Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38205

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

Cayman Islands	**98-1144595**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4560 Jinke Road Bldg. 1, Fourth Floor Pudong Shanghai, China	
(Address of principal executive offices)	**201210 (Zip Code)**

+86 21 6163 2588
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 1 Ordinary Share, par value $0.00006 per share	**ZLAB**	**The Nasdaq Global Market**
Ordinary Shares, par value $0.00006 per share*	**9688**	**The Stock Exchange of Hong Kong Limited**

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of April 30, 2021, 94,908,743 ordinary shares of the registrant, par value $0.00006 per share, were outstanding, of which 65,326,281 ordinary shares were held in the form of American Depositary Shares.

Zai Lab Limited
Quarterly Report on Form 10-Q

PART I—FINANCIAL INFORMATION

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial information and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission, or SEC, on March 1, 2021.

This discussion contains certain forward-looking statements that involve risks and uncertainties. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially," "contemplate," "project," "seek," "target," "would" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information, including all matters that are not historical facts. These forward-looking statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Factors that might cause such a difference include, but are not limited to, those discussed in the "Risk Factors" section of our Annual Report on Form 10-K and those "Risk Factors" discussed below in Part II, Item 1A. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Quarterly Report on Form 10-Q, speak only as of their date, and except as required by law, we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Item 1. Financial Statements

Zai Lab Limited

Unaudited condensed consolidated balance sheets

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

	Notes	As of March 31, 2021 $	As of December 31, 2020 $
Assets			
Current assets:			
Cash and cash equivalents	3	1,013,420	442,116
Short-term investments	5	—	744,676
Accounts receivable (net of allowance of $2 and $1 as of March 31, 2021 and 2020, respectively)		8,815	5,165
Inventories	6	12,629	13,144
Prepayments and other current assets		14,321	10,935
Total current assets		1,049,185	1,216,036
Restricted cash, non-current	4	743	743
Investments in equity investees	7	1,473	1,279
Prepayments for equipment		244	274
Property and equipment, net	8	29,016	29,162
Operating lease right-of-use assets		16,652	17,701
Land use rights, net		7,784	7,908
Intangible assets, net		1,585	1,532
Long term deposits		910	862
Value added tax recoverable		23,698	22,141
Total assets		**1,131,290**	**1,297,638**
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		41,415	62,641
Current operating lease liabilities		5,602	5,206
Other current liabilities	11	45,639	30,196
Total current liabilities		92,656	98,043
Deferred income		16,657	16,858
Non-current operating lease liabilities		12,307	13,392
Total liabilities		**121,620**	**128,293**
Commitments and contingencies (Note 18)			
Shareholders' equity			
Ordinary shares (par value of $0.00006 per share; 500,000,000 shares authorized, 88,519,172 and 74,666,725 shares issued and outstanding as of March 31, 2021 and 2020, respectively)		5	5
Additional paid-in capital		1,967,802	1,897,467
Accumulated deficit		(946,513)	(713,603)
Accumulated other comprehensive loss	15	(11,624)	(14,524)
Total shareholders' equity		**1,009,670**	**1,169,345**
Total liabilities and shareholders' equity		**1,131,290**	**1,297,638**

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

Zai Lab Limited

Unaudited condensed consolidated statements of operations

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

	Notes	Three Months Ended March 31, 2021 $	2020 $
Revenue	9	20,103	8,218
Expenses:			
Cost of sales		(7,505)	(2,084)
Research and development		(203,852)	(33,742)
Selling, general and administrative		(35,838)	(18,714)
Loss from operations		(227,092)	(46,322)
Interest income		214	1,655
Interest expenses		—	(59)
Other expense, net		(6,227)	(3,125)
Loss before income tax and share of gain (loss) from equity method investment		(233,105)	(47,851)
Income tax expense	10	—	—
Share of gain (loss) from equity method investment		195	(137)
Net loss		(232,910)	(47,988)
Net loss attributable to ordinary shareholders		(232,910)	(47,988)
Loss per share - basic and diluted	12	(2.64)	(0.66)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		88,374,928	72,956,538

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

Zai Lab Limited

Unaudited condensed consolidated statements of comprehensive loss

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

	Three Months Ended March 31,	
	2021	2020
	$	$
Net loss	(232,910)	(47,988)
Other comprehensive income, net of tax of nil:		
Foreign currency translation adjustments	2,900	3,539
Comprehensive loss	**(230,010)**	**(44,449)**

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

Zai Lab Limited

Unaudited condensed consolidated statements of shareholders' (deficit) equity

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

	Ordinary shares		Additional paid in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total
	Number of Shares	Amount				
		$	$	$	$	$
Balance at December 31, 2020	87,811,026	5	1,897,467	(713,603)	(14,524)	1,169,345
Issuance of ordinary shares upon vesting of restricted shares	81,600	0	0	—	—	—
Exercise of shares option	58,364	0	702	—	—	702
Issuance of ordinary shares in connection with collaboration and license arrangement (Note 16)	568,182	0	62,250	—	—	62,250
Issuance cost adjustment for secondary listing	—	—	65	—	—	65
Share-based compensation	—	—	7,318	—	—	7,318
Net loss	—	—	—	(232,910)	—	(232,910)
Foreign currency translation	—	—	—	—	2,900	2,900
Balance at March 31, 2021	88,519,172	5	1,967,802	(946,513)	(11,624)	1,009,670
Balance at December 31, 2019	68,237,247	4	734,734	(444,698)	4,620	294,660
Issuance of ordinary shares upon vesting of restricted shares	80,200	0	0	—	—	—
Exercise of shares option	49,278	0	346	—	—	346
Issuance of ordinary shares upon follow-on public offering, net of issuance cost of $740	6,300,000	0	280,568	—	—	280,568
Share-based compensation	—	—	6,463	—	—	6,463
Net loss	—	—	—	(47,988)	—	(47,988)
Foreign currency translation	—	—	—	—	3,539	3,539
Balance at March 31, 2020	74,666,725	4	1,022,111	(492,686)	8,159	537,588

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

Zai Lab Limited

Unaudited condensed consolidated statements of cash flows

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

	Three Months Ended March 31,	
	2021	2020
	$	$
Operating activities		
Net loss	(232,910)	(47,988)
Adjustments to reconcile net loss to net cash used in operating activities:		
Allowance for doubtful accounts	1	1
Inventory write-down	14	—
Depreciation and amortization expenses	1,448	1,070
Amortization of deferred income	(78)	(78)
Share-based compensation	7,318	6,463
Noncash research and development expenses (Note 16)	62,250	—
Share of (gain) loss from equity method investment	(195)	137
Loss on disposal of property and equipment	4	—
Noncash lease expenses	1,322	1,062
Changes in operating assets and liabilities:		
Accounts receivable	(3,651)	(296)
Inventories	502	(45)
Prepayments and other current assets	(3,386)	(1,375)
Long term deposits	(47)	(349)
Value added tax recoverable	(1,558)	(1,156)
Accounts payable	(21,226)	4,495
Other current liabilities	21,707	(1,408)
Operating lease liabilities	(893)	(663)
Deferred income	(122)	289
Net cash used in operating activities	(169,500)	(39,841)
Cash flows from investing activities:		
Proceeds from maturity of short-term investments	743,902	50,000
Purchase of property and equipment	(1,683)	(1,043)
Purchase of intangible assets	(214)	(5)
Net cash used in investing activities	742,005	48,952
Cash flows from financing activities:		
Repayment of short-term borrowings	—	(1,430)
Proceeds from exercises of stock options	702	346
Proceeds from issuance of ordinary shares upon public offerings	—	281,295
Payment of public offering costs	(973)	(727)
Net cash (used in) provided by financing activities	(271)	279,484
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	(930)	(947)
Net increase in cash, cash equivalents and restricted cash	571,304	287,648
Cash, cash equivalents and restricted cash - beginning of period	442,859	76,442
Cash, cash equivalents and restricted cash - end of period	1,014,163	364,090
Supplemental disclosure on non-cash investing and financing activities:		
Payables for purchase of property and equipment	439	280
Payables for intangible assets	26	11
Payables for public offering costs	26	—
Supplemental disclosure of cash flow information:		
Cash and cash equivalents	1,013,420	363,580
Restricted cash, non-current	743	510
Total cash and cash equivalents and restricted cash	1,014,163	364,090
Interest paid	—	67

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

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

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 focused on developing and commercializing therapies that address medical conditions with unmet medical needs including, in particular, oncology, autoimmune disorders and infectious diseases.

The Group's principal operations and geographic markets are in mainland China (hereinafter referred to as "China"), Hong Kong, Macau and Taiwan (hereinafter collectively referred to as "Greater China"). The Group has a substantial presence in Greater China and the United States.

2. Basis of presentation and consolidation and significant accounting policies

(a) Basis of presentation

The unaudited condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). In the opinion of management, these financial statements reflect all normal recurring adjustments and accruals necessary for a fair statement of the Company's unaudited condensed consolidated financial statements for such periods. The results of operations for any interim period are not necessarily indicative of the results for the full year. The December 31, 2020 condensed consolidated balance sheets data were derived from audited financial statements, but do not include all disclosures required by U.S. GAAP. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

(b) Principles of consolidation

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

(c) Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating the current expected credit losses for financial assets, assessing the impairment of long-lived assets, discount rate of operating lease liabilities, revenue recognition, allocation of the research and development service expenses to the appropriate financial reporting period based on the progress of the research and development projects, share-based compensation expenses, recoverability of deferred tax assets and a lack of marketability discount of the ordinary shares issued in connection with collaboration and license arrangement (Note 16). 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) 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.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Group primarily include cash, cash equivalents and restricted cash, short-term investments, accounts receivable, prepayments and other current assets, accounts payable and other payables. As of March 31, 2021 and December 31, 2020, the carrying values of cash and cash equivalents, short-term investments, accounts receivable, prepayments and other current assets, accounts payable and other payable approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximates its fair value based on the nature of the assessment of the ability to recover these amounts.

(e) Recent accounting pronouncements

Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, *Income taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Group adopted this standard on January 1, 2021. There was no material impact to the Group's financial position or results of operations upon adoption.

(f) Significant accounting policies

For a more complete discussion of the Company's significant accounting policies and other information, the unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

3. Cash and cash equivalents

	As of	
	March 31, 2021	December 31, 2020
	$	$
Cash at bank and in hand	1,012,587	441,283
Cash equivalents	833	833
	1,013,420	442,116
Denominated in:		
US$	186,078	297,813
RMB (note (i))	37,732	23,898
Hong Kong dollar ("HK$")	789,029	119,695
Australian dollar ("A$")	581	710
	1,013,420	442,116

Note:

(i) Certain cash and bank balances denominated in RMB were deposited with banks in China. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the government of the People's Republic of China ("PRC").

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

4. Restricted cash, non-current

The Group’s restricted cash balance of $743 and $743 as of March 31, 2021 and December 31, 2020, respectively, was long-term bank deposits held as collateral for issuance of letters of credit. These deposits will be released when the related letters of credit are settled by the Group.

5. Short-term investments

Short-term investments are primarily comprised of time deposits with original maturities between three months and one year.

As of March 31, 2021, the Group held no short-term investment. As of December 31, 2020, the Group’s short-term investments consisted entirely of short-term held to maturity debt instruments with high credit ratings, which were determined to have no risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of December 31, 2020.

6. Inventories

The Group’s inventory balance of $12,629 and $13,144 as of March 31, 2021 and December 31, 2020, respectively, mainly consisted of finished goods purchased from Tesaro Inc., now GlaxoSmithKline (GSK), and NovoCure Limited (“NovoCure”) for distribution in Hong Kong, as well as finished goods, work in process and certain raw materials for ZEJULA commercialization in China.

	As of	
	March 31, 2021	December 31, 2020
	$	$
Finished goods	2,703	3,041
Raw materials	9,588	10,103
Work in process	338	—
Inventories	12,629	13,144

The Group write-down inventory for any excess or obsolete inventories or when the Group believe that the net realizable value of inventories is less than the carrying value. During the three months ended March 31, 2021 and 2020, the Group recorded write-downs of $43 and $nil, respectively, in cost of revenues.

7. Investments in equity investees

In June 2017, the Group entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd. (“JING”), an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. The capital contribution by the Group was RMB26,250 in cash, which was paid by the Group in 2017 and 2018, representing 20% and 18% of the equity interest of JING as of December 31, 2020 and March 31, 2021 respectively. The Group accounts for this investment using the equity method of accounting due to the fact that the Group can exercise significant influence on the investee. The Group recorded its gain on deemed disposal in this investee of $463 and share of loss of $268 for the three months ended March 31, 2021, and recorded share of loss in this investee of $137 for the three months ended March 31, 2020.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

8. Property and equipment, net

Property and equipment consist of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Office equipment	428	430
Electronic equipment	2,876	2,646
Vehicle	194	143
Laboratory equipment	12,357	11,933
Manufacturing equipment	12,116	12,198
Leasehold improvements	9,642	9,641
Construction in progress	2,915	2,423
	40,528	39,414
Less: accumulated depreciation	(11,512)	(10,252)
Property and equipment, net	29,016	29,162

Depreciation expenses for the three months ended March 31, 2021 and 2020 were $1,340 and $1,006, respectively.

9. Revenue

The Group's revenue is primarily derived from the sale of ZEJULA and Optune in China and Hong Kong. The table below presents the Group's net product sales for the three months ended March 31, 2021 and 2020.

	Three Months Ended March 31,	
	2021	2020
	$	$
Product revenue - gross	46,555	8,937
Less: Rebate	(26,452)	(719)
Product revenue - net	20,103	8,218

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

The following table disaggregates net revenue by product for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	$	$
ZEJULA	12,606	6,345
Optune	7,130	1,873
Others	367	—
Total product revenue - net	20,103	8,218

10. Income Tax

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

The Company recorded a full valuation allowance against deferred tax assets of all its consolidated entities because all entities were in a cumulative loss position as of March 31, 2021 and December 31, 2020. No unrecognized tax benefits and related interest and penalties were recorded in any of the periods presented.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

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

11. Other current liabilities

Other current liabilities consist of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Payroll	7,694	13,694
Professional service fee	3,274	3,128
Payables for purchase of property and equipment	439	788
Advance from customers	3,280	—
Accrued rebate to distributors	23,166	7,067
Others (note (i))	7,786	5,519
Total	45,639	30,196

Note:

(i) Others are mainly payables to employees for exercising the share-based compensations, tax payables, payables for purchase of intangible assets, and payables related to travel and business entertainment expenses and conference fee.

12. Loss per share

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

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss attributable to ordinary shareholders	(232,910)	(47,988)
Denominator:		
Weighted average number of ordinary shares- basic and diluted	88,374,928	72,956,538
Net loss per share-basic and diluted	(2.64)	(0.66)

As a result of the Group's net loss for the three months ended March 31, 2021 and 2020, share options and non-vested restricted shares outstanding in the respective periods were excluded from the calculation of diluted loss per share as their inclusion would have been anti-dilutive.

	As of	
	March 31, 2021	March 31, 2020
Share options	8,693,274	9,903,396
Non-vested restricted shares	480,010	725,068

13. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of March 31, 2021:

Company Name	Relationship with the Group
MEDx (Suzhou) Translational Medicine Co., Ltd. (Formerly known as Qiagen (Suzhou) translational medicine Co., Ltd)	Significant influence held by Samantha Du's (Director, Chairwoman and Chief Executive Officer of the Company) immediate family

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

For the three months ended March 31, 2021 and 2020, the Group incurred $103 and $55 research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for product research and development services, respectively. All of the transactions are carried out with normal business terms and are on arms’ length basis.

14. Share-based compensation

Share options

On March 5, 2015, the Board of Directors of the Company approved an Equity Incentive Plan (the “2015 Plan”) which is administered by the Board of Directors. Under the 2015 Plan, the Board of Directors may grant options to purchase ordinary shares to management including officers, directors, employees and individual advisors who render services to the Group to purchase an aggregate of no more than 4,140,945 ordinary shares of the Group (“Option Pool”). Subsequently, the Board of Directors approved the increase in the Option Pool to 7,369,767 ordinary shares.

In connection with the completion of the initial public offering (the “IPO”), the Board of Directors has approved the 2017 Equity Incentive Plan (the “2017 Plan”) and all equity-based awards subsequent to the IPO would be granted under the 2017 Plan.

For the three months ended March 31, 2020, the Group granted 842,500 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from $44.94 to $51.48 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five or three-year period, with 20% or 33.3% of the awards vesting beginning on the anniversary date one year after the grant date.

