOLUTION.** In the event the parties hereto are unable to settle a dispute between them regarding this Agreement through friendly consultation, such dispute shall be referred to and finally settled by arbitration at the Hong Kong International Arbitration Centre in accordance with the UNCITRAL Arbitration Rules (the “**UNCITRAL Rules**”) in effect, which rules are deemed to be incorporated by reference into this Section 17 applying the laws of Hong Kong, without regard to its principles of conflicts of laws. The arbitration tribunal shall consist of three (3) arbitrators to be appointed according to the UNCITRAL Rules (the “**Arbitration Board**”). The language of the arbitration shall be English. The Arbitration Board shall decide any such dispute or claim strictly in accordance with the governing law specified in Section 19.5. Judgment upon any arbitral award rendered hereunder may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The costs and expenses of the arbitration, including the fees of the Arbitration Board, shall be borne equally by each party to the dispute or claim, and each party shall pay its own fees, disbursements and other charges of its counsel; provided that the Arbitration Board shall have the right to allocate the costs and expenses between each party as the Arbitration Board deems equitable. Any award made by the Arbitration Board shall be final and binding on each of the parties that were parties to the dispute. The parties expressly agree to waive the applicability of any laws and regulations that would otherwise give the right to appeal the decisions of the Arbitration Board so that there shall be no appeal to any court of law for the award of the Arbitration Board, and a party shall not challenge or resist the enforcement action taken by any other party in whose favor an award of the Arbitration Board was given.

18. **COVENANT AGAINST ASSIGNMENT.** The Employee may not assign any rights or delegate any of the duties of the Employee under this Agreement. As used in this provision, “assignment” and “delegation” shall mean any sale, gift, pledge, hypothecation, encumbrance, or other transfer of all or any portion of the rights, obligations, or liabilities in or arising from this Agreement to any person or entity, whether by operation of law or otherwise, and regardless of the legal form of the transaction in which the attempted transfer occurs.

19. **MISCELLANEOUS.**

19.1 **Notices.** Any notice, request, demand or other communication required or permitted to be given to a party pursuant to the provisions of this Agreement will be in writing and will be effective and deemed given under this Agreement on the earliest of: (i) the date of personal delivery, (ii) the date of transmission by facsimile or e-mail, with confirmed transmission and receipt, (iii) two (2) days after deposit with an internationally-recognized courier or overnight service such as Federal Express, DHL, or (iv) five (5) days after mailing via certified mail, return receipt requested. All notices not delivered personally or by facsimile will be sent with postage and other charges prepaid and properly addressed to the party to be notified at the address set forth on the signature pages hereto.

19.2 **Gender; Time.** The parties agree that any use of words in any gender in this Agreement shall also refer to the masculine, feminine or neuter gender, as the case may require. Time is of the essence in performance of the rights and obligations under this Agreement.

19.3 **Survival.** The provisions set forth in Sections 8, 9, 13, 16, 17, and 19 of this Agreement shall survive the termination of this Agreement.

19.4 **Binding Agreement; Benefit.** The provisions of this Agreement will be binding upon and will inure to the benefit of the respective heirs, legal representatives and successors of the parties hereto.

19.5 **Governing Law.** This Agreement will be governed by, and construed and enforced in accordance with, the laws of Hong Kong, without giving effect to its principles or rules of conflict laws to the extent such principles or rules would require or permit the application of the laws of another jurisdiction.

19.6 **Waiver of Breach.** The waiver by either party of a breach of any provision of this Agreement by the other party must be in writing and will not operate or be construed as a waiver of any subsequent breach by such other party.

19.7 **Entire Agreement; Amendments.** This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements or understanding among the parties with respect thereto (including, without limitation, that certain offer letter dated as of January 4, 2018). This Agreement may be amended only by an agreement in writing signed by each of the parties hereto.

19.8 **Headings.** The Section headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement.

19.9 **Severability.** Subject to the provisions of Section 16 above, any provision of this Agreement that is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction.

19.10 Assignment. This Agreement is personal in its nature and the parties hereto shall not, without the consent of the other party hereto, assign or transfer this Agreement or any rights or obligations hereunder, provided, however, that the rights and obligations of the Company hereunder shall be assignable and delegable in connection with any subsequent merger, consolidation, sale of all or substantially all of the assets or shares of the Company or similar transaction involving the Company or a successor corporation.

19.11 Confidentiality. The Employee agrees not to disclose this Agreement or its terms to any person or entity, other than the Employee's agents, advisors or representatives, except as consented to by the Company in writing or as may be required by law.