For the three months ended March 31, 2021, the Group granted 15,100 share options to certain management and employees of the Group at the exercise price of $162.02 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

The weighted-average grant-date fair value of the options granted in the three months ended March 31, 2021 and 2020 were $162.02 and $48.68 per share, respectively. The Group recorded compensation expense related to the options of $5,549 and $4,921 for the three months ended March 31, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2021	2020
	$	$
Selling, general and administrative	3,259	2,744
Research and development	2,290	2,177
Total	5,549	4,921

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

As of March 31, 2021, there was $67,009 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 1.41 years which is determined based on the number of shares and unrecognized years.

Non-vested restricted shares

For the three months ended March 31, 2020, 50,000 ordinary shares were authorized for grant to the independent directors. The restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the three months ended March 31, 2020, 12,000 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the three months ended March 31, 2021, 19,260 ordinary shares were authorized for grant to the independent directors. The restricted shares will vest and be released from the restrictions in full on the first anniversary from the date of the agreement. Upon termination of the independent directors' service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

For the three months ended March 31, 2021, 3,100 ordinary shares were authorized for grant to certain management. One fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management's service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

The Group measured the fair value of the non-vested restricted shares as of respective grant dates and recognized the amount as compensation expense over the deemed service period using a graded vesting attribution model on a straight-line basis.

As of March 31, 2021, there was $17,469 of total unrecognized compensation expense related to non-vested restricted shares. The Group recorded compensation expense related to the restricted shares of $1,769 and $1,542 for the three months ended March 31, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2021	2020
	$	$
Selling, general and administrative	1,211	1,068
Research and development	558	474
Total	1,769	1,542

15. Accumulated other comprehensive income (loss)

The movement of accumulated other comprehensive income (loss) is as follows:

	Foreign currency translation adjustments
	$
Balance as of December 31, 2020	(14,524)
Other comprehensive income	2,900
Balance as of March 31, 2021	(11,624)

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

16. Licenses and collaborative arrangement

The following is a description of the Group’s significant ongoing collaboration agreements for the three months ended March 31, 2021.

License and collaboration agreement with Deciphera Pharmaceuticals, LLC (“Deciphera”)

In June 2019, the Group entered into a license agreement with Deciphera, pursuant to which it obtained an exclusive license under certain patents and know-how of Deciphera to develop and commercialize products containing ripretinib in the field of the prevention, prophylaxis, treatment, cure or amelioration of any disease or medical condition in humans in Greater China.

Under the terms of the agreement, the Group paid Deciphera an upfront license fee of $20,000 and two milestone payments of $7,000, and accrued for a milestone payments of $5,000. The Group also agreed to pay certain additional development, regulatory and commercial milestone payments up to an aggregate of $173,000, and certain tiered royalties (from low-to-high teens on a percentage basis and subject to certain reductions) based on the net sales of the licensed products in the territory.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Deciphera.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

License agreement with Turning Point Therapeutics Inc (“Turning Point”)

In July 2020, the Group entered into an exclusive license agreement with Turning Point pursuant to which Turning Point exclusively licensed to the Group the rights to develop and commercialize products containing repotrectinib as an active ingredient in all human therapeutic indications, in Greater China.

Under the terms of the agreements, the Group paid an upfront payment of $25,000 to Turning Point. Turning Point is also eligible to receive up to $151,000 in development, regulatory and sales milestones. Turning Point will also be eligible to receive certain tiered royalties (from mid-to-high teens on a percentage basis and subject to certain reductions) based on annual net sales of repotrectinib in Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Turning Point.

In January 2021, the Group entered into a license agreement with Turning Point, which expanded their collaboration. Under the terms of the new agreement, the Group obtained exclusive rights to develop and commercialize TPX-0022, Turning Point’s MET, SRC and CSF1R inhibitor, in Greater China.

The Group paid an upfront license fee in the amount of $25,000 to Turning Point. The Group also agreed to pay certain development, regulatory and commercial milestone payments up to an aggregate of $336,000. Turning Point will also be eligible to receive certain tiered royalties (from mid-teens to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of TPX-0022 in Greater China. In addition, Turning Point will have the right of first negotiation to develop and commercialize an oncology product candidate discovered by the Group.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

License and collaboration agreement with Five Prime Therapeutics, Inc. (“Five Prime”)

In December 2017, the Group entered into a license and collaboration agreement with Five Prime (a company later acquired by Amgen Inc.), pursuant to which it obtained an exclusive license under certain patents and know-how of Five Prime to develop and commercialize products containing Five Prime’s proprietary afucosylated FGFR2b antibody known as bemarituzumab (FPA144) as an active ingredient in the treatment or prevention of any disease or condition in humans in Greater China.

Under the terms of the agreement, the Group made an upfront payment of $5,000 and a milestone payment of $2,000 to Five Prime. Additionally, the Group also agreed to pay further development and regulatory milestone payments of up to an aggregate of $37,000 to Five Prime and certain tiered royalties (from high-teens to low-twenties on a percentage basis and subject to certain reductions) based on the number of patients the Group enrolls in the bemarituzumab study.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Five Prime.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

License agreement with Cullinan Pearl Corp. (“Cullinan”)

In December 2020, the Group entered into a license agreement with Cullinan, a subsidiary of Cullinan Management, Inc., formerly Cullinan Oncology, LLC, pursuant to which it obtained an exclusive license under certain patents and know-how of Cullinan to develop, manufacture and commercialize products containing CLN-081 as an active ingredient in all uses in humans and animals in Greater China.

Under the terms of the agreement, the Group paid an upfront payment of $20,000 to Cullinan. Cullinan is also eligible to receive up to $211,000 in development, regulatory and sales-based milestone payments. Cullinan is also eligible to receive certain tiered royalties (from high-single-digit to low-teen tiered royalties on a percentage basis and subject to certain reductions) based on annual net sales of CLN-081 in Greater China.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Cullinan.

License agreement with Takeda Pharmaceutical Company Limited (“Takeda”)

In December 2020, the Group entered into an exclusive license agreement with Takeda. Under the terms of the license agreement, Takeda exclusively licensed to the Group the right to exploit products in the licensed field during the term.

Under the terms of the agreement, the Group paid an upfront payment of $6,000 to Takeda. Takeda is also eligible to receive up to $481,500 in development, regulatory and sales-based milestone payments. Takeda is also eligible to receive certain tiered royalties (from high-single-digit to low-teen tiered royalties on a percentage basis and subject to certain reductions) based on net sales of each product sold by selling party during each year of the applicable royalty term.

The Group has the right to terminate this agreement at any time by providing written notice of termination to Takeda.

Collaboration and license agreement with argenx BV (“argenx”)

In January 2021, the Group entered into a collaboration and license agreement with argenx. The Group received an exclusive license to develop and commercialize products containing argenx’s proprietary antibody fragment, known as efgartigimod, in Greater China. The Group is responsible for the development of the licensed compound and licensed product, and will have the right to commercialize such licensed product in the territory.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

Pursuant to the collaboration and license agreement, a share issuance agreement was entered into between the Group and argenx. As the upfront payment to argenx, the Group issued 568,182 ordinary shares of the Company to argenx with par value $0.00006 per share on the closing date of January 13, 2021. In determining the fair value of the ordinary shares at closing, the Company considered the closing price of the ordinary shares on the closing date and included a lack of marketability discount because the shares are subject to certain restrictions. The fair value of the shares on the closing date was determined to be $62,250 in the aggregate. The Group recorded this upfront payment in research and development expenses.

In addition, the Group made a non-creditable, non-refundable development cost-sharing payment of $75,000 to argenx. Argenx is also eligible to receive a cash payment of $25,000 upon the first regulatory approval of a licensed product by the U.S. Food and Drug Administration for myasthenia gravis and tiered royalties (from mid-teen to low-twenties on a percentage basis and subject to certain reductions) based on annual net sales of all licensed product in the territory.

Full details of the licenses and collaborative arrangements are included in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the SEC on March 1, 2021. As noted above, the Group has entered into various license and collaboration agreements with third party licensors to develop and commercialize product candidates. Based on the terms of these agreements the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. Based on management’s evaluation of the progress of each project noted above, the licensors will be eligible to receive from the Group up to an aggregate of approximately $2,871,396 in future milestone payments upon the achievement of contractually specified development milestones, such as regulatory approval for the product candidates, which may be before the Group has commercialized the product or received any revenue from sales of such product candidate, which may never occur.

17. Restricted net assets

The Group’s ability to pay dividends may depend on the Group receiving distributions of funds from its Chinese 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 unaudited condensed 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 Chinese subsidiary was established as domestic invested enterprise and therefore is subject to the above-mentioned restrictions on distributable profits.

During the three months ended March 31, 2021 and 2020, no appropriation to statutory reserves was made because the Chinese 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 Chinese subsidiary is restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulation in China may further restrict the Group’s Chinese subsidiary from transferring funds to the Group in the form of dividends, loans and advances. As of March 31, 2021 and December 31, 2020, amounts restricted are the paid-in capital of the Group’s Chinese subsidiaries, which amounted to $306,010 and $205,858, respectively.

18. Commitments and Contingencies

(a) Purchase commitments

As of March 31, 2021, the Group’s commitments related to purchase of property and equipment contracted but not yet reflected in the unaudited condensed consolidated financial statement were $16,991 and $5,507 which are expected to be incurred within one year and within one to two years, respectively.

Zai Lab Limited

Notes to the unaudited condensed consolidated financial statements

(In thousands of U.S. dollars (“$”) and Renminbi (“RMB”) except for number of shares and per share data)

(b) Contingencies

The Group is a party to or assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 16).

19. Subsequent Event

In April 2021, the Company closed an underwritten public offering of 4,776,000 American depositary shares (“ADSs”) at a price of $150.00 per ADS and 224,000 ordinary shares at a price of HK$1,164.20 per ordinary share. In addition, the underwriters fully exercised their option to purchase an additional 716,400 ADSs at the public offering price. Total proceeds, net of underwriting fees and offering expenses, were approximately $818,052.

In April 2021, the Group granted 479,363 share options to certain management and employees of the Group at the exercise price of $130.96 per share under the 2017 Plan. These options granted have a contractual term of ten years and generally vest over a five-year period, with 20% of the awards vesting beginning on the anniversary date one year after the grant date.

In April 2021, 188,150 ordinary shares were authorized for grant to certain management and employees of the Group. One-fifth of the restricted shares will vest and be released from the restrictions on each yearly anniversary from the date of the agreement. Upon termination of the certain management’s service with the Group for any reason, any shares that are outstanding and not yet vested will be immediately forfeited.

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

Overview

We are a commercial stage, biopharmaceutical company with a substantial presence in both Greater China and the United States. We are discovering, developing and commercializing innovative products that target medical conditions with unmet needs affecting patients in China and worldwide, particularly in the areas of oncology, autoimmune disorders, and infectious diseases. As of May 10, 2021, we have three commercialized products that have received marketing approval and eleven programs in late-stage product development.

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Developing high quality product candidates requires a significant investment related to our research and development activities over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Our ability to generate profits and to generate positive cash flow from operations over the next several years depends upon our ability to successfully market our current three commercial products ZEJULA, Optune and QINLOCK®, and our other product candidates that we are able to successfully commercialize. We expect to continue to incur substantial expenses related to our research and development activities. In particular, our licensing and collaboration agreements require us to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones as well as tiered royalties based on the net sales of the licensed products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our consolidated financial statements and totaled $171.3 million for the three months ended March 31, 2021. In addition, we expect to incur substantial costs related to the commercialization of our product candidates, in particular during the early launch phase.

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

Recent Developments

Recent Business Developments

In January 2021, we entered into an exclusive development and commercialization agreement with argenx, a global immunology company, for efgartigimod in Greater China. Pursuant to the terms of the agreement, we have agreed to fund and undertake all clinical development and regulatory submissions in the territories, participate in certain global studies, and plan to launch and commercialize the licensed product once approved. argenx received a $75.0 million (before a lack of marketability discount) upfront payment in the form of 568,182 newly issued our ordinary shares calculated at a price of $132.00 per share, and received $75.0 million as a guaranteed non-creditable, non-refundable development cost-sharing payment, and will receive an additional $25.0 million milestone payment upon approval of efgartigimod in the United States. argenx is also eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis) based on annual net sales of efgartigimod in the licensed territories.

In addition, in January 2021, we entered into an exclusive development and commercialization agreement with Turning Point for TPX-0022, its MET, SRC and CSF1R inhibitor, in Greater China. Turning Point received a $25.0 million upfront payment, and will receive up to approximately $336.0 million in potential development, regulatory and sales-based milestone payments. Turning Point will also be eligible to receive tiered royalties (mid-teen- to low-twenties on a percentage basis) based on annual net sales of TPX-0022 in the licensed territories.

In March 2021, we received approval from the China National Medical Products Administration (NMPA) for our New Drug Application for QINLOCK for the treatment of adult patients with advanced gastrointestinal stromal tumors who have received prior treatment with three or more kinase inhibitors, including imatinib.

In April 2021, we successfully completed a global follow-on offering of our American Depositary Shares and ordinary shares and raised approximately $857.5 million, not including underwriting discounts and commissions and other offering expenses.

Recent Regulatory Developments

PRC Medical Device Regulations

The sale and marketing of imported medical device products in China are subject to notifications (for Class I devices) or registrations (for Class II and III devices) with the NMPA. We launched Optune in China in June 2020 after the NMPA approved Optune in May 2020 in combination with temozolomide for the treatment of patients with newly diagnosed GBM and also as a monotherapy for the treatment of patients with recurrent GBM. Optune is regulated as a Class III imported medical device in China, and we act as the Chinese legal agent for our collaboration partner, Novocure, who is the foreign marketing authorization holder (MAH) for Optune in China. We are preparing to submit to the NMPA a Marketing Authorization Application for Optune Lua for the treatment of unresectable, locally advanced or metastatic malignant pleural mesothelioma.

The Chinese State Council passed new Medical Device Regulations (State Council Order #739), or Order #739, to replace the existing Medical Device Regulations (State Council Order #680), or Order #680. Order #739 was recently published by the National Medical Products Administration (NMPA) and will become effective on June 1, 2021. Order #739 largely follows the legislative structure of Order #680. We, as the Chinese legal agent for Optune in China, are subject to the statutory compliance requirements under Order #680 and will be subject to similar requirements under Order #739. The following updates from Order #739 we believe are the most relevant to our compliance obligations and our business operations in China:

- *Chinese legal agent*. Under Order #739, foreign device MAHs will still need to appoint a Chinese legal entity to submit regulatory applications and correspond with regulatory authorities. Nevertheless, the local appointees may only need to play a secondary role to assist the foreign device MAHs in the performance of compliance obligations under Order #739.
- *Liabilities for non-compliance*. Order #739 significantly increases MAH's liabilities for non-compliance. Order #739 also introduces personal liability on the legal representatives, main responsible persons, directly responsible supervisors or other personnel of MAHs. While Order #680 does not differentiate the liability of local legal agents from the foreign device MAHs, Order #739 makes it clear that local appointees will assume a lesser degree of liability compared to the foreign device MAHs. If local appointees fail to perform the statutory responsibilities and obligations on behalf of the MAHs, they will be subject to administrative fines up to RMB 0.5 million, and their responsible personnel will only be subject to a five-year debarment. In comparison, foreign MAHs who refuse to fulfill the administrative penalties can result in a ten-year import ban.
- *MAH system*. The MAH system will be rolled out nationwide. MAHs will be responsible for the safety and effectiveness of their products during the entire product life cycle. They must establish a quality management system and ensure its effectiveness, define and implement a post-approval study and risk control plan, conduct adverse event monitoring and re-evaluation, establish and implement the product tracing and recall system, and fulfill other statutory obligations imposed by the NMPA.
- *Clinical evidence*. The NMPA will allow versatile clinical evidence to demonstrate product safety and effectiveness. Such evaluation can be based on clinical study data or analysis of clinical literature and clinical data on predicate devices.
- *Expanded access*. Expanded access to investigational devices will be made available for patients in the study sites upon ethics committee approval and the patients' giving informed consent, provided that the investigational devices are used for critical, life-threatening diseases without an effective treatment method and can confer clinical benefits on patients based on medical judgment.

PRC Biosecurity Law

On April 15, 2021, the PRC Biosecurity Law took effect.

Factors Affecting our Results of Operations

Research and Development Expenses

We believe our ability to successfully develop product candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high quality product candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of product candidates has been steadily advancing and expanding, with eleven late-stage clinical product candidates being investigated.

To date, we have financed our activities primarily through private placements, our initial public offering in September 2017, a secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through March 31, 2021, we have raised approximately $164.6 million in private equity financing and approximately $1,644.6 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, our secondary listing and our follow-on offerings. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $169.5 million and $39.8 million, for the three months ended March 31, 2021 and March 31, 2020, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our eleven late-stage clinical product candidates and continue research and development of our clinical and pre-clinical-stage product candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. 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.