19.12 Further Assurances. The Employee agrees to execute, acknowledge, seal and deliver such further assurances, documents, applications, agreements and instruments, and to take such further actions, as the Company may reasonably request in order to accomplish the purposes of this Agreement.

19.13 Costs. Each of the parties shall pay all costs and expenses incurred or to be incurred by such party in negotiating and preparing this Agreement and in closing and carrying out the transactions contemplated by this Agreement.

19.14 Interpretation of Agreement. This Agreement has been negotiated at arm's length between persons knowledgeable in the matters dealt with in this Agreement. In addition, each party has been represented by experienced and knowledgeable legal counsel. Accordingly, any rule of law, or any legal decision that would require interpretation of any ambiguities in this Agreement against the party that has drafted it, is of no application and is waived.

19.15 Counterparts. The parties may execute this Agreement in any number of counterparts and, as so delivered, the counterparts shall together constitute one and the same document. The parties agree that each such counterpart is an original and shall be binding upon all of the parties, even though all of the parties are not signatories to the same counterpart.

19.16 No Third-Party Rights. Nothing in this Agreement is intended to grant to any third party (other than the parties' respective successors in title and permitted assigns) any right to enforce any term of this Agreement or to confer on any third party (other than the parties' respective successors in title and permitted assigns) any benefits under this Agreement. No person who is not a party to this Agreement shall have any right under the Contracts (Rights of Third Parties) Ordinance (Chapter 623 of the Laws of Hong Kong) to enforce any term of this Agreement.

*[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]*

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

**COMPANY:**

ZAI Lab (HK) Limited

By: /s/ Smantha Du  
Print Name: Smantha (Ying) Du  
Title: CEO and Chairman

Address:

4560 Jinke Road  
Pudong New Area  
Shanghai, China 201210  
Attention: Chief Executive Officer  
Facsimile:  
E-mail:

**EMPLOYEE:**

William Ki Chul Cho

/s/ William Ki Chul Cho

Address: XXX

E-Mail: XXX

EXHIBIT A

AGREEMENT REGARDING CONFIDENTIALITY, TRADE SECRETS, INTELLECTUAL PROPERTY AND COMPETITIVE  
ACTIVITIES

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## COMPLIANCE AGREEMENT

THIS AGREEMENT REGARDING CONFIDENTIALITY, TRADE SECRETS, INTELLECTUAL PROPERTY, AND COMPETITIVE ACTIVITIES (this “**Agreement**”) is entered into as of the Effective Date set forth on the signature page hereof between Zai Lab (Hong Kong) Limited, a limited company organized under the laws of Hong Kong (“**Company**”), and the undersigned employee of Company (“**I**,” “**me**,” or “**Employee**”). Company, along with its Affiliates now has and expects to develop confidential and proprietary materials and highly sensitive information of immeasurable value which I recognize must be carefully protected for Company to be successful. To induce Company to employ me and in consideration of my employment by Company, the sufficiency of which I expressly acknowledge, Company and I hereby agree, intending to be legally bound, as follows:

For the purposes of this Agreement, the term “**Affiliates**” means, with respect to any specified person, any other person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified person. For the purposes of this definition, “control” when used with respect to any specified person means the power to direct the management and policies of such person, directly or indirectly, whether through ownership of voting securities, by contract or otherwise; and the terms “controlling” and “controlled” have meanings correlative to the foregoing.

### 1. Company Confidential Materials and Information.

(a) Confidential Information. The following materials and information, whether having existed, now existing, or to be developed or created during the term of my employment by Company (herein referred to collectively as the “**Confidential Information**”) are covered by this Agreement:

(1) All information relating to existing or proposed products or services based on proprietary technology of Company or any of its Affiliates, whether owned or licensed by Company and/or its Affiliates, and proprietary technology in various stages of research and development which are not generally known to the public (such as inventions, trade secrets, know-how, design specifications, methodologies, procedures, techniques, and information management processes);

(2) All information relating to the products or services of Company or any of its Affiliates, whether existing or in various stages of research and development, which is not generally known to the public (such as know-how, specifications, technical or medical data, processes, techniques, methodologies, and strategies);

(3) All information not generally known to the public concerning or relating to the way Company or any of its Affiliates conducts its business (such as internal business procedures, controls, plans, licensing techniques, contracts and practices, supplier, subcontractor and prime contractor names and contracts and other vendor information, computer system passwords and other computer security controls, financial information, distributor information, information supplied by clients and customers of Company or any of its Affiliates, and employee data);