Selling, General and Administrative Expenses

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

Our Ability to Commercialize Our Product Candidates

As of March 31, 2021, eleven of our product candidates are in late-stage clinical development and various others are in clinical and pre-clinical development in China and the United States. Our ability to generate revenue from our product candidates is dependent on their receipt of regulatory approval for and successful commercialization of such products, which may never occur. Certain of our product 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 product under these agreements as well as tiered royalties based on the net sales of the licensed products. These upfront payments and milestone payments upon the achievement of certain development and regulatory milestones are recorded in research and development expense in our unaudited condensed consolidated financial statements and totaled $171.3 million and $9.2 million for the three months ended March 31, 2021 and 2020, 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” in our Annual Report on Form 10-K for the year ended December 31, 2020.

People’s Republic of China

Our subsidiaries incorporated in China are governed by the EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for up to following five years. For more information, see “Taxation—Material People’s Republic of China Taxation” in our Annual Report on Form 10-K for the year ended December 31, 2020.

Hong Kong

Our subsidiaries incorporated in Hong Kong are subject to two-tiered tax rates for the three months ended March 31, 2021 and 2020 on assessable profits earned in Hong Kong where the profits tax rate for the first HK$2 million of assessable profits is subject to profits tax rate of 8.25% and the assessable profits above HK$2 million is subject to profits tax rate of 16.5%. Our subsidiaries incorporated in Hong Kong did not have assessable profit for the three months ended March 31, 2021 and 2020.

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 unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report. 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)	Three months ended March 31, 2021	2020
Comprehensive Loss Data:		
Revenue	$ 20,103	$ 8,218
Expenses:		
Cost of sales	(7,505)	(2,084)
Research and development	(203,852)	(33,742)
Selling, general and administrative	(35,838)	(18,714)
Loss from operations	$ (227,092)	$ (46,322)
Interest income	214	1,655
Interest expenses	—	(59)
Other expense, net	(6,227)	(3,125)
Loss before income tax and share of loss from equity method investment	$ (233,105)	$ (47,851)
Income tax expense	—	—
Share of gain (loss) from equity method investment	195	(137)
Net loss attributable to ordinary shareholders	$ (232,910)	$ (47,988)
Weighted-average shares used in calculating net loss per ordinary share, basic and diluted	88,374,928	72,956,538
Net loss per share, basic and diluted	$ (2.64)	$ (0.66)

Three Months Ended March 31, 2021 Compared to Three Months Ended March 31, 2020

Revenue

Our revenue is primarily derived from the sale of ZEJULA and Optune in China and Hong Kong. The amount of revenue of ZEJULA for the three months ended March 31, 2021, was adjusted by the normal process in China to compensate distributors for products recently sold at prices prior to the National Reimbursement Drug List ("NRDL") implementation. The following table disaggregates net revenue by product for the three months ended March 31, 2021 and 2020:

	Three months ended March 31,			
(in thousands)	2021	%	2020	%
ZEJULA	$ 12,606	62.7	$ 6,345	77.2
Optune	7,130	35.5	1,873	22.8
Others	367	1.8	—	—
Total product revenue—Net	$ 20,103	100.0	$ 8,218	100.0

Research and Development Expenses

The following table sets forth the components of our research and development expenses for the periods indicated.

	Three months ended March 31,			
(in thousands)	2021	%	2020	%
Research and development expenses:				
Personnel compensation and related costs	$ 12,697	6.2	$ 10,004	29.6
Licensing fees	171,282	84.0	9,240	27.4
Payment to CROs/CMOs/Investigators	15,526	7.6	9,830	29.1
Other costs	4,347	2.2	4,668	13.9
Total	$ 203,852	100.0	$ 33,742	100.0

Research and development expenses increased by $170.2 million to $203.9 million for the three months ended March 31, 2021 from $33.7 million for the three months ended March 31, 2020. The increase in research and development expenses included the following:

- $2.7 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 three months ended March 31, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $162.0 million for increased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees;
- $5.7 million for increased payment to CROs, CMOs and investigators in the three months ended March 31, 2021 as we advanced our drug candidate pipeline; and

The following table summarizes our research and development expenses by program for the three months ended March 31, 2021 and 2020, respectively:

	Three months ended March 31,			
(in thousands)	2021	%	2020	%
Research and development expenses:				
Clinical programs	$ 186,256	91.4	$ 20,332	60.3
Pre-clinical programs	2,500	1.2	688	2.0
Unallocated research and development expenses	15,096	7.4	12,722	37.7
Total	$ 203,852	100.0	$ 33,742	100.0

During the three months ended March 31, 2021, 91.4% and 1.2% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the three months ended March 31, 2020, 60.3% and 2.0% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. Although we manage our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any given time.

Selling, General and Administrative Expenses

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

(in thousands)	Three months ended March 31, 2021	%	2020	%
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	$ 23,412	65.3	$ 13,042	69.7
Professional service fees	3,583	10.0	2,027	10.8
Other costs	8,843	24.7	3,645	19.5
Total	$ 35,838	100.0	$ 18,714	100.0

Selling, general and administrative expenses increased by $17.1 million to $35.8 million for the three months ended March 31, 2021 from $18.7 million for the three months ended March 31, 2020. The increase in general and administrative expenses included the following:

- $10.4 million for increased personnel compensation and related costs which was primarily attributable to increased commercial and administrative personnel costs, due to hiring of more personnel during the three months ended March 31, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- $1.5 million for increased professional service fee, mainly attributable to our increased legal, compliance, accounting and investor and public relations expenses associated with being a public company; and
- $5.2 million for increased other costs, mainly including selling, rental, and administrative expenses primary attributable to the commercial operation in Hong Kong and China.

Interest Income

Interest income decreased by $1.5 million, to $0.2 million for the three months ended March 31, 2021, from $1.7 million for the three months ended March 31, 2020 primary due to the decrease of short-term investments balance.

Interest Expenses

Interest expenses is nil for the three months ended March 31, 2021, compared to $0.1 million for the three months ended March 31, 2020, as all the short-term borrowings were repaid in 2020.

Share of loss from equity method investment

In June 2017, we entered into an agreement with three third-parties to launch JING Medicine Technology (Shanghai) Ltd., or JING, an entity that will provide services for drug discovery and development, consultation and transfer of pharmaceutical technology. We account for our investment using the equity method of accounting because we do not control the investee but have the ability to exercise significant influence over the operating and financial policies of the investee. The capital contribution by us was RMB 26.3 million in cash, which was paid in 2017 and 2018, representing 20% and 18% of the equity interest of JING as of December 31, 2020 and March 31, 2021 respectively. We recorded the gain on deemed disposal in this investee of $0.5 million and share of loss of $0.3 million for the three months ended March 31, 2021, and recorded share of loss in this investee of $0.1 million for the three months ended March 31, 2020.

Other Expense, net

Other expense, net increased by $3.1 million for the three months ended March 31, 2021 and 2020 primarily as a result of a decrease in governmental subsidies and increase in foreign exchange loss.

Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of $232.9 million for the three months ended March 31, 2021 compared to net loss attributable to ordinary shareholders of $48.0 million for the three months ended March 31, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Revenue recognition

In 2018, we adopted of ASC Topic 606 ("ASC 606"), *Revenue from Contracts with Customers*, in recognition of revenue. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration expected to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Our revenue is all from product sales. We recognize revenue from product sales when we have satisfied the performance obligation by transferring control of the product to the customers. Control of the product generally transfers to the customers when the delivery is made and when title and risk of loss transfers to the customers. Cost of sales mainly consists of the acquisition cost of products and royalty fees.

We have applied the practical expedients under ASC 606 with regard to assessment of financing components and concluded that there is no significant financing component given that the period between delivery of goods and payment is generally one year or less. We have generated product sales revenue since 2018. For the three months ended March 31, 2021 and 2020, our product revenues were primarily generated from the sale of ZEJULA (niraparib) and OPTUNE (Tumor Treating Fields) to customers.

In China, we sell the products to distributors, who ultimately sell the products to healthcare providers. Based on the nature of the arrangements, the performance obligations are satisfied upon the product's delivery to distributors. Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amount of unpaid or unbilled rebates, if any, is recorded as a reduction of revenue. Estimated rebates are determined based on contracted rates, sales volumes and level of distributor inventories. We regularly review the information related to these estimates and adjust the amount accordingly.

In Hong Kong, we sell the products to customers, which are typically healthcare providers such as oncology centers. We utilize a third party for warehousing services. Based on the nature of the arrangement, we have determined that we are a principal in the transaction since we are primarily responsible for fulfilling the promise to provide the products to the customers, maintain inventory risk until delivery to the customers and have latitude in establishing the price. Revenue is recognized at the amount to which we expect to be entitled in exchange for the sale of the products, which is the sales price agreed with the customers. Consideration paid to the third party is recognized in operating expenses.

We did not recognize any contract assets and contract liabilities as of March 31, 2021 and 2020.

Share-Based Compensation

We grant share options and non-vested restricted shares to eligible employees, management and directors and account 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. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. We determined the fair value of the stock options granted to employees using the Black-Scholes option valuation model.

We also grant share options to eligible non-employees and account for these share-based awards in accordance with ASC 718, *Compensation-Stock Compensation*. Non-employees' share-based awards are measured at the grant date fair value of the awards and recognized as expenses (1) immediately at grant date if no vesting conditions are required; or (2) using graded vesting method over the requisite service period, which is the vesting period. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. We determined the fair value of the stock options granted to non-employees using the Black-Scholes option valuation model.

Fair Value Measurements

We apply ASC Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement.

ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Include other inputs that are directly or indirectly observable in the marketplace.

Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches, for example, to measuring the fair value of assets and liabilities: (1) market approach, (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of our company primarily include cash, cash equivalents and restricted cash, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities. As of each reporting date, the carrying values of cash and cash equivalents, short-term investment, accounts receivable, prepayments and other current assets, short-term borrowings, accounts payable and other current liabilities approximated their fair values due to the short-term maturity of these instruments, and the carrying value of restricted cash approximates its fair value based on the nature of and the assessment of the ability to recover these amounts.

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 March 31, 2021 and December 31, 2020, we did not have any significant unrecognized uncertain tax positions.

B. Liquidity and Capital Resources

To date, we have financed our activities primarily through private placements, our September 2017 initial public offering on the Nasdaq stock exchange, our September 2020 secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through March 31, 2021, we have raised approximately $164.6 million in private equity financing and approximately $1,644.6 million in net proceeds after deducting underwriting commissions and the offering expenses payable by us in our initial public offering, subsequent follow-on offerings, and our secondary listing. Our operations have consumed substantial amounts of cash since inception. The net cash used in our operating activities was $169.5 million and $39.8 million, for the three months ended March 31, 2021 and 2020, respectively.

As of March 31, 2021, we had cash, cash equivalents and restricted cash of $1,014.2 million. Our expenditures as a company principally focused on research and development, are largely discretionary and as such our current losses and cash used in operations do not present immediate going concern issues. Based on our current operating plan, we expect that our existing cash and cash equivalents as of May 10, 2021, will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months after the date that the financial statements included in this Quarterly Report are issued. However, in order to bring to fruition our research and development objectives, we will ultimately need additional funding sources and there can be no assurances that they will be made available.

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020:

(in thousands)	Three months ended March 31, 2021	2020
Net cash used in operating activities	$ (169,500)	$ (39,841)
Net cash provided by investing activities	742,005	48,952
Net cash (used in) provided by financing activities	(271)	279,484
Effect of foreign exchange rate changes	(930)	(947)
Net increases in cash, cash equivalents and restricted cash	$ 571,304	$ 287,648

Net cash used in operating activities

During the three months ended March 31, 2021, our operating activities used $169.5 million of cash, which resulted principally from our net loss of $232.9 million, adjusted for non-cash charges of $72.1 million, and cash provided in our operating assets and liabilities of $8.7 million. Our net non-cash charges during the three months ended March 31, 2021 primarily consisted of $62.3 million non-cash research and development expenses, a $1.4 million depreciation expense, a $7.3 million share-based compensation expense and a $1.3 million non-cash lease expense.

Net cash provided by investing activities

Net cash provided by investing activities was $742.0 million for the three months ended March 31, 2021 compared to $49.0 million for the three months ended March 31, 2020. The increase in cash provided by investing activities was primary due to the proceeds from maturity of short-term investments.

Net cash provided by financing activities

Net cash used in financing activities was $0.3 million for the three months ended March 31, 2021 compared to the net cash provided by financing activities of $279.5 million for the three months ended March 31, 2020. The cash used in financing activities was mainly attributable to the payment of costs of our secondary listing on Stock Exchange of Hong Kong in September 2020 net off by the proceeds from exercises of stock options. The decrease in cash provided by financing activities was primary due to the issuance of ADSs in our follow-on offering during the three months ended March 31, 2020.

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 our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021.

D. Trend Information

Other than as described elsewhere in this Quarterly Report on Form 10-Q, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

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 March 31, 2021. Amounts we pay in future periods may vary from those reflected in the table.

(in thousands)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Purchase Obligations	$22,498	$16,991	$ 5,507	$ —	$ —
Operating Lease Obligations	18,232	5,573	6,228	4,379	2,052

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

For more information regarding recently issued accounting standards, please see “Part II—Item 8—Financial Statements and Supplementary Data—Recent accounting pronouncements” in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Foreign Exchange Risk

Renminbi, or RMB, is not a freely convertible currency. The State Administration of Foreign Exchange, under the authority of the People’s Bank of China (“PBOC”), controls the conversion of RMB into foreign currencies. The value of RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. The cash and cash equivalents of our company included aggregated amounts of RMB247.9 million and RMB155.9 million, which were denominated in RMB, as of March 31, 2021 and December 31, 2020, respectively, representing 4% and 5% of the cash and cash equivalents as of March 31, 2021 and December 31, 2020, respectively.

Our business mainly operates in China with a significant portion of our transactions settled in RMB, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. Although, in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the exchange rate between the U.S. dollar and the RMB because the value of our business is effectively denominated in RMB, while the ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. The conversion of RMB into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. On July 21, 2005, China changed its decade-old policy of pegging the value of the RMB to the U.S. dollar. Under the revised policy, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the RMB against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the RMB and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that China's government would increase the flexibility of the exchange rate, and thereafter allowed the RMB to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, in August 2015, the PBOC significantly devalued the RMB.

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 and short-term investment. The carrying amounts of cash and cash equivalents and short-term investment represent the maximum amount of loss due to credit risk. As of March 31, 2021 and December 31, 2020, all of our cash and cash equivalents and short-term investments were held by major financial institutions located in China and international financial institutions outside of China which we believe are of high credit quality, and we will continually monitor the credit worthiness of these financial institutions.

Inflation

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of March 31, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the three months ended March 31, 2021, there have not been any changes in our internal controls over financial reporting (as such item is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended) that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We may be, from time to time, subject to claims and suits arising in the ordinary course of business. Although the outcome of these and other claims cannot be predicted with certainty, management does not believe that the ultimate resolution of these matters will have a material adverse effect on our financial position or on our results of operations. We are not currently a party to, nor is our property the subject of, any actual or threatened material legal or administrative proceedings.

Item 1A. Risk Factors

There have been no material changes from the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 1, 2021.

The following is a summary of significant risk factors and uncertainties that may affect our business which are discussed in more detail in our Annual Report on Form 10-K for the year ended December 31, 2020:

- our ability to successfully commercialize ZEJULA, Optune, QINLOCK and any other products and product candidates that we may obtain regulatory approval for;
- the anticipated amount, timing and accounting of revenues; contingent, milestone, royalty and other payments under licensing, collaboration, and acquisition agreements; tax positions and contingencies; collectability of receivables; pre-approval inventory; cost of sales; research and development costs; compensation and other selling, general and administrative expenses; amortization of intangible assets; foreign currency exchange risk; estimated fair value of assets and liabilities; and impairment assessments;
- expectations, plans and prospects relating to sales, pricing, growth and launch of our marketed and pipeline products;
- the potential impact of increased product competition in the markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways, including generic or biosimilar versions of our products;
- patent terms, patent term extensions, patent office actions and expected availability and any period of regulatory exclusivity;
- the timing, outcome and impact of administrative, regulatory, legal or other proceedings related to our patents and other proprietary and intellectual property rights, tax audits, assessments and settlements, pricing matters, sales and promotional practices, product liability and other matters;
- the drivers for growing our business, including our plans and intention to commit resources relating to discovery, research and development programs and business development opportunities as well as the potential benefits and results of certain business development transactions;
- our ability to finance our operations and business initiatives and obtain funding for such activities;
- the expectations, development plans and anticipated timelines, including costs and timing of potential clinical trials, filings and approvals of our products, product candidates and pipeline programs, including collaborations with third-parties, as well as the potential therapeutic scope of the development and commercialization of our and our collaborators' pipeline products;
- reputational or financial harm to our business arising from adverse safety events, including product liability claims or lawsuits affecting our or any of our licensors' marketed products, generic or biosimilar versions of our or any of our licensors' marketed products or any other products from the same class as one of our or any of our licensors' products;
- unexpected impacts on our business operations including sales, expenses, supply chain, manufacturing, cyber-attacks or other privacy or data security incidents, research and development costs, clinical trials and employees;
- the potential impact of measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures, including the impact of pricing actions and reduced reimbursement for our products;
- our manufacturing capacity, use of third-party contract manufacturing organizations, plans and timing relating to changes in our manufacturing capabilities or activities in new or existing manufacturing facilities;
- lease commitments, purchase obligations and the timing and satisfaction of other contractual obligations;
- the impact of new laws, regulatory requirements, judicial decisions and accounting standards;
- the disruption of our business relationships with our licensors;
- the direct and indirect impact of the COVID-19 pandemic on our business and operations, our and our partners' ability to effectively travel, as needed, during the COVID-19 pandemic, and the duration and impact of COVID-19 or any of its variants that may affect, precipitate or exacerbate one or more of any of the risks and uncertainties mentioned in this section;
- our ability to effectively manage our growth;

- the disruption in the capital or credit markets which may adversely impact our ability to obtain necessary capital or credit market financing;
- the geopolitical tensions that exist between China and the United States may adversely affect our business, our ability to grow, and our access to necessary capital or credit markets;
- our ability to retain key executives and to attract, retain and motivate personnel; and
- other risks and uncertainties, including those listed under “Part I—Item 1A—Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020.