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(4) All information not generally known to the public that pertains to Company's or any of its Affiliates' marketing plans and strategies; forecasts and projections; marketing practices, procedures and policies; discounts; margins; costs; credit terms; pricing practices, procedures and policies; procedures and policies; and customer data including customer lists, information, contracts, representatives, requirements and needs, specifications, preferences, data provided by or about prospective, existing or past customers and contract terms applicable to such customers (such as customer lists, printouts, databases, marketing plans, marketing reports, strategic business plans, marketing analyses and management reports, and listings of potential customers and leads);

(5) Any information pertaining to Company or any of its Affiliates in addition to the foregoing which is not generally known to the public or within the industry or trade areas in which Company or any of its Affiliates competes which gives Company or any of its Affiliates any advantage over its competitors; and

(6) All physical embodiments of the foregoing information in any tangible form, whether written, electronic, or machine-readable in nature.

(b) General Knowledge. The general skills, knowledge, and experience gained during my employment with Company or information publicly available is not considered Confidential Information. Also, upon termination of my employment with Company for any reason, I shall not, subject to the provisions of Sections 3(a) and 3(b) below, be restricted from working with a person or entity which has independently developed information or materials similar to Confidential Information as long as I comply with my continuing obligations under this Agreement.

(c) Employee Obligations. During my employment with Company, I acknowledge and agree that I will have access to Confidential Information and materials and will occupy a position of trust and confidence with respect to Company's affairs and business. I agree to take the following steps to preserve the confidential and proprietary nature of Confidential Information and materials.

(1) Non-Use; Non-Disclosure. During and after my employment with Company regardless of the reason why my employment ended, I will not use, disclose, or transfer any Confidential Information other than as authorized by Company within the scope of my duties with Company, and will not use in any way other than in Company's business any Confidential Information, including information or material received by Company from others and intended by Company to be kept in confidence by its recipients. I understand that I am not allowed to sell, license, or otherwise exploit any products or services which embody or otherwise exploit in whole or in part any Confidential Information or materials.

(2) Disclosure Prevention. I will take all reasonable precautions to prevent the inadvertent or accidental disclosure of Confidential Information.

(3) Removal of Confidential Information. I will not remove any Confidential Information or documents, materials, or property containing Confidential Information from Company's or any of its Affiliates' premises or make copies of such documents, materials, or property except for use in Company's business and in accordance with Company's policies regarding security of confidential information.

(4) Return All Materials. I will return to Company all Confidential Information and all other documents, materials, and property of Company (including any copies of the foregoing) at any time upon the request of Company, and in any event and without such request, immediately upon the termination of my employment with Company regardless of the reason for termination. I agree not to retain any documents, materials, or property (including copies) containing any Confidential Information or otherwise belonging to Company after my employment ends, regardless of the reason. I agree to deliver and sign the "Termination Certificate" attached hereto as Exhibit A.

(5) Computer Security. During my employment with Company, I agree to use only those Company computer resources (both on and off Company's premises) for which I have been granted access and then only to the extent authorized. I agree to comply with Company's policies and procedures concerning computer security.

(6) Communications Systems. I understand that Company maintains an electronic mail system, a voice mail system, a computer network that includes access to the Internet, and related facilities for the purpose of business communications. I acknowledge that these systems, network, and related facilities, as well as all electronic or voice communications and all data or materials transmitted thereon, are Company property, and Company retains the right to review any and all electronic mail communications, voice communications, internet sites accessed, and data and materials stored or transmitted, with or without notice, at any time.

## **2. Proprietary Information and Ideas and Inventions.**

(a) Prior Information. I agree to inform Company of any apparent conflicts between my work for Company and any pre-existing obligations I may have to preserve the confidentiality of another's proprietary information or materials. Otherwise, by signing this Agreement and accepting employment with Company, Company may conclude that no such conflict exists, and I agree thereafter to make no such claim against Company. I agree not to disclose to Company or any of its Affiliates or use in Company's business any information or material relating to the business of any third person and intended by that person not to be disclosed to Company or its Affiliates.

(b) Ideas and Inventions. Attached hereto as Exhibit B is a list describing all inventions, original works of authorship, developments, improvements, and trade secrets which were made by me prior to employment with Company, which belong to me or a former employer, which relate to Company's business, and which are not assigned to Company hereunder (collectively referred to as "**Prior Inventions**"); or, if no such list is attached, I represent that there are no such Prior Inventions. If in the course of employment with Company, I incorporate any invention, improvement, development, concept, discovery, product, copyrightable material, trade or other proprietary information owned by me or in which I have an interest, into any product, service, process, composition, machine, or other property (including Confidential Information) of Company, Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license to make, modify, use, and sell such item as part of or in connection with such product, service, process, composition, or machine, or other property.



(c) Disclosure and Assignment to Company. I agree to promptly make full written disclosure to Company and will hold in trust for the sole right and benefit of Company or its designee, all right, title, and interest in and to any and all inventions, developments, concepts, improvements, or trade secrets, whether or not patentable or registrable under copyright or similar laws, which I may solely or jointly conceive or develop or reduce to practice, or cause to be conceived or developed or reduced to practice while I am performing services within the scope of my employment with Company (either on Company's premises or elsewhere) or utilizing Company facilities (collectively referred to as "**Inventions**"), and I hereby forever irrevocably transfer and assign to Company, or its designee, all right, title, and interest in and to all such Inventions. This Section 2(c) shall not apply to assign to Company any of my rights in any invention that I develop entirely on my own time without using Company's equipment, supplies, facilities, or trade secret information, except for inventions that either (1) relate, at the time that the invention is conceived or reduced to practice, to Company's business or to actual or demonstrably anticipated research or development activities of Company; or (2) result from any work performed by me for Company.

(d) Works of Authorship. I acknowledge and agree that all writings or works of authorship, including without limitation, business planning documents, marketing materials, operations manuals, software program code, drawings, procedural diagrams, and other documentation of any kind produced by me in the course of my work for Company are works produced for hire and the property of Company, including without limitation any copyrights on those writings; but to the extent any such writing produced by me in the course of my work for Company may not, by operation of law or otherwise, be a work made for hire, I hereby forever irrevocably transfer and assign to Company the ownership of copyright in such works, whether published or unpublished.

(e) Moral Rights. I understand that the term "moral rights" means any rights of paternity or integrity, including any right to claim authorship of a copyrightable work, to object to a modification of such copyrightable work, and any similar right existing under the judicial or statutory law of any country in the world or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right." I forever hereby waive and agree never to assert any moral rights I may have in any copyrightable work that is assigned to Company as a result of Section 2(d) hereof, even after any termination of my employment with Company.

(f) Patent and Copyright Registrations. I agree to assist Company, or its designee, at Company's expense, in every proper way to secure Company's rights in the Inventions and any copyrights, patents, mask work rights, or other intellectual property rights relating thereto in any and all countries, including the disclosure to Company of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments, and all other instruments which Company shall deem necessary in order to apply for and obtain such rights and in order to assign and convey to Company, its successors, assigns, and nominees the sole and exclusive rights, title, and interest in and to such Inventions, and any copyrights, patents, mask work rights, or other intellectual property rights relating thereto. I further agree that my obligation to execute or cause to be executed, when it is in my power to do so, any such instrument or papers shall continue after the termination of this Agreement. If Company is unable because of my mental or physical incapacity or for any other reason to secure my signature to apply for or to pursue any application for any United States or foreign patents or copyright registrations covering Inventions or original works of authorship assigned to Company as above, then I hereby irrevocably designate and appoint Company and its duly authorized officers and agents as my agent and attorney in fact, to act for and on my behalf and to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters, patent or copyright registrations thereon with the same legal force and effect as if executed by me.

### 3. Non-Competition and Non-Solicitation.

I hereby agree to comply with the restrictions set forth in this Section 3.

(a) Non-Competition.

(1) I hereby covenant and agree that I shall not engage in competition with the business that Company or any of its Affiliates conducts or conducted at any time during my employment or which Company or any of its Affiliates is actively engaged in planning to conduct at the time of my termination of employment (collectively, the “**Business**”). As indicated above in Section 1(c)(1), at any time after the termination of this Agreement, I will not make use of Company’s Confidential Information or information concerning any invention, or any other confidential matter relating to Company’s business that I may in any way acquire by reason of my employment with Company.

(2) During my employment and for a period of one (1) year immediately following the termination of my employment with Company for any reason, I will not, directly or indirectly, whether as owner, partner, investor, consultant, agent, employee, co-venturer or otherwise, compete with the Business within any country in which Company or its Affiliates conducts or, at the time of my employment, is actively engaged in planning to conduct Business. The foregoing, however, shall not prevent my passive ownership of two percent (2%) or less of the equity securities of any publicly traded company.