These factors should not be construed as exhaustive and should be read with the other cautionary statements and other information in our Annual Report on Form 10-K for the year ended December 31, 2020 and our other filings with the SEC.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

Effective on May 7, 2021, the Board appointed Tao Fu as the Chief Strategy Officer of the Company. Concurrently with his appointment as Chief Strategy Officer, Mr. Fu voluntarily resigned from his positions as the President and Chief Operating Officer of the Company and from his position as a director of the Company, effective immediately. In his new role as Chief Strategy Officer of the Company, Tao Fu will focus on the Company’s corporate development and other strategic objectives.

Item 6. Exhibits.

Exhibit Index

Exhibit Number	Exhibit Title
3.1	Fifth Amended and Restated Memorandum Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021)
3.2	Fourth Amended and Restated Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.3	Registrant's Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on September 1, 2017)
4.4	Third Amended and Restated Shareholders Agreement between Zai Lab Limited and other parties named therein dated June 26, 2017 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (File No. 333-219980) filed with the SEC on August 15, 2017)
4.5	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act (incorporated by reference to Exhibit 4.5 to our Annual Report on Form 10-K (File No. 001-38205) filed with the SEC on March 1, 2021)
10.1*^	Collaboration and License Agreement between argenx BV and Zai Auto Immune (Hong Kong) Limited dated January 6, 2021
10.2*^	License Agreement between Turning Point Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated January 10, 2021
10.3*^	Amendment No. 1 to License Agreement between Turning Point Therapeutics, Inc. and Zai Lab (Shanghai) Co., Ltd. dated March 31, 2021
31.1*	Certification of Chief Executive Officer Required by Rule 13a-14(a)
31.2*	Certification of Chief Financial Officer Required by Rule 13a-14(a)
32.1**	Certification of Chief Executive Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code
32.2**	Certification of Chief Financial Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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

SIGNATURES

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

ZAI LAB LIMITED

Dated: May 10, 2021

By: /s/ Billy Cho
Name: Billy Cho
Title: Chief Financial Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.1
Execution Version

COLLABORATION AND LICENSE AGREEMENT

between

ARGENX BV

and

ZAI AUTO IMMUNE (HONG KONG) LIMITED

Dated as of 6 January 2021

TABLE OF CONTENT

SCHEDULES:

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Exhibit 10.1
Execution Version

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "**Agreement**") is made and entered into effective as of 6 January 2021 (the "**Effective Date**") by and between argenx BV, a private limited company organized under the laws of Belgium with its principal place of business at Industriepark Zwijnaarde 7, 9052 Zwijnaarde (Ghent), Belgium ("**Licensor**"), and Zai Auto Immune (Hong Kong) Limited, a Hong Kong company, with an address at Room 2301, 23F, Island Place Tower, 510 King's Road, North Point, Hong Kong ("**Licensee**") and, solely with respect to Section 15.16 Zai Lab Limited, a China company, with an address at 4F, Bldg 1, Jinchuang Plaza 4560 Jinke Rd Shanghai, China, 201210 ("**Parent**"). Licensor and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Licensor Controls (as defined herein) certain intellectual property rights with respect to the Licensed Compound (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein);

WHEREAS, the Parties wish to collaborate on the development and commercialization of the Licensed Products in the Territory, in each case in accordance with the terms and conditions set forth below, taking into account the strong wish of the Licensor to have the commercialisation of the Licensed Product start as soon as possible in the Territory; and

WHEREAS, Licensor and Licensee wish to collaborate on the development and commercialization of the Licensed Products in the Territory, in each case in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE I
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Accounting Standards**" means, (a) with respect to Licensee, that Licensee shall maintain records and books of accounts in accordance with United States Generally Accepted Accounting Principles (GAAP), consistently applied and (b) with respect to Licensor, that Licensor shall maintain records and books of accounts in accordance with International Financial Reporting Standards (IFRS), consistently applied.

1.2 "**Acquiring Person**" has the meaning set forth in Section 7.8.3.

1.3 "**Additional Indication**" means, with respect to Licensed Products, each indication in the Field other than the Initial Indications, including any indication in which Licensed Products may be used in combination with one or more products of the Licensee.

1.4 "**Affiliate**" means, with respect to a Person, any subsidiary or any other Person that, directly or indirectly, through one or more intermediaries, is controlled by or is under common control with such Person. For purposes of this definition, "**control**" and, with correlative meanings, the terms "**controlled by**" and "**under common control with**" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of Voting Stock, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the Voting Stock or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.5 "**Agreement**" has the meaning set forth in the preamble hereto.

1.6 "**Alliance Manager**" has the meaning set forth in Section 2.11.

1.7 "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or jurisdiction hereunder.

1.8 "**Biosimilar Product**" means, with respect to a given Licensed Product in a particular jurisdiction after Regulatory Approval of such Licensed Product in such jurisdiction, a Third Party biologic product (a) whose licensing, approval, or marketing authorization relies in whole or in part on (i) a prior Regulatory Approval granted such Licensed Product or (ii) any data generated in support of a prior Regulatory Approval granted such Licensed Product, and (b) is determined by the competent Regulatory Authority of such jurisdiction to be interchangeable with the respective Licensed Product, including in terms of quality, safety, efficacy and dosing regimen.

1.9 "**Binding Forecast**" has the meaning set forth in Section 5.3;

1.10 "**Board of Directors**" has the meaning set forth in the definition of Change of Control.

1.11 "**Breaching Party**" has the meaning set forth in Section 13.2.1.

1.12 "**Bundling Sale**" has the meaning set forth in Section 8.4.7.

1.13 "**Business Day**" means a day other than a Saturday or Sunday on which banking institutions in Ghent, Belgium and Shanghai, the PRC are open for business.

1.14 "**Calendar Quarter**" means each successive period of three (3) months of the Gregorian calendar commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.15 "**Calendar Year**" means each successive period of twelve (12) months of the Gregorian calendar commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.16 "**Change of Control**" with respect to either Party or a Controlling Entity of such Party shall be deemed to have occurred if any of the following occurs during the Term:

1.16.1. any "person" or "group" (as defined below) (a) is or becomes the "beneficial owner" (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party or its Controlling Entity then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of such Party or its Controlling Entity representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party or its Controlling Entity or (b) has the power, directly or indirectly, to elect a majority of the members of such Party's or its Controlling Entity's board of directors, or similar governing body ("**Board of Directors**"); the Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity; or

1.16.2. such Party or its Controlling Entity enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the members of the Board of Directors of such Party or its Controlling Entity immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or its Controlling Entity or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party or its Controlling Entity immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party or its Controlling Entity representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party or its Controlling Entity immediately prior to such transaction; or

1.16.3. such Party sells or transfers to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of such Party's assets to which this Agreement relates; or

1.16.4. the holders of capital stock of such Party or its Controlling Entity approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change in Control: (a) "**person**" and "**group**" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "**group**" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (b) a "**beneficial owner**" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (c) the terms "**beneficially owned**" and "**beneficially own**" shall have meanings correlative to that of "**beneficial owner**."

1.17 "**Clinical Data**" means all Information with respect to the Licensed Compound or any Licensed Product made, collected, or otherwise generated under or in connection with a Clinical Trial, including any data (including raw data), reports, and results with respect thereto.

1.18 "**Clinical Trial**" means a Clinical Phase I Trial, Clinical Phase II Trial, or Clinical Phase III Trial, and such other tests and studies in human subjects that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Licensed Product for one (1) or more indications, including tests or studies that are intended to expand the Product Labeling for such Licensed Product with respect to such indication.

1.19 "**Clinical Phase I Trial**" means a study in humans which provides for the first administration to humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics.

1.20 "**Clinical Phase II Trial**" means a clinical study (other than a Clinical Phase I Trial) in humans of the safety, dose ranging and efficacy of a product, which is prospectively designed to generate sufficient data (if successful) to commence pivotal studies/Clinical Phase III Trials.

1.21 "**Clinical Phase III Trial**" means a controlled, and usually multicenter, clinical study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in humans in the indication being investigated in a manner sufficient to submit an application to obtain Regulatory Approval to market such product.

1.22 "**COGS**" has the meaning ascribed thereto in **Schedule 1.22**.

1.23 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of Licensed Products, including activities related to marketing, promoting, distributing, and importing such Licensed Products, and interacting with Regulatory Authorities regarding any of the foregoing. For clarity, Commercialization does not include Manufacturing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.24 "**Commercially Reasonable Efforts**" means, with respect to the performance of Development, Commercialization or other applicable activities with respect to the Licensed Products by Licensee, the carrying out of such activities using efforts and resources comparable to the efforts and resources commonly used in the biopharmaceutical industry for products of similar market potential at a similar stage in development or product life (without regard to the particular circumstances of Licensee, including any other product opportunities of Licensee) taking into account relevant factors such as safety, regulatory issues, intellectual property issues, and reimbursement. "Commercially Reasonable Efforts" shall be determined on a jurisdiction-by-jurisdiction and indication-by-indication basis, Commercially Reasonable Efforts require, with respect to the applicable obligation, that Licensee shall [***].

1.25 "**Commercial Supply Agreement**" has the meaning set forth in Section 5.3.

1.26 "**Committee**" means the JSC, the JDC, the JMC, the JCC, the JFC or another Sub-Committee (together, the "**Committees**").

1.27 "**Competing Product**" means any product that [***] mode of action.

1.28 "**Compliance Self-Audit**" has the meaning set forth in Section 6.10.

1.29 "**Confidential Information**" means any technical, business, or other information or data provided orally, visually, in writing or other form by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information relating to the terms of this Agreement, the Licensed Compound or any Licensed Product, any Exploitation of the Licensed Compound or Licensed Products, any Information with respect thereto developed by or on behalf of a Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of either Party. The Licensed Know- How, Product Improvements and the Regulatory Data owned by Licensor pursuant to the terms of this Agreement are deemed to be Licensor's Confidential Information and Licensee is deemed to be the receiving Party and Licensor the disclosing Party with respect thereto. The existence and terms of this Agreement, are the Confidential Information of each Party, with each Party being deemed the receiving Party of such Confidential Information.

1.30 "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue or otherwise (other than by operation of the license and other grants in ARTICLE 7), to gr ant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent, or other property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.31 "**Controlling Entity**" means, with respect to a Party, any Person that controls such Party. For purposes of this definition, "control" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of Voting Stock, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the Voting Stock or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

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

1.33 "**CRO**" means a contract research organization.

1.34 "**CTA**" means an application filed with a Regulatory Authority for authorization to commence human clinical studies, including (a) a Clinical Trial Application as defined in the PRC Drug Administration Law or an equivalent in other jurisdictions, and (b) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.35 "**Default Notice**" has the meaning set forth in Section 13.2.1(a).

1.36 "**Development**" means with regard to the Licensed Compound and the Licensed Product all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, Clinical Trials, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to any of the foregoing, including the preparation and submission of CTAs, the maintenance of a pharmacovigilance and safety database, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. For clarity, Development does not include Manufacturing. When used as a verb, "**Develop**" means to engage in Development.

1.37 "**Development Plan**" means a development plan setting forth in reasonable detail all Development activities to be performed by Licensee (a) to seek, obtain and maintain Regulatory Approvals for Licensed Products in the Territory, and (b) with respect to its responsibilities to perform Development activities for Global Trials in the Territory; which plan shall include in reasonable detail all items listed in Section 3.2.1.

1.38 "**Dollars**" or "**$**" means United States Dollars.

1.39 "**Drug Approval Application**" means an application filed with a Regulatory Authority for the approval of a pharmaceutical product to be marketed in the Territory.

1.40 "**Effective Date**" means the effective date of this Agreement as set forth in the preamble hereto.

1.41 "**EMA**" means the European Medicines Agency, and any successor agency(ies) or authority having substantially the same function.

1.42 "**Exploit**" or "**Exploitation**" means to make, have made, import, export, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of.

1.43 "**FcRn**" means the neonatal Fc receptor (UniProt ID: P55899).

1.44 "**FDA**" means the United States Food and Drug Administration, and any successor agency(ies) or authority having substantially the same function.

1.45 "**Field**" means all uses of the Licensed Products for any preventative or therapeutic indications, in humans and animals.

1.46 "**First Commercial Sale**" means, with respect to a given Licensed Product and a given jurisdiction, the first commercial sale for monetary value for use or consumption by the end user in an arm's length transaction of such Licensed Product to a Third Party in such jurisdiction after Regulatory Approval for such Licensed Product has been obtained in such jurisdiction. "First Commercial Sale" will not include any distribution or other sale solely for patient assistance, named patient use, compassionate use, or other patient access programs, non-registrational or registrational studies or similar programs or studies, in each case where a Licensed Product is supplied without charge or at the actual Manufacturing cost thereof (without allocation of indirect costs or any markup).

1.47 "**Global Marketing Guidelines**" has the meaning set forth in Section 6.5.

1.48 "**Global Trial**" means Development activities related to a Clinical Trial for a Licensed Product that are (a) conducted outside the Territory, or both inside and outside the Territory, and (b) are intended to support Regulatory Filings both inside and outside the Territory.

1.49 "**Global Trial Plan**" has the meaning set forth in Section 3.3.1.

1.50 "**Good Clinical Practice**" or "**GCP**" means, in respect of a Clinical Trial, the highest of the then current standards required by Applicable Law of: (a) the European Union, including Directive 2001/20/EC and guidance published by the European Commission or EMA in relation to such Directive; (b) the United States, including the provisions of Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 50, 54, 56, 312, 314, 320, 601 and 610); (c) Japan; (d) the People's Republic of China; or (e) such other countries in which a Licensed Product is tested.

1.51 "**Good Laboratory Practice**" or "**GLP**" means, in respect of laboratory activities, the highest of the then current standards required by Applicable Law of: (a) the European Union, including the Directive 2004/9/EC, Directive 2004/10/EC, guidance published by the European Commission or EMA in relation to such Directives and any local laws, rules and regulations that implement such Directives and guidance; (b) the United States, including the FDA's Good Laboratory Practice regulations at 21 C.F.R. Part 58; (c) Japan; (d) the People's Republic of China; or (e) such other countries in which a Licensed Product is tested.

1.52 [***]

1.53 "**Indemnification Claim Notice**" has the meaning set forth in Section 12.3.

1.54 "**Indemnified Party**" has the meaning set forth in Section 12.3.

1.55 "**Information**" means all knowledge of a technical, scientific, business and other nature, including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Regulatory Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents (e.g., plasmids, proteins, cell litres, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

1.56 "Initial Indications" means the indications set out in the initial Development Plan attached hereto as **Schedule 3.2.1.**

1.57 "**In-licensing Agreements**" means the [***].

1.58 "**JCC**" has the meaning set forth in Section 2.4.

1.59 "**JDC**" has the meaning set forth in Section 2.2.

1.60 "**JFC**" has the meaning set forth in Section 2.5.

1.61 "**JMC**" has the meaning set forth in Section 2.3.

1.62 "**JSC**" has the meaning set forth in Section 2.1.

1.63 "**Joint Program IP**" has the meaning set forth in Section 9.1 2(c).

1.64 "**Joint Patents**" means Patents claiming Joint Program IP.

1.65 "**Licensed Compound**" means Licensor's proprietary antibody fragment known as efgartigimod, an FcRn blocker, as more fully set forth in **Schedule 1.65**. The definition of Licensed Compound does not include any [***].

1.66 "**Licensee**" has the meaning set forth in the preamble hereto.

1.67 "**Licensee Indemnitees**" has the meaning set forth in Section 12.2.

1.68 "**Licensed Know-How**" any Information that is Controlled by Licensor or any of its Affiliates as of the Effective Date or, subject to Sections 7.7.3 and 15.3.2, during the Term the practice of which is necessary or useful for, or that is actually used in, the Development or Commercialization of Licensed Compound or Licensed Products.

1.69 "**Licensed Patents**" means all Patents that (a) are owned or Controlled by Licensor or any of its Affiliates as of the Effective Date or, subject to Sections 7.7.3 and 15.3.2, at any time during the Term (including Licensor's interests in Joint Patents), and (b) (i) claim the composition of matter or a method of use of the Licensed Compound or a Licensed Product or the Manufacture thereof, or (ii) are necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or the Licensed Products in the Field in the Territory. The Licensed Patents existing at the Effective Date are listed in **Schedule 1.69**.

1.70 "**Licensed Product**" means any biopharmaceutical product containing the Licensed Compound as an active pharmaceutical ingredient, alone or in combination with one (1) or more other active ingredients (in the same formulation), in any and all forms, presentations, delivery systems, dosages, and formulations.

1.71 "**Licensed Technology**" means the Licensed Patents and the Licensed Know-How.

1.72 "**Licensor**" has the meaning set forth in the preamble hereto.

1.73 "**Licensor Indemnitees**" has the meaning set forth in Section 12.1.

1.74 "**Lonza Agreement**" means that certain Multi-Product License Agreement between Lonza Sales AG and arGEN-X N.V. (currently argenx SE) dated February 4, 2015.

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

1.76 "**Manufacture**" and "**Manufacturing**" means all activities related to the synthesis, making, production, processing, purifying, filling, finishing, packaging, labeling, shipping, and holding of the Licensed Compound, any Licensed Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre- clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.77 "**Net Sales**" means the gross amounts invoiced or otherwise billed (or, if not invoiced or billed, received as barter, non-cash consideration or otherwise), byLicensee, its Affiliates and sublicensees in connection with the sale, lease or other transfer for value of Licensed Products to Third Parties; less (a) amounts actually allowed or credited for [***] (to the extent not already reflected in or deducted from the gross amount invoiced), excluding [***], (b) packing costs, insurance costs, freight out, transportation costs, VAT and import duties imposed on the transaction, (c) wholesaler, cash discounts and distributor costs in amounts customary in the trade to the extent actually granted or incurred, included in the invoice, separately itemized on the invoice and not already reflected in or deducted from in the gross amount invoiced, (d) bad debt written off under Accounting Standards [***] with reasonable collection efforts and added back if collected, in each case (a), (b), (c), and (d) to the extent allocable to the Licensed Products; provided that, in no event (i) shall the [***] (ii) shall any item of deduction be counted more than once and (iii) shall VAT be deducted for the purposes of calculating Net Sales if and to the extent such amounts are finally reimbursable to Licensee. In addition, in determining Net Sales, the following shall apply:

1.77.1. All of the foregoing deductions must be calculated in accordance with then current Accounting Standards, consistently applied, during the applicable calculation period throughout the selling, leasing or otherwise transferring party's organization.

1.77.2. Net Sales shall not include sales between or among Licensee and its Affiliates or subcontractors except if for end use.

1.77.3. Any discounts, rebates, chargebacks and other deduction will be fairly and equitably allocated to the Licensed Products, as applicable, and other products or processes of Licensee and its Affiliates or subcontractors such that a Licensed Product, as applicable, does not bear a disproportionate portion of any such deductions.

1.77.4. For purposes of calculating the Net Sales of any Licensed Products sold, leased or transferred, in exchange for consideration other than for cash in any jurisdiction, the price for such Licensed Products, as applicable, will equal the weighted average price of such Licensed Products, as applicable, that are sold for cash in such jurisdiction during the prior Calendar Year (or, if none, the average price of such Licensed Products, as applicable, that are sold for cash in the Territory during the applicable Calendar Quarter) in similar quantities.

For clarity, no deductions from Net Sales shall be made (a) for commissions paid to individuals, whether they are independent sales agents or employees or (b) for the cost of collections.

1.78 "**New Global Trial**" has the meaning set forth in Section 3.3.1(a).

1.79 "**NMPA**" means the Chinese National Medical Products Administration, and any successor agency(ies) or authority(ies) having substantially the same function.

1.80 "**Non-Breaching Party**" has the meaning set forth in Section 13.2.1.

1.81 "**Non-Cooperative Jurisdiction**" means a jurisdiction that is a jurisdiction with no taxation or a low taxation or a non-cooperative jurisdiction, all within the meaning of Article 307, §1/2 of the Belgian Income Tax Code 1992).

1.82 "**Parent**" has the meaning set forth in the preamble hereto.

1.83 "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.84 "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations secured by existing or future extension or restoration mechanisms, including revalidations, reissues, renewals, substitutions, re-examinations and extensions (including any patent term adjustments, patent term extensions, supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

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

1.86 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 4.8.

1.87 "**Product Improvement**" has the meaning set forth in Section 9.1.2(a).

1.88 "**Product Infringement**" has the meaning set forth in Section 9.3.1.

1.89 "**Product Labeling**" means, with respect to a Licensed Product in a jurisdiction in the Territory, (a) the Regulatory Authority-approved full prescribing information for such Licensed Product for such jurisdiction, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Licensed Product in such jurisdiction.

1.90 "**Product Trademarks**" means the Trademark(s) designated by Licensor for use by Licensee for the Development or Commercialization of Licensed Products in the Territory in accordance with the terms of this Agreement and Licensor's global brand strategy, and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

1.91 "**Program IP**" means all Information and inventions that are conceived, discovered, developed, or otherwise made by or on behalf of either or both Parties (or their respective Affiliates or subcontractors) in the performance of activities under this Agreement, whether or not patented or patentable, and any and all Patents and other intellectual property rights with respect thereto.

1.92 "**Publication**" means any publication or presentation in relation to Development activities for Licensed Products.

1.93 "**Quality Agreement**" shall mean a quality agreement setting out further administrative, technical and quality provisions regarding the subject of such quality agreement, pertaining to Manufacture and supply of Licensed Product (for Development or Commercialization purposes or the conduct of Development activities, as applicable), GCP activities or phannacovigilance activities including any intermediary version thereof.

1.94 [***].

1.95 "**Regulatory Approval**" means, with respect to a jurisdiction, any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize a Licensed Compound or Licensed Product in such jurisdiction, including, where applicable, (a) pricing or reimbursement approval in such jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) approval of Product Labeling.

1.96 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (e.g., the NMPA, EMA or FDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Exploitation of the Licensed Compound or Licensed Products in the Territory.

1.97 "**Regulatory Data**" means all non-clinical data, Clinical Data and other data contained in Regulatory Documentation.

1.98 "**Regulatory Documentation**" means all (a) Regulatory Filings and Regulatory Approvals, (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes of calls and in-person meetings and official contact reports relating to any communications with any Regulatory Authority) and adverse event files, and (c) Clinical Data and data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to a Licensed Compound or Licensed Products.

1.99 "**Regulatory Exclusivity**" means, with respect to a Licensed Product in a jurisdiction in the Territory, any additional market protection, other than Patent protection, granted by a Regulatory Authority for such Licensed Product in such jurisdiction which confers an exclusive Commercialization period during which Licensee can exclusively market and sell such Licensed Product in such jurisdiction through such regulatory exclusivity right.

1.100 "**Regulatory Filings**" means any filing with any Regulatory Authority with respect to the Development, Manufacture or Commercialization of the Licensed Compound or a Licensed Product. Unless expressly provided otherwise, Regulatory Filings include CTAs and Drug Approval Applications.

1.101 "**Royalty Term**" has the meaning set forth in Section 8.4.2.

1.102 "**Segregate**" means, with respect to a Competing Product, to segregate the research, development, manufacture, and commercialization activities relating to such Competing Product from the Development, Manufacture, and Commercialization activities with respect to the Licensed Compound and the Licensed Product under this Agreement, including by ensuring that: (a) no personnel involved in performing the research, development, manufacture, and commercialization, as applicable, of such Competing Product have access to non-public plans or non-public information relating to the Development, Manufacture, and Commercialization of the Licensed Compound or the Licensed Product or any other relevant Confidential Information of the applicable Party; and (b) no personnel involved in performing the Development, Manufacture, and Commercialization of the Licensed Compound or the Licensed Product have access to non-public plans or information relating to the research, development, manufacture, and commercialization of such Competing Product; provided, that, in either case ((a) or (b)), senior management personnel may review and evaluate plans and information regarding the research, development, manufacture, and commercialization of such Competing Product solely in connection with monitoring the progress of products and to make portfolio decision-making among product opportunities.

1.103 "**Senior Officer**" means, with respect to Licensor, its Chief Executive Officer (or its designee and direct report), and with respect to Licensee, its Chief Executive Officer (or its designee and direct report).

1.104 "**Share Issuance Agreement**" means the Share Issuance Agreement attached hereto as **Schedule 8.1**.

1.105 "**Sole Program IP**" has the meaning set forth in Section 9.1.2(b).

1.106 "**Sole Program Patents**" means Patents claiming Sole Program IP.

1.107 "**Sub-Committee**" has the meaning set forth in Section 2.6.

1.108 "**Subcontractable Affiliate**" means with regard to Licensee, any Affiliate that is controlled directly or indirectly by Licensee or Parent (as "controlled by" is defined in Section 1.4).

1.109 "**Sublicensable Affiliate**" means with regard to Licensee, any Affiliate that directly or indirectly controls Licensee or which is directly or indirectly controlled by Licensee, but expressly excluding any Affiliates under common control with Licensee (as "control", "controlled by" and "under common control with" are defined in Section 1.4).

1.110 "**Term**" has the meaning set forth in Section 13.1.

1.111 "**Territory**" means the People's Republic of China ("**PRC**"), Hong Kong, Macau and Taiwan.

1.112 "**Territory Marketing Materials**" has the meaning set forth in Section 6.5.

1.113 "**Territory-specific PoC Trials**" means any Clinical Phase I Trial and Clinical Phase II Trial for a Licensed Product that is designed to show clinical proof of concept for a new indication, and for which all or substantially all of the activities are conducted in the Territory.

1.114 "**Territory-specific Trials**" means any Clinical Trial for a Licensed Product for which all or substantially all of the activities are conducted in the Territory for obtaining Regulatory Approval for such Licensed Product in one (1) or more indications in the Field in the Territory, excluding any Territory-specific PoC Trials.

1.115 "**Third Party**" means any Person other than Licensor, Licensee and their respective Affiliates.

1.116 "**Third Party Claims**" has the meaning set forth in Section 12.1.

1.117 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.118 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.119 [***] means that certain patent license agreement [***]

1.120 "**Valid Claim**" means (a) a claim of an issued and unexpired Patent within the Licensed Patents (including the Joint Patents) that has not (i) irretrievably lapsed or expired, irretrievably been abandoned, or irretrievably been disclaimed; or (ii) been held invalid, unenforceable, or non-patentable by a court or other appropriate body that has competent jurisdiction, such holding being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim in a pending Patent application that is included in the Licensed Patents that is being prosecuted in good faith and has been pending (from the earliest priority date) for ten (10) years or less and that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

1.121 "**VAT and Indirect Taxes**" means any value added, sales, purchase, turnover or consumption tax as may be applicable in any relevant jurisdiction.

1.122 "**Voting Stock**" has the meaning set forth in the definition of Change of Control.

1.123 "**Withholding Income Tax**" has the meaning set forth in Section 8.7.2.

1.124 "**Withholding Tax**" has the meaning set forth in Section 8.7.2.

ARTICLE II
COLLABORATION MANAGEMENT

2.1. Joint Steering Committee. Within [***] days following the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**"). The JSC shall include senior executives of each Party. The JSC shall: (a) approve updates and amendments to the Development Plan (including timelines and budgets); (b) monitor the activities of the other Committees; (c) resolve any dispute referred to it by a Committee in accordance with Section 2.9; and (d) perform such other functions that are expressly delegated to the JSC in this Agreement or as mutually agreed by the Parties in writing.

2.2. Joint Development Committee. Within [***] days following the Effective Date, the Parties shall establish a joint development committee (the "**JDC**"). JDC shall include individuals from each Party with reasonable expertise in the areas of product development, clinical development and regulatory matters. The JDC shall be the forum for discussion of all Development related activities in the Territory, and shall: (a) oversee and monitor the Development activities for Licensed Products in the Territory in accordance with the Development Plan, and review Development reports and discuss at meetings the status, progress and results of the Development activities performed by Licensee in the Territory; (b) discuss the design of [***] Trials that are to be performed in the Territory; (c) perform the tasks and make the decisions delegated to the JDC under ARTICLE 3 and ARTICLE 4 of this Agreement; (d) serve as a forum for exchanging and discussing Regulatory Documentation, Regulatory Data and other technical information, and discussing strategies for, and the status of, obtaining Regulatory Approvals for Licensed Products in the Territory; (e) serve as a forum for discussing status of obtaining Regulatory Approvals for Licensed Products outside the Territory and (f) perform such other functions that are expressly delegated to the JDC in this Agreement or by the JSC.

2.3. Joint Manufacturing Committee. Within [***] days following the Effective Date, the Parties shall establish a joint manufacturing committee (the "**JMC")**. The JMC shall include individuals from each Party with reasonable expertise in the area of biological product manufacturing. The JMC shall be the forum for discussion of all Manufacturing related activities related to the Territory, and shall: (a) oversee and coordinate the clinical and commercial supply of Licensed Products for the Territory [***] (c) discuss any Manufacturing matters with respect to the Licensed Compound and Licensed Products designated for use in the Territory; and (d) perform such other functions that are expressly delegated to the JMC in this Agreement or by the JSC.

2.4. Joint Commercialization Committee. At least [***] prior to the anticipated filing of the first Drug Approval Application for the first Licensed Product in the Territory, the Parties shall establish a joint commercialization committee (the "**JCC**"). The JCC shall include individuals from each Party with reasonable expertise in the areas of sales and marketing, operations, and market access. The JCC shall be the forum for discussion of all Commercialization related activities in the Territory, and shall: (a) discuss, approve and update the Commercialization Plans and any amendments thereto; (b) ensure that the Commercialization activities in the Territory are consistent with Licensor's global brand, the Global Marketing Guidelines, and the Commercialization strategy outside the Territory, (c) establish a process to review and comment on the application of the Global Marketing Guidelines to the Territory and on the Territory Marketing Materials; (d) monitor and discuss the progress of the Commercialization of Licensed Products in the Field in the Territory in accordance with the Commercialization Plans and exchange information on the Commercialization of Licensed Product outside the Territory; (e) [***] and (f) perform the other functions that are expressly delegated to the JCC in this Agreement or by the JSC in writing.

2.5. Joint Finance Committee. Within [***] days following the Effective Date, the Parties shall establish a joint finance committee (the "**JFC**"). The JFC shall include individuals from each Party with reasonable expertise in the areas of accounting, budgeting and financial reporting. The JFC shall be the forum for discussion of all finance related issues in relation to the Territory, and shall: (a) coordinate budgeting, accounting, financial reporting and other financial activities provided for in this Agreement; (b) if requested by the JSC, develop a process for the development of budgets by the Committees in order to assist in reconciling payments owed by one Party to the other in connection with Development activities, and the approval of such budgets by the JSC, including the Development budgets; and (c) perform such other functions that are expressly delegated to the JFC in this Agreement or by the JSC.

2.6. Sub-committees. From time to time, the JSC may establish and delegate duties to Sub-committees (each, a "**Sub-committee**") on an "as-needed" basis to oversee particular projects or activities. Each Sub-committee shall have the responsibility delegated to it in writing by the JSC, provided that in no event shall the authority of a Sub-committee exceed the responsibilities and authority of the JSC.

2.7. Membership of Committees. Each Committee shall be composed of an equal number of representatives appointed by each Party. Each Committee shall be initially composed of three (3) representatives of each Party until otherwise agreed by the Parties. Each Party may replace any of its Committee representatives at any time upon written notice to the other Party. Each Committee shall be co-chaired by one designated representative of each Party. The co-chairpersons of each Committee shall not have any greater authority than any other representative on the Committee.

2.8. Meetings and Minutes of Committees. Each Committee shall meet quarterly, or as otherwise agreed to by the Parties. The co-chairpersons of the Committee shall be responsible for calling meetings on no less than [***] notice, or upon the request of a Party on shorter notice if the other Party consents to such shorter notice (such consent not to be unreasonably withheld, conditioned or delayed). Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least [***] in advance of the applicable meeting; provided, that under exigent circumstances requiring input by the Committee, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (such consent not to be unreasonably withheld, conditioned or delayed). The co-chairpersons of the Committees shall prepare and circulate for review and approval of the Parties minutes of each meeting within [***] after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the Committee.

2.8.1. Procedural Rules. Each Committee shall have the right to adopt such standing titles as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Committee shall exist whenever there is present at a meeting at least one representative appointed by each Party. Representatives of the Parties on the Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed.

2.8.2. Decision-making. Each Committee shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one representative appointed by each Party.

2.8.3. Further Participants. Employees or consultants of either Party that are not representatives of the Parties on the Committee may attend meetings of the Committee; provided, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the Committee, and (b) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in ARTICLE 10.

2.9. Dispute Resolution.

2.9.1. Escalation to the JSC. If the JDC, JMC, JCC, JFC or a Sub-Committee fails to reach consensus on any matter within its authority for a period in excess of [***] days following the date on which such matter was first presented to such Committee, the matter shall be referred to the JSC.

2.9.2. Dispute Resolution by Senior Officers. If the JSC fails to reach consensus on: (i) any matter referred to it by the JDC, JMC, JCC, JFC or a Sub-Committee that is within such Committee's authority, or (ii) any matter within the JSC's authority, within [***] following the date on which such matter was first presented to the JSC, then, unless this Agreement expressly provides otherwise, such matter shall be escalated to the Senior Officers for resolution, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers fail to reach consensus on any matter referred to them within [***] after such issue was first referred to them, then, the following shall apply:

(a) such dispute shall be finally and definitively resolved by the Senior Officer of Licensee for matters within the authority of a Committee that are primarily related to the Development and Commercialization of Licensed Products in the Field in the Territory except for matters that (i) would materially adversely affect the Development or Commercialization of Licensed Compound or Licensed Product, (ii) would materially adversely affect the safety of the Licensed Compound or Licensed Product, (iii) [***] or (iv) are subject to Licensor's final decision making authority pursuant to Section 2.9.2(b). For clarity, Licensee's final-decision making authority shall include any decision to finally determine Licensee's pricing strategy for the Licensed Products in the Territory, |[***] and

(b) such dispute shall be finally and definitively resolved by the Senior Officer of Licensor for: (i) matters that would materially adversely affect the Development or Commercialization of Licensed Compound outside the Territory or would materially adversely affect the safety of the Licensed Product, provided that Licensor may not use such final decision-making authority in a manner that would materially adversely affect the Development or Commercialization of Licensed Compound or Licensed Product in the Territory; (ii) [***], provided, however, that Licensor may not use its final decision-making authority to: (A) approve a trial design to which Licensee objects in good faith as not being likely to support a Regulatory Approval of the respective Licensed Product in the Territory, or (B) increase the total number of human subjects to be enrolled in such Territory-specific POC Trial beyond the number of human subjects set forth in the Development Plan for such Territory-specific POC Trial; (iv) matters relating to Manufacturing; (v) matters relating to Publications [***]:

(c) provided, further, that, neither Party may exercise its final decision-making authority under Section 2.9.2(a) or Section 2.9.2(b) in a manner that would (i) negate any consent right or other right specifically allocated to the other Party under this Agreement, (ii) require the other Party to perform activities that the other Party has not agreed to perform as set forth in this Agreement, or (iii) require the other Party to perform any act that it reasonably believes to be inconsistent with any Applicable Law.

(d) except for matters expressly set forth under Section 2.9.2(a) or Section 2.9.2(b), neither Party shall have final decision-making authority for any other matter and any such remaining dispute shall be resolved pursuant to Section 15.5.2. Notwithstanding the foregoing, mutual agreement of the Parties is required for (i) any decision for Licensee to participate in a New Global Trial and (ii) any amendments to the Development Plan (including activities, timelines and budgets).

2.10. Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Neither Committee shall have the power to, and neither Party shall exercise its final decision making authority in a

manner that would, (a) amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 15.7 or compliance with which may only be waived as provided in Section 15.10; (b) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (c) make decisions outside the scope of those matters expressly delegated to it in this Agreement. For clarity, the Committees have no approval rights with respect to matters related to the Licensed Compound or Licensed Product outside the Territory or outside the Field, which matters are within Licensor's sole discretion.

2.11. Alliance Manager. Promptly after the Effective Date, each Party shall appoint an individual who is an employee of such Party and proficient in English (each, an "**Alliance Manager**") to oversee contact between the Parties for all matters between meetings of the Committees, including sharing of information regarding material Development updates of the Licensed Product that are under the purview of the Committees or for which information exchange is otherwise provided for under this Agreement, and who shall have such other responsibilities as the Parties may agree in writing. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers will attend the JSC meetings as non-voting participants.

2.12. Discontinuation of Committees. A Committee shall continue to exist until the Parties mutually agree to disband such Committee. Once a Committee has been discontinued, any requirement of Licensee to provide Information, documents or other materials to such Committee shall be deemed a requirement to provide such Information, documents or other materials to Licensor.

2.13. Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the Committees.

ARTICLE III
DEVELOPMENT

3.1. General. Licensee will be responsible, under JDC oversight, for the Development activities to support the Regulatory Approval of the Licensed Product in the Field in the Territory, and will conduct the Development of the Licensed Compound and Licensed Products in accordance with the Development Plan, or as otherwise explicitly permitted under this Agreement. Licensor will be responsible, at its sole discretion, for all Development activities that are conducted outside the Territory.

3.2. Territory-specific Development.

3.2.1. Development Plan; Updates; Amendments.

(a) The Development Plan shall include all material Development activities to be performed by Licensee in the Territory for the Development of the Licensed Compound and Licensed Products, including: (i) all Territory-specific Trials and Territory-specific PoC Trials; (ii) all material Development activities to be performed by Licensee in the Territory as part of a Global Trial; (iii) a plan for preparing and submitting Regulatory Filings in the Territory and obtaining and maintaining Regulatory Approvals for Licensed Products in the Territory; (iv) all other material Development activities that are required to seek, obtain and maintain Regulatory Approvals in the Territory for the Initial Indications and any Additional Indications approved by the JSC; and (v) [***].

(b) The initial Development Plan is attached hereto as **Schedule 3.2.1**. The Development Plan (including estimated timelines and estimated budgets) may be updated and amended from time to time only with the approval of the JSC, as described in this Section 3.2.1. To the extent that the initial Development Plan as of the Effective Date does not include all of the items listed in Section 3.2.1(a), the Parties will cooperate through the JSC, JDC and JFC in good faith to amend such Development Plan to include such further detail.

(c) The JDC shall review the Development Plan (including milestones and estimated timelines and estimated budgets) at least annually and prepare any recommended updates. The JDC shall submit all such updates to the JSC for review and approval.

(d) Either Party may submit a proposed update or amendment to the Development Plan to the JDC from time to time, including changes to the Territory-specific Trials and Territory-specific PoC Trials or proposal for new Territory-specific Trials and Territory-specific PoC Trials. The JDC shall discuss such proposal at its next meeting, and submit such proposal to the JSC for review and approval together with a recommendation as to whether to approve such update or amendment.

3.2.2. Development in Additional Indications.

(a) Upon the request of either Party, the JDC shall discuss the Development of Licensed Products in an Additional Indication in the Territory. The JDC shall submit such request to the JSC for review and approval together with a recommendation on whether to approve the Development in such Additional Indication.

(b) If the JSC approves the Development of Licensed Products in an Additional Indication, the JDC shall prepare an update to the Development Plan, including all material Development activities that are required to obtain Regulatory Approval in such Additional Indications, estimated milestones and estimated timelines, and submit such update to the JSC for review and approval.

3.2.3. Conduct of Development Activities; Diligence.

(a) Licensee shall use Commercially Reasonable Efforts to execute and to perform or cause to be performed, the Development activities allocated to it in the Development Plan, including Territory-specific Trials, Territory-specific PoC Trials and those parts of the Global Trials to be performed by Licensee in the Territory in accordance with the Development Plan, and shall use Commercially Reasonable Efforts to meet the timelines set out in the Development Plan. Without limiting the generality of the foregoing, Licensee shall: (i) obtain and maintain (itself or through its Affiliates or subcontractors) sufficient facilities, personnel (with appropriate qualifications and experience), equipment, materials and other resources as reasonably required to complete the Development activities allocated to it in the Development Plan; and (ii) use Commercially Reasonable Efforts to [***].

(b) If at any time Licensor has a reasonable basis to believe that Licensee is in material breach of its diligence obligations under this Section 3.2.3, then Licensor may so notify Licensee in writing, specifying the basis for its belief, and, without limitation to any other right or remedy available to Licensor hereunder, at Licensor's request, the Parties shall meet within [***] days after such notice to discuss in good faith Licensor's concerns and Licensee's Development efforts with respect to the Licensed Products in the Field in the Territory.

(c) Licensee shall conduct the Development of Licensed Products in the Field in the Territory in accordance with all Applicable Laws and GLP and GCP requirements applicable to it and consistent, from a safety perspective, with the manner in which Licensor is conducting the Development of Licensed Products outside the Territory; provided, that Licensor has provided notice to the JDC of such safety standards. The Parties will in good faith negotiate a suitable GxP Quality Agreement for the Development activities.

(d) Licensee will keep Licensor reasonably informed of all material aspects of Licensee's, its Affiliates' and sublicensees' Development of Licensed Products in the Field in the Territory. Without limiting the foregoing, subject to Applicable Law, the Parties will discuss in good faith and coordinate, through the JDC, Licensee's material Development activities for Licensed Products in the Field in the Territory, including the design and commencement of Clinical Trials and any other material Development steps. Licensee will consider in good faith Licensor's input and comments with respect thereto, and any final decision within the JDC's decision making authority shall be made in accordance with Section 2.9.2.

(e) Licensee shall perform, and shall cause its subcontractors to perform, any and all of its Development activities under this Agreement in good scientific manner, in compliance with all Applicable Law and GCP and GLP, and in accordance with the covenants set forth in Section 11.3.

(f) Neither Licensee nor its Affiliates shall, directly or indirectly, whether alone or together with a Third Party. Develop the Licensed Compound or Licensed Products outside the Territory or outside the Field.

3.3. Global Trials.

3.3.1. New Global Trials.

(a) If Licensor intends to perform a Global Trial for which activities are not contemplated by the Development Plan (a "**New Global Trial**"), it shall provide an outline of the design of such Global Trial to the JDC. The JDC will discuss in its next meeting whether and which activities of such Global Trial (e.g., the percentage of patient enrolment in the Territory) can be allocated to Licensee for performance in the Territory. If the Parties reach consensus in the JDC that part of a New Global Trial will be performed by Licensee in the Territory, the JDC will prepare an update to the Development Plan, and will submit such proposal to the JSC for review and approval.

(b) If the JSC, and after dispute resolution in accordance with 2.9.2, the Senior Officers, fail to reach unanimous agreement on the participation of Licensee in a New Global Trial, or the scope of such participation by Licensee, Licensor shall be free to perform such New Global Trial without the involvement of the Licensee, whether solely or in collaboration with any Third Party.

(c) If Licensee does not participate in a New Global Trial for a particular Licensed Product in a particular indication, [***]. Notwithstanding the foregoing, in the event Licensee is required by the Regulatory Authority in the Territory to provide such Clinical Data for such Global Trial in support of Licensee's other Development or Commercialization activities for an indication for which Licensee has borne such share of costs, then, [***].

3.3.2. Global Trial Plan; Updates; Amendments. The plan for the Global Trials may be amended from time to time by Licensor ("Global Trial Plan"). Licensor may update or amend the Global Trial Plan in its sole discretion, provided that: (a) Licensor may not allocate any Development activities to be performed as part of a Global Trial to the Territory without the approval of the JSC; and (b) Licensor may not increase the number of human subjects to be enrolled in the Territory as part of a Global Trial beyond [***] of the total number of human subjects enrolled in such Global Trial worldwide. Licensor will regularly (if and when applicable) provide to Licensee, through the JDC, updates or amendments to the Global Trial Plan. For the avoidance of doubt, the Development activities that are to be performed by Licensee as part of a Global Trial will in any case also be included in the Development Plan, and Licensee will perform these activities in accordance with the Development Plan (as amended or updated in accordance with Sections 3.3.1(a) or 3.3.3).

3.3.3. Changes to Global Trial. If Licensor intends to make changes to a Global Trial that is part of the Development Plan or if such changes affect the Territory, including an increase of human subjects to be enrolled by Licensee as part of such Global Trial in the Territory, it shall provide a proposal of such change to the JDC. The JDC will discuss such proposed change in its next meeting, if it reaches consensus on such change to the Global Trial affecting the Territory, it will prepare an amendment to the Development Plan, and will submit such proposed amendment to the JSC for review and approval.

3.3.4. Conduct of Global Trials. Licensee will perform all Development activities that are to be performed in the Territory as part of a Global Trial in accordance with the Development Plan and Section 3.2.3; provided that Licensor shall have the right to conduct such activities as provided in Section 3.3.1(b). Licensor will perform all Development activities that are to be performed outside the Territory as part of a Global Trial in which Licensee is participating in accordance with the Global Trial Plan and in good scientific manner, in compliance with all Applicable Law and GCP and GLP, and in accordance with the covenants set forth in Section 11.3.

3.4. Sponsorship of Clinical Trials. Unless otherwise agreed upon by the Parties or required by Applicable Law, as between the Parties, | [***]. In connection with the performance of any such Clinical Trial for which Licensor is the sponsor and Licensee, its Affiliates or sublicensees is performing in the Territory, (a) at Licensee's request, Licensor will provide reasonable assistance in connection with establishing and conducting such Clinical Trial, including assistance with all applications required by Applicable Law and (b) Licensee shall reimburse Licensor for (i) any out-of-pocket costs inclined in providing such assistance and (ii) for any internal costs incurred in providing such assistance beyond [***] per Clinical Trial or that extends beyond [***] after commencement of such Clinical Trial, in each case, within [***] after receipt of an invoice therefor. Licensee will be responsible for the implementation and the day-to-day management of all Clinical Trials to be performed in the Territory in accordance with this Agreement, including Territory-specific Trials and that part of Global Trials that is to be performed in the Territory. Without limiting the foregoing, Licensee shall be responsible for recruiting, enrolling, dosing, treating, and providing follow-up support to, all human subjects that are to participate in a Territory-specific Trial or in a Global Trial in the Territory in accordance with the Development Plan.

3.5. Ownership in Clinical Data; Data Sharing. Subject to the rights granted to Licensee under Section 7.1, Licensor shall own all Clinical Data resulting from Clinical Trials performed in relation to Licensed Products in the Territory (including all Clinical Data resulting from Territory-specific Trials or Global Trials), and Licensee shall assign to Licensor, and hereby assigns to Licensor, all of its right, title and interest in, to and under such Clinical Data. Section 9.1.3 shall apply accordingly. Licensee shall provide to Licensor all Clinical Data and analyses resulting from Clinical Trials performed in the Territory. As reasonably requested by Licensee, Licensor shall cooperate to exchange all Clinical Data and analyses that are (a) necessary or useful to support Regulatory Approval for Licensed Product in the Territory, and (b) from (i) a New Global Trial for which Licensee is not prohibited from having a right to use such Clinical Data pursuant to Section 3.3.1, (ii) a Global Trial for which Licensee is performing activities in the Territory pursuant to the Development Plan or (iii) a Clinical Trial for Licensed Product commenced prior to the Effective Date; provided that, (A) for any such Clinical Data and analyses generated on behalf of Licensor or its Affiliate by a Third Party after the Effective Date in a Clinical Trial that is not part of the Global Trial Plan existing as of the Effective Date, Licensor shall only be required to exchange such Clinical Data and analyses to the extent Controlled by Licensor or any of its Affiliates; (B) Licensor shall use diligent efforts to obtain Control of such Clinical Data and analyses in its agreement with such Third Party to enable such exchange with Licensee; and (C) if Licensor cannot obtain such Control in its agreement with a particular Third Party such that Licensor cannot provide Licensee with the Clinical Data or analyses generated by such Third Party with respect to the Licensed Product, then Licensor shall not have the right to provide such Third Party with any Clinical Data or analyses generated by Licensee with respect to the Licensed Product under this Agreement (other than safety data, which Licensor shall have the right to provide). Notwithstanding the foregoing, nothing in this Agreement shall require Licensor to provide to Licensee any Clinical Data that Licensor is not allowed to share due to restrictions resulting from informed consent forms or Applicable Law.

3.6. Development Reports.

3.6.1. On a Licensed Product-by-Licensed Product basis, Licensee shall, on a quarterly basis during the Term (without limiting any more frequent reporting obligations otherwise agreed pursuant to this Agreement), provide the JDC with written reports in English language summarizing the following with respect to the Licensed Products: (a) the results and progress of all Development activities that Licensee has performed, or caused to be performed, since the preceding report (including details of safety and efficacy data from Clinical Trials of Licensed Products in the Field in the Territory), (b) Licensee's Development activities in process, (c) the future material activities such Party expects to initiate during the then-current Calendar Year, including timelines related thereto, (d) updates regarding material regulatory matters, including an update of all Drug Approval Applications filed, in each case on a jurisdiction-by-jurisdiction basis, (e) such other information as Licensor may reasonably request relating to the Development in order to enable Licensor to assess Licensee's compliance with its Development obligations under this Agreement with respect to the Licensed Products.

3.6.2. On a Licensed Product-by-Licensed Product basis, Licensor shall discuss at meetings of the JDC (no more than on a quarterly basis) the following with respect to the Licensed Products outside the Territory: (a) an overview of the results and progress of Development since the preceding report, (b) an overview of Development activities in process, (c) an overview of the future material activities Licensor expects to initiate during the then-current Calendar Year, including timelines related thereto, and (d) jurisdictions in which Drug Approval Applications have been filed.

3.7. Development Funding.

3.7.1. Territory-specific Development Costs.

(a) Subject to Section 3.7.1(b), as between the Parties, Licensee shall be solely responsible for all costs and expenses in connection with Licensee's, its Affiliates and sublicensees' Development of Licensed Products in the Field in the Territory, including for pre-clinical studies, Territory-specific Trials and Territory-specific PoC Trials.

(b) Licensor will compensate Licensee for [***] of the human subjects enrolled in a Territory-specific PoC Trial in accordance with, and up to the number of subjects set forth in, the mutually agreed Development Plan at [***].

3.7.2. Global Trials.

(a) Subject to Section 3.3.1(c), 3.7.2(b) and Section 3.7.2(c), Licensor will be responsible for all costs and expenses incurred by Licensor in connection with a Global Trial.

(b) Licensee will be responsible for all costs and expenses incurred by Licensee in connection with a Global Trial in the Territory in accordance with the Development Plan, including all costs and expenses for recruiting, enrolling, dosing, treating, and providing follow-up support to, the human subjects to be enrolled by Licensee as part of such Global Trial in the Territory in accordance with the Development Plan; provided, however, that for each Global Trial, unless the Parties agree otherwise, a maximum of [***] of the total number of human subjects participating in such Global Trial worldwide will be allocated to the Territory.

(c) If Licensee fails to enroll the number of human subjects to be enrolled by Licensee in the Territory as part of a Global Trial as set forth in the Development Plan for such Global Trial or otherwise agreed upon by the Parties in good faith, before the 'last patient in' for such Global Trial (excluding patients to be enrolled by Licensee), and such failure or shortfall is not attributable to Licensor's breach of this Agreement, Licensor's breach of the applicable clinical supply agreement between the Parties or any material delay caused by any actions or inactions of Licensor, Licensee shall [***]. In the event Licensee enrolls more than the number of human subjects originally agreed upon by the Parties to be enrolled by Licensee in the Territory as part of a Global Trial, Licensee shall [***].

3.7.3. Payments Terms. To the extent any reimbursement costs are due from one Party to the other, then within [***] after the end of each calendar month, each Party shall provide the other a written accounting of the costs incurred by such Party that are reimbursable in whole or in part under this Agreement together with supporting documentation for any Third Party costs for such calendar month. Within [***] of receipt by the Parties of each such written accountings for a calendar month. Licensor shall provide Licensee with a reconciliation report setting forth the net payment due from one Party to the other Party to effectuate the sharing of costs as set forth herein. The Party that is owed money pursuant to such reconciliation report shall issue an invoice to the paying Party for the applicable net payment set forth in such reconciliation report promptly after receipt (or delivery, as applicable) of such reconciliation report. The Party receiving such invoice shall pay to the other Party the undisputed amount of such invoice within [***] after receipt of such invoice.

ARTICLE IV
REGULATORY MATTERS

4.1. Regulatory Strategy. The Parties will discuss and determine in the JDC the regulatory strategy for the Licensed Products in the Field in the Territory.

4.2. Regulatory Lead. Licensor (or its designee) shall be the holder of all Regulatory Filings and Regulatory Approvals for Licensed Products in the Field in the Territory, and Licensee shall be the local legal representative of Licensor (or Licensor's designee) for all regulatory matters with respect to the Licensed Products in the Field in the Territory; provided that, if Applicable Laws in the Territory allow Licensee to hold such Regulatory Approvals and Regulatory Filings for the Licensed Product in the Territory and such transfer would be mutually beneficial, the Parties shall discuss in good faith (but shall have no obligation to enter into) an amendment to this Agreement providing for the transfer of such Regulatory Approvals and Regulatory Filings to Licensee. Licensee shall be the main point of contact for the regulatory relationship and communication with Regulatory Authorities within the Territory, and shall be responsible, at Licensee's sole expense (including payment of all filing fees and all other associated costs), for making Regulatory Filings, and obtaining and maintaining Regulatory Approvals for Licensed Products in the Field in Territory, in accordance with this Agreement and the applicable Development Plan.

4.3. Regulatory Filings and Approvals. Licensee will file all CTAs and Drug Approval Applications on behalf, and in the name of Licensor, and will hold all Regulatory Approvals in the name of Licensor or Licensor's designee. Licensor or its designee will support Licensee, as may be reasonably necessary or appropriate for Licensee to comply with its regulatory obligations hereunder, including by providing necessary documents, signatures or other materials required by Applicable Law or Regulatory Authorities.

4.4. Regulatory Communication and Meetings.

(a) Subject to Section 4.4(b), Licensee shall provide to Licensor copies of all material Regulatory Filings (and an English translation thereof) in the Territory prior to submission with a reasonable amount of time (and in any case, to the extent practicable, at least [***] prior to the envisaged date of submission) to allow Licensor to review and comment on such Regulatory Filings. Licensee will endeavour to inform Licensor in advance of an intention to present a draft Regulatory Filing for review to Licensor and at Licensor's request, to the extent practicable, an additional term of no more than [***] shall be given for review and comments to such submission by Licensor. Licensee will consider in good faith all of Licensor's comments and proposed revisions and will address such comments and proposed revisions, in each case, prior to submission, in the event of a disagreement between the Parties with respect to the implementation of Licensor's comments and proposed revisions, such disagreement shall be escalated to the JSC. As used herein, "material" Regulatory Filings shall mean all CTAs and filings for Regulatory Approval, as well as supporting Regulatory Documentation therefor.

(b) In case an exigent action is required. Licensee shall notify Licensor prior to submitting any material Regulatory Filings in the Territory, and shall provide Licensor with copies of such submitted Regulatory Filings (and an English translation thereof) promptly and in no case later than [***] after its submission. At Licensor's request, Licensee shall provide Licensor copies of all other Regulatory Filings (and an English translation thereof) [***].

(c) As between the Parties, Licensor retains the right (in its sole discretion) to conduct all regulatory activities with respect to the Licensed Products outside the Territory. Additionally, with respect to (i) any Global Trial that Licensee is participating in, (ii) any New Global Trials of Licensed Products in the Territory for which Licensee has a right to use Clinical Data pursuant to Section 3.3.1, and (iii) Clinical Trials for Licensed Product commenced prior to the Effective Date, Licensor shall provide Licensee with copies of material Regulatory Filings and material Regulatory Documentation relating to any such Clinical Trials in the United States, Japan, European Union, United Kingdom promptly after submission or receipt thereof, as applicable, provided that, (A) for any such Regulatory Filings and Regulatory Documentation generated on behalf of Licensor or its Affiliate by a Third Party after the Effective Date that is not related to a Clinical Trial as part of the Development Plan existing as of the Effective Date, Licensor shall only be required to provide copies of such Regulatory Filings and Regulatory Documentation to the extent Controlled by Licensor or any of its Affiliates; (B) Licensor shall use diligent efforts to obtain Control of such Regulatory Filing and Regulatory Documentation in its agreement with such Third Party to enable such provision to Licensee; and (C) if Licensor cannot obtain such Control in its agreement with a particular Third Party such that Licensor cannot provide Licensee with such Regulatory Filing or Regulatory Documentation generated or by such Third Party with respect to the Licensed Product, then Licensor shall not have the right to provide such Third Party with any Regulatory Filing or Regulatory Documentation generated by Licensee with respect to the Licensed Product under this Agreement, (other than safety data, which Licensor shall have the right to provide). Notwithstanding the foregoing, nothing in this Agreement shall require Licensor to provide to Licensee any Regulatory Filing or Regulatory Documentation that Licensor is not allowed to share due to restrictions resulting from informed consent forms or Applicable Law.

4.5. Regulatory Documentation and Regulatory Data. Licensee shall promptly provide Licensor access to, and an English translation of, all Regulatory Documentation in the Territory that is held by Licensee or its subcontractors, when and as such Regulatory Documentation becomes available. Subject to the rights granted to Licensee under Section 7.1, Licensor shall own all Regulatory Documentation and all Regulatory Data in the Territory, and Licensee shall assign to Licensor, and herewith assigns to Licensor, all of Licensee's rights, title and interest in, to and under such Regulatory Documentation and Regulatory Data.

4.6. Audits of Systems, Processes and Procedures. Upon reasonable advance notice and at reasonable times and no more frequently than once per Calendar Year (unless for cause), Licensor or its representatives shall be entitled to conduct an audit of any system, process or practice used by Licensee for the conduct and quality control of Licensee's activities under this Agreement, including the safety and regulatory systems, procedures or practices of Licensee and its subcontractors relating to the Licensed Products. Licensor shall treat all information subject to review under this Section 4.6 as Confidential Information of Licensee.

4.7. Regulatory Authority Inspections and Actions.

(a) Each Party shall promptly notify the other Party of any announced or unannounced inspection of such Party, its Affiliates, or subcontractors (including clinical trial sites and manufacturing sites) relating to Licensed Products by any Regulatory Authority in the Territory and shall provide the other Party with all information in such Party's Control related thereto. The other Party will have the right to be present at such inspection, and participate to the extent allowed under Applicable Law, as relevant and agreed between the Parties. If a prior notification is not reasonably feasible, despite good faith efforts of the inspected Party, the inspected Party shall notify the other Party promptly upon such inspection, but in no case later than 48 hours thereafter. The inspected Party will provide the other Party with a written summary in English of any findings of a Regulatory Authority relating to Licensed Products following a regulatory inspection (and any written correspondences in relation thereto) within [***] following any such inspection, and will provide the other Party with an unredacted copy of any report issued by such Regulatory Authority in the Territory (including a certified English translation thereof if such report is not in English) within [***] following such inspection, or a shorter timeframe if necessary to accommodate deadlines set for responses to Regulatory Authorities.

(b) If any Regulatory Authority in the Territory takes, or gives notice of its intent to take, any regulatory action with respect to any activity of Licensee relating to the Licensed Product and (i) such action is reasonably likely to have a material adverse effect on the label, safety, Development or Commercialization of the Licensed Product outside of the Territory, then Licensee shall notify Licensor of such notice within [***] of its receipt thereof and (ii) for other material regulatory actions. Licensee shall notify Licensor within than [***] thereafter. Licensee will address Licensor's comments to Licensor's reasonable satisfaction.

4.8. Pharmacovigilance. Both Parties shall make good faith efforts to within [***] after the Effective Date, enter into an agreement with regard to a process for the exchange of safety data (including post-marketing spontaneous reports received by each Party and its Affiliates) between the Parties in a mutually agreed format in order to monitor the safety of the Licensed Compounds and Licensed Products and to meet reporting requirements with any applicable Regulatory Authority ("**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall include procedures regarding the receipt, investigation, recording, communication, and exchange (as between the Parties), and regulatory submission of, adverse event reports, exposure during pregnancy reports, and any other information concerning the safety of the Licensed Products, including those matters set forth on **Schedule 4.8**.

4.9. Global Safety Database. Licensor will set up, hold, and maintain a global safety database for Licensed Products. Licensee shall provide Licensor with all information necessary or desirable for Licensor to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse drug experiences, from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, and Clinical Trials for Licensed Product, in each case in the form reasonably requested by Licensor. It is understood that each Party and its Affiliates, licensees and sublicensees shall have the right to access, use and disclose such information in the global safety database for Licensed Products if such disclosure is reasonably necessary to comply with Applicable Laws or requirements of any applicable Regulatory Authority.

ARTICLE V
MANUFACTURING

5.1. Manufacturing Right. Subject to Section 5.4, Licensor shall have the sole right and, subject to the terms of this Agreement, any pre-clinical or clinical supply agreement, and the Commercial Supply Agreement, responsibility to Manufacture and supply Licensee's requirements of the Licensed Compound and Licensed Products.

5.2. Pre-Clinical and Clinical Supply. Licensor shall, either by itself or through its CMO, Manufacture and supply to Licensee all quantities of Licensed Compound and Licensed Products required by Licensee in accordance with this Agreement for the Development of Products (including for Clinical Trials), subject to and in accordance with the terms and conditions of one or more clinical supply agreernent(s) and associated Quality Agreernent(s) to be negotiated and agreed between Licensee and Licensor in good faith no later than [***] after the Effective Date, taking into account the terms and conditions of the In-licensing Agreements and other third party contracts relevant to the Licensor supply chain, including production of drug substance, drug product and fill and finish services and as of the date hereof, including contracts with [***]. All pre-clinical and clinical supply of Licensed Compound and Licensed Products will be at [***]. Licensor's best estimate of COGS to Manufacture and supply Development quantities of Licensed Compound and Licensed Products to Licensee as of the Effective Date is set forth on **Schedule 5.3**.

5.3. Commercial Supply. On a Licensed Product-by-Licensed Product basis, upon the request of Licensee, but in any case no later than six months prior to the first anticipated approval in the Territory, the Parties will negotiate and agree in good faith on a commercial supply agreement (each a "**Commercial Supply Agreement**") with respect to such Licensed Product (including a Quality Agreement) under which Licensor (or its CMO) will Manufacture and supply to Licensee the quantities of Licensed Product required by Licensee, whereby:

(a) terms and conditions applicable to Licensor (or its Affiliates) pursuant to the In-licensing Agreements and other third party contracts relevant to the Licensor supply chain, including production of drug substance, drug product and fill and finish services and the maximum capacities available thereunder, shall be taken into account;

(b) a binding forecast will be made by Licensee, mirroring the binding forecasting mechanisms and principles applicable to Licensor in its contracts with third party manufacturers ("**Binding Forecast**");

(c) distinctions will be made where relevant between the different formulations of Licensed Product; and

(d) commercial supply of Licensed Products will be at COGS plus a handling fee of [***] and will be delivered EXW manufacturing site (Incoterms 2020) (Licensor's best estimate of COGS to Manufacture and supply commercial supply of Licensed Product to Licensee as of the Effective Date is set forth on **Schedule 5.3**), all as to be further agreed in the Commercial Supply Agreement.

5.4. Manufacture by Licensee.

5.4.1. From time to time, the Parties, through the JMC, will evaluate the option to perform a technology transfer for the Manufacture of Licensed Products designated for the Territory from Licensor to Licensee in the light of demand increase and supply requirements considering the forecasts provided by Licensee under the Commercial Supply Agreement. [***].

5.4.2. Without limiting the foregoing, in the event of a supply shortage or supply failure that results in Licensor being unable to supply the quantities of Licensed Product set out in Licensee's Binding Forecast under either the clinical supply agreement negotiated pursuant to Section 5.2 or the Commercial Supply Agreement, then Licensor shall allocate its available supply of Licensed Product between Licensee, itself, its Affiliates and Third Party licensees: (a) first to supply patients who are already on study drug in registration Clinical Trials or early access programs before commercial supply; (b) then for commercial supply on a pro-rata basis determined based on [***], and (c) then for new patients in registration Clinical Trials, all as to be further set out in the Commercial Supply Agreement.

5.4.3. If Licensor fails to supply at least [***] of Licensee's Binding Forecast (a) during or during [***] or (b) during [***], then (i) the Parties shall discuss in good faith and at Licensee's request, Licensor shall use Commercially Reasonable Efforts to secure any approvals required under the Lonza Agreement to perform a manufacturing technology transfer to, at Licensee's election, either Licensee, its Affiliate or a qualified Third Party CMO acceptable to Licensor (such acceptance not to be unreasonably withheld, conditioned or delayed) and (ii) if such approval is granted, the Parties shall amend this Agreement, to include additional provisions related to such manufacturing technology transfer and the Manufacture of Licensed Compound and Licensed Product in the Territory by or for Licensee. Licensee acknowledges and agrees that any such manufacturing technology transfer and any associated amendment to this Agreement shall be subject to the terms of the Lonza Agreement and any approvals required by the Lonza Agreement.

ARTICLE VI
COMMERCIALIZATION

6.1. Commercialization Generally.

6.1.1. Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible for Commercialization of the Licensed Products in the Field in the Territory at Licensee's own cost and expense.

6.1.2. Notwithstanding the foregoing, subject to Applicable Law, Licensee will discuss in good faith and coordinate with Licensor with respect to Licensee's Commercialization activities for Licensed Products in the Field in the Territory. Licensee will consider in good faith Licensor's input and comments with respect thereto. Without limiting the foregoing, if Licensor determines, in its reasonable discretion, that a given Commercialization activity for Licensed Products in the Field in the Territory is reasonably likely to pose a material safety issue or otherwise adversely impact the Licensed Products outside the Field or outside the Territory, then Licensor will have the right to notify Licensee thereof in writing and consult with Licensee in connection therewith and, thereafter, Licensee will not (and will cause its subcontractors not to) conduct the applicable Commercialization activity unless and until a mutually agreed resolution is approved by the JCC.

6.1.3. As between the Parties, Licensor retains the right (in its sole discretion) to Commercialize the Licensed Products outside the Field or outside the Territory.

6.2. Commercialization Plan and Diligence.

6.2.1. On an indication-by-indication basis, at least [***] prior to the first anticipated filing of a Drug Approval Application of a Licensed Product in such indication in the Territory, Licensee shall present a commercialization plan for Licensed Product(s) in such indication to the JCC for review and approval (each, a "**Commercialization Plan**"). The Commercialization Plan for the Initial Indications shall be designed to be consistent with Licensor's global brand, commercialization and pricing strategy and shall be substantially in the form attached hereto as **Schedule 6.2.1**. and shall include: [***] Licensee may, from time-to-time, but at least annually, propose amendments to the Commercialization Plans for the JCC's review and approval. Each Commercialization Plan (including any amendments thereto) shall be consistent with Licensor's global brand and Global Marketing Guidelines, high-level Commercialization strategy and the diligence obligations set forth below.

6.2.2. Licensee shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in each Initial Indication and, if the Parties agree to collaborate on one or more Additional Indication(s), such Additional Indication(s), in each case, in the PRC (not including Hong Kong, Taiwan or Macau) and shall do so consistent with the approved Commercialization Plans. Without limiting the generality of the foregoing, Licensee shall use Commercially Reasonable Efforts to make the First Commercial Sale of the Licensed Product in each indication as soon as reasonably practicable following the issuance of the respective Regulatory Approval, and in all cases shall do so [***]after the later of [***].

6.2.3. Licensee shall, and shall cause its subcontractors to, comply with all Applicable Law with respect to the Commercialization of the Licensed Products.

6.2.4. If at any time Licensor has a reasonable basis to believe that Licensee is in material breach of its obligations under this Section 6.2, then Licensor may so notify Licensee in writing, specifying the basis for its belief, and, without limitation to any other right or remedy available to Licensor hereunder, at Licensor's request, the Parties shall meet within [***] days after such notice to discuss in good faith Licensor's concerns and Licensee's Commercialization plans with respect to the Licensed Products.

6.3. [***]

6.3.1. [***]

6.3.2. [***]

6.4. Statements and Compliance with Applicable Law. Licensee shall, and shall cause its subcontractors to, comply with all Applicable Law (as well as any other compliance or regulation agreed upon in writing by the Parties) with respect to the Commercialization of the Licensed Products. Licensee shall avoid, and shall cause its Affiliates, employees, representatives, agents, and subcontractors to avoid, taking, or failing to take, any actions that Licensee knows would jeopardize the goodwill or reputation of Licensor or the Licensed Products or any Trademark associated therewith. Without limitation to the foregoing, Licensee shall in all material respects conform its practices and procedures relating to the Commercialization of the Licensed Products and educating the medical community in the Territory with respect to the Licensed Products to any applicable industry association regulations and policies in the Territory, as the same may be amended from time to time, and Applicable Law.

6.5. Training and Promotion Materials. The JCC will review and discuss the application to the Territory of Licensor's global guidelines for branding, positioning, core messages and messaging for promotion materials, training programs and marketing materials (collectively, the "**Global Marketing Guidelines**"). Licensor shall provide Licensee with copies of Licensor's promotional materials, market research, health economics and outcomes research, medical affairs or other materials related to Licensor's Commercialization of the Licensed Product outside the Territory or globally that Licensor determines are reasonably necessary to promote consistency globally. Licensee shall have the right to use such materials solely to prepare promotion materials, training programs and marketing materials for the Licensed Product in the Field in the Territory ("**Territory Marketing Materials**"). All translations of any of Licensor's materials and the Territory Marketing Materials shall be owned by Licensor and Licensee hereby assigns to Licensor, all of its right, title and interest in, to and under such Territory Marketing Materials. Licensee shall ensure the Territory Marketing Materials are consistent with all Applicable Laws and, unless otherwise approved by the JCC, the Global Marketing Guidelines. Licensee shall not use any Territory Marketing Materials that Licensor reasonably determines would materially adversely affect the Commercialization or global brand of Licensed Compound or Licensed Product. The JCC will establish a process under which Licensee will provide Licensor with copies of the Territory Marketing Materials upon Licensor's reasonable request and the Parties will review and comment on the application of the Global Marketing Guidelines to the Territory with respect to such Territory Marketing Materials. For clarity, Licensor shall have sole discretion with respect to the Global Marketing Guidelines and neither the JCC nor any other Committee shall have any approval rights over the Global Marketing Guidelines.

6.6. Booking of Sales; Distribution. Licensee or its Affiliates shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Licensed Products in the Field in the Territory and perform or cause to be performed all related services. Licensee shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Licensed Products in the Field in the Territory.

6.7. Commercialization Reports.

6.7.1. Commencing upon filing a Drug Approval Application for a Licensed Product in the Field in the Territory, Licensee shall provide to Licensor, through the JCC, at least on a Calendar Yearly basis, a report summarizing (a) the Commercialization activities it or its subcontractors have performed, or caused to be performed, during the applicable reporting period and on a Calendar Year-to-date basis for Licensed Products in the Field in the Territory; (b) its Commercialization activities in process and the fixture activities it expects to initiate during the then-current Calendar Year, including estimated timelines related thereto; (c) a non-binding twenty-four month sales forecast on a regional basis for Net Sales for Licensed Products in the Territory, including details on estimated expected new patients and estimated total number of patients on therapy; and (d) such other information as Licensor may reasonably request relating to the Commercialization of the Licensed Products in order to enable Licensor to assess Licensee's compliance with its Commercialization obligations under this Agreement with respect to the Licensed Products.

6.7.2. Licensee shall keep Licensor regularly and timely informed on the status of any application for pricing or reimbursement approval for Licensed Products in the Field in the Territory, including any discussion with the applicable Regulatory Authority with respect thereto, in accordance with ARTICLE 4.

6.7.3. Licensee shall report to Licensor the First Commercial Sale in each country in the Territory within [***] days of such occurrences.

6.8. Product Trademarks. The Parties will discuss, through the JCC, the Product Trademarks that Licensor has seemed for the Licensed Product in the Territory and such other Product Trademarks as Licensor may choose, in consultation with Licensee, for Licensee's use in the Territory. Licensee shall conduct all Commercialization activities in the Territory in accordance with Licensor's global brand strategy.

6.9. Diversion. Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates and subcontractors shall not, either directly or indirectly, promote, market, distribute, import, export, 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 or otherwise Commercialize Licensed Products (a) in the case of Licensee, outside the Territory or for use outside the Field or (b) in the case of Licensor, for use in the Field in the Territory. Without limiting the foregoing, neither Party shall engage, nor permit its Affiliates or subcontractors to engage, in (x) 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 (i) in the case of Licensee, outside the Territory or for uses outside the Field or (ii) in the case of Licensor, for use in the Field in the Territory, or (y) solicitation of orders from any prospective purchaser located (i) in the case of Licensee, outside the Territory or (ii) in the case of Licensor, for use in the Field in the Territory. If either Party receives any request for Licensed Products for use from a prospective purchaser located outside of its respective territory or, in the case of Licensee, for use outside the Field, such Party shall promptly refer that order to the other Party. Licensee shall not, nor shall it permit its Affiliates or subcontractors to, deliver or tender (or cause to be delivered or tendered) any Licensed Products for use outside the Territory or outside the Field. For clarity, this Section 6.9 is not intended to preclude Licensor from providing supply of Licensed Products to the Territory as set forth in this Agreement or a supply agreement or from conducting Development activities in the Territory as permitted in this Agreement.

6.10. Compliance Self-Audit. Licensor shall at least once per Calendar Year perform (or have performed) an audit of its compliance with Applicable Laws (the "**Compliance Self-Audit**"). Licensee will on [***] of each Calendar Year (commencing on [***] 2022) provide the JSC with a written report of the outcome of its annual Compliance Self-Audit, in any case specifying any material non-compliance with Applicable Laws in relation to the Development or Commercialization of Licensed Products, its expected impact and the remedial actions taken or to be taken and report on how the remediation has been implemented. The report of the Compliance Self-Audit shall be discussed at the JSC. The Parties will cooperate to maintain any privileged nature of such report and related communications.

ARTICLE VII
GRANT OF RIGHTS

7.1. Grants to Licensee. Subject to the terms and conditions of this Agreement, Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee:

7.1.1. an exclusive (including with regard to Licensor and its Affiliates) license, with the right to grant sublicenses in accordance with Section 7.2, under the Licensed Technology to Develop the Licensed Compound and the Licensed Products in the Field in the Territory in accordance with the applicable Development Plans and Global Trials Plans (in each case as approved or subsequently amended by the JDC), and Commercialize the Licensed Compound and the Licensed Products in the Field in the Territory; and

7.1.2. subject to the next sentence, an exclusive right to Exploit (including a right of reference to) the Regulatory Approvals and other Regulatory Documentation relating to Licensed Products in the Territory Controlled by Licensor during the Term as necessary for purposes of Developing and Commercializing the Licensed Compound and Licensed Products in the Field in the Territory in accordance with the terms of this Agreement. Notwithstanding anything to the contrary, if Licensee has not borne its share of the global Development costs relating to a New Global Trial for a particular Licensed Product in a particular indication in accordance with Section 3.7.2 or Section 3.3.1(c), as applicable, then Licensee shall not have the right to use [***]; provided that, if Licensee is required by the Regulatory Authority in the Territory to provide or reference such Regulatory Data or Regulatory Documentation in support of Licensee's other Development or Commercialization activities for an indication for which Licensee has borne such share of costs, then, at Licensee's request, Licensor will discuss in good faith granting Licensee the right to provide or reference such Regulatory Data or Regulatory Documentation for such indications to the extent so required.

7.2. Sublicenses. Licensee shall have the right to grant sublicenses under the licenses granted in Section 7.1 to: (a) Sublicensable Affiliates, provided that any such sublicense shall automatically terminate, and all rights shall revert back to Licensee in case such Sublicensable Affiliate ceases to be a Sublicensable Affiliate; and (b) to Affiliates that are not Sublicensable Affiliates and Third Parties with the prior written approval of Licensor. Licensee shall cause each sublicensee to comply with the applicable terms and conditions of this Agreement. Licensee hereby guarantees the performance of its sublicensees, and the giant of any such sublicense shall not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such sublicensee. All sublicenses shall be consistent with and expressly made subject to the terms and conditions of this Agreement. Sublicensee must agree in writing to be bound by the applicable terms and conditions of this Agreement, and each sublicense agreement shall indicate that Licensor is a third party beneficiary of such sublicense agreement. In case a Sublicensable Affiliate that has been granted a sublicense under this Agreement ceases to be a Sublicensable Affiliate, the respective sublicense agreement shall automatically terminate, and all rights shall revert back to Licensee. A copy of any sublicense agreement executed by Licensee (which must have received Licensor's prior written approval in case of a sublicense agreement with a Third Party as set forth above) shall be provided to Licensor within [***] days after its execution. As between the Parties, Licensee shall be fully responsible for all acts and omissions of its sublicensees.

7.3. Use of Affiliates and CROs. Licensee may subcontract its rights and obligations under this Agreement to: (a) Subcontractable Affiliates; and (b) to Affiliates that are not Subcontractable Affiliates and Third Parties with the prior written approval of Licensor (such approval not to be unreasonably withheld); provided that, in each case of (a) and (b), (i) no such permitted subcontracting shall relieve Licensee of any liability or obligation hereunder except to the extent satisfactorily performed by such subcontractor, and (ii) the agreement pursuant to which Licensee engages any subcontractor must (x) be consistent in all material respects with this Agreement, (y) contain an obligation to assign to Licensee ownership of all Information and Patents that are created, conceived or discovered by such subcontractor in the performance of such activities and that is related to the Licensed Compound or Licensed Products, and (z) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property, and all other relevant provisions of this Agreement. As between the Parties, Licensee shall be fully responsible for all acts and omissions of its sublicensees.

For distribution activities, Licensee may use the Third Parties set forth on **Schedule 7.3** subject to [***], whereby (1) [***] and (2) [***].

7.4. Grants to Licensor. Subject to the terms and conditions of this Agreement, Licensee (on behalf of itself and its Affiliates) hereby grants to Licensor an exclusive, royalty free, perpetual, irrevocable license, with the right to grant sublicenses through multiple tiers, to Exploit the Sole Program IP and the Sole Program Patents Controlled by Licensee for the Development, Manufacture or Commercialization of Licensed Products outside the Territory.

7.5. Retention of Rights.

7.5.1. Except as expressly provided herein, neither Party grants any right or license, including any rights or licenses to any Patents, Information, regulatory documentation, any corporate names, Trademarks or logos owned or used by such Party or any of its Affiliates, or any other Patent or intellectual property rights not otherwise expressly granted herein, whether by estoppel, implication or otherwise.

7.5.2. Notwithstanding the grants in this ARTICLE 7, Licensor reserves the right to conduct Clinical Trials in the Territory to the extent this Agreement provides Licensor the right to do so, including pursuant to Section 3.3.

7.6. Confirmatory Patent License. Licensor shall execute all documents, give all declarations and reasonably cooperate with Licensee to the extent such documents, declarations or cooperation is/are required for the recording or registration of the licenses granted hereunder at the various patent offices in the Territory for the benefit of Licensee. Licensee shall reimburse Licensor for its reasonable out-of-pocket costs associated therewith.

7.7. In-licensing Agreements.

7.7.1. Licensee acknowledges that the In-licensing Agreements were executed prior to the Effective Date. Accordingly, any rights under the In-licensing Agreement that are sublicensed to Licensee under this Agreement are subject to the terms of the In-licensing Agreements and in no event shall this Agreement operate in any manner that would violate the terms of the In-licensing Agreements. Licensor will not amend, modify or terminate any Inlicensing Agreement in any manner that would materially adversely affect Licensee's rights under this Agreement or materially increase Licensee's obligations under this Agreement, in each case, without Licensee's prior written consent. Licensor shall promptly provide Licensee with a copy of any amendment to an In-licensing Agreement if such amendment impacts Licensee's rights or obligations under this Agreement. Without limiting the foregoing, (a) the terms of the In-licensing Agreements set forth in **Schedule 7.7.1** shall be binding upon Licensee as if it were a party to the In-licensing Agreements to the extent applicable to the Territory and (b) Licensor shall have the right to forward reports and other Information provided by Licensee hereunder in accordance with the In-licensing Agreements.

7.7.2. Where the Patents in-licensed under the In-licensing Agreements are licensed to Licensor on a non-exclusive basis, the rights granted to Licensee under Section 7.1 shall be exclusive with respect to Licensor's non-exclusive rights.

7.7.3. Other In-Licenses. If, after the Effective Date, Licensor or its Affiliates enters into an agreement for rights to Patents or Information of a Third Party that claim or cover improvements or modifications to the Licensed Products (such as a new delivery system or another active ingredient intended for use in combination with the Licensed Compound), Licensor shall provide Licensee with written notice thereof. If Licensee desires to use such Patents or Information in connection with the Development or Commercialization of Licensed Product in the Field in the Territory, it shall provide written notice to Licensor and the Parties shall discuss and negotiate in good faith the economic and other terms upon which Licensor would giant Licensee rights to such Patents and Information. Unless and until the Parties have entered into an agreement or amendment to this Agreement providing for a grant of rights to Licensee under such Patents and Information, such Patents and Information shall be excluded from the Licensed Patents and Licensed Know-How.

7.8. Exclusivity with Respect to the Territory.

7.8.1. During the Term and for a period of [***], except in case of termination of the Agreement by Licensee due to a material breach of Licensor, Licensee shall not, and shall cause its Affiliates not to (a) directly or indirectly, research, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory, or (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory.

7.8.2. During the Term, Licensor shall not, and shall cause its Affiliates not to (a) directly or indirectly, research, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory, (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory or (c) except as permitted in Section 3.3.1(b), giant a license to a Third Party to Develop the