(b) Non-Solicitation. Both during my employment and for one (1) year immediately following the termination of my employment with Company for any reason, I will not, on behalf of myself or any other person, except as authorized by Company within the scope of my duties with Company: (i) solicit, recruit, or encourage any of Company’s or its Affiliates’ employees to leave or terminate their employment with Company or such Affiliate; (ii) hire or employ any of Company’s or its Affiliates’ employees (or any person who was an employee of Company or any of its Affiliates within six (6) months of such action); or (iii) induce any customer or prospective customer (with respect to which I played a role in soliciting or providing goods or services during the twelve (12) month period prior to the termination of my employment), supplier, vendor, licensee, independent contractor or other business relation of Company or any of its Affiliates to cease doing business with Company or any of its Affiliates, or to modify its business relationship with Company or any of its Affiliates in a manner adverse to Company or any of its Affiliates.

### 4. General Provisions.

(a) Enforcement. I acknowledge that the obligations in this Agreement have unique, very substantial and immeasurable value to Company and its Affiliates, that Company and its Affiliates are engaged in a highly competitive industry, that I am receiving significant consideration in connection with this Agreement and my employment with Company, and that I have sufficient assets and skills to provide a livelihood for myself while such covenants remain in force. In the event that any of the obligations in this Agreement shall be determined by any court of competent jurisdiction to be unenforceable by reason of their extending for too great a period of time or over too great a geographical area or by reason of their being too extensive in any other respect, such obligation shall be interpreted and modified to extend only over the maximum period of time for which it may be enforceable and over the maximum geographical area as to which it may be enforceable and to the maximum extent in all other respects as to which it may be enforceable, all as determined by such court in such action. If modification of such obligations is not possible, then the court shall sever such obligations and enforce each and every remaining obligation in this Agreement.

(b) Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of Hong Kong without giving effect to its principles or rules of conflict laws to the extent such principles or rules would require or permit the application of the laws of another jurisdiction.

(c) Dispute Resolution.

(1) Any dispute or claim arising out of or in connection with or relating to this Agreement, or the breach, termination or invalidity hereof (including the validity, scope and enforceability of this arbitration provision), shall be finally resolved by arbitration in Hong Kong under the auspices of the Hong Kong International Arbitration Centre (the "Arbitration Center") and in accordance with the Hong Kong International Arbitration Centre Procedures for the Administration of International Arbitration ("Arbitration Rules") as are in force at the date of this Agreement and as may be amended by the rest of this Section 4(c). For the purpose of such arbitration, there shall be three (3) arbitrators ("**Arbitration Board**"). The claimant or claimants (collectively) shall select one (1) arbitrator and the respondent or respondents (collectively) shall select one (1) arbitrator. All selections shall be made within thirty (30) days after the selecting party gives or receives the demand for arbitration. Such arbitrators shall be freely selected, and the parties shall not be limited in their selection to any prescribed list. The Chairman of the Arbitration Center shall select the third arbitrator. If any arbitrator to be appointed by a party as not been appointed and consented to participate within thirty (30) days after the selection of the first arbitrator, the relevant appointment shall be made by the Chairman of the Arbitration Center.

(2) All arbitration proceedings shall be conducted in English. The Arbitration Board shall decide any such dispute or claim strictly in accordance with the governing law specified in Section 4(b). Judgment upon any arbitral award rendered hereunder may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be.

(3) In order to preserve its rights and remedies, any party shall be entitled to seek preservation of property in accordance with applicable law from any court of competent jurisdiction or from the arbitration tribunal pending the final decision or award of the arbitration tribunal.

(4) The parties agree to facilitate the arbitration by (a) cooperating in good faith to expedite (to the maximum extent practicable) the conduct of the arbitration, (b) making available to one another and to the Arbitration Board for inspection and extraction all documents, books, records, and personnel under their control or under the control of a person controlling or controlled by such party if determined by the Arbitration Board to be relevant to the dispute, (c) conducting arbitration hearings to the greater extent possible on successive business days and (d) using their best efforts to observe the time periods established by the Arbitration Rules or by the Arbitration Board for the submission of evidence and briefs.

(5) The costs and expenses of the arbitration, including the fees of the Arbitration Board, shall be borne equally by each party to the dispute or claim, and each party shall pay its own fees, disbursements and other charges of its counsel; *provided* that the Arbitration Board shall have the right to allocate the costs and expenses between each party as the Arbitration Board deems equitable.

(6) Any award made by the Arbitration Board shall be final and binding on each of the parties that were parties to the dispute. The parties expressly agree to waive the applicability of any laws and regulations that would otherwise give the right to appeal the decisions of the Arbitration Board so that there shall be no appeal to any court of law for the award of the Arbitration Board, and a party shall not challenge or resist the enforcement action taken by any other party in whose favor an award of the Arbitration Board was given.

(d) Publications. I agree not to submit any writing for publication or deliver any speech that contains any information relating to the Business, unless I receive advance clearance from an authorized representative of Company.

(e) Publicity. I hereby grant to Company the right to use my name and likeness, without additional consideration, on, in, and in connection with technical, marketing, and/or disclosure materials published by or for Company.

(f) Miscellaneous. This Agreement is my entire agreement with Company with respect to the subject matter referred to herein, superseding any prior oral, written, express, or implied negotiations and agreements. This Agreement may not be changed in any respect except by a written agreement signed by both myself and an officer of Company. If any provision of this Agreement is held to be invalid, illegal, or unenforceable for any reason, the validity, legality, and enforceability of the remaining provisions will not in any way be affected or impaired thereby.

*[Signature Page to Follow]*

By my signature below, I acknowledge that I have reviewed this Agreement Regarding Confidentiality, Trade Secrets, Intellectual Property, and Competitive Activities carefully and understand that the covenants and obligations it contains are binding on me.

/s/ William Cho

(Signature)

William Cho

(Print Name)

Accepted and agreed to on  
behalf of Zai Lab (Hong Kong) Limited

By: /s/ Samantha Du

Name: Samantha (Ying) Du

Title: CEO and Chairman

Effective Date: March 2, 2018

*[Signature Page to Compliance Agreement]*

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**EXHIBIT A**

TERMINATION CERTIFICATE

This is to certify that I do not have in my possession, and that I have returned to Zai Lab (Hong Kong) Limited (“**Company**”) in compliance with Section 1(c)(4) of the Agreement Regarding Confidentiality, Trade Secrets, Intellectual Property and Competitive Activities between me and Company (the “**Compliance Agreement**”), all Confidential Information (as that term is defined in Section 1 of the Compliance Agreement) of Company and all other documents, materials, and property of Company (including any copies of the foregoing).

I further certify that I have complied with all the terms of the Compliance Agreement signed by me, including the reporting of any inventions and original works of authorship (as defined therein), conceived or made by me (solely or jointly with others) covered by the Compliance Agreement. Except to the extent set forth below, I acknowledge and agree that I have no prior inventions or original works of authorship other than those, if any, identified by me on Exhibit B to the Compliance Agreement at the time that I signed the Compliance Agreement.

Termination Date: \_\_\_\_\_

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Print Name)

**EXHIBIT B**

LIST OF PRIOR INVENTIONS  
AND ORIGINAL WORKS OF AUTHORSHIP

Title	Date	Identifying Number or Brief Description
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\_\_\_\_\_ No inventions or improvements

\_\_\_\_\_ Additional Sheets Attached

Signature of Employee: \_\_\_\_\_

Print Name of Employee: \_\_\_\_\_

Date: \_\_\_\_\_

**Certification by the Principal Executive Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Samantha Du, certify that:

1. I have reviewed this annual report on Form 20-F of Zai Lab Limited (the “Company”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the Company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the Company’s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and
5. The Company’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: April 30, 2018

By: /s/ Samantha Du  
Samantha Du  
Chief Executive Officer



**Certification by the Principal Financial Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, William Cho, certify that:

1. I have reviewed this annual report on Form 20-F of Zai Lab Limited (the “Company”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the Company’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the Company’s internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting; and
5. The Company’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company’s auditors and the audit committee of the Company’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal control over financial reporting.

Date: April 30, 2018

By: /s/ William Cho  
William Cho  
Chief Financial Officer

**Certification by the Principal Executive Officer  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the annual report of Zai Lab Limited (the "Company") on Form 20-F for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

Date: April 30, 2018

By: /s/ Samantha Du  
Samantha Du  
Chief Executive Officer

**Certification by the Principal Financial Officer  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the annual report of Zai Lab Limited (the "Company") on Form 20-F for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

Date: April 30, 2018

By: /s/ William Cho  
William Cho  
Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-221616 on Form S-8 of our report dated April 30, 2018, relating to the consolidated financial statements and financial statement schedule of Zai Lab Limited and its subsidiaries (the “Group”), appearing in this Annual Report on Form 20-F of Zai Lab Limited for the year ended December 31, 2017.

/s/ Deloitte Touche Tohmatsu Certified Public Accountants LLP

Shanghai, China  
April 30, 2018

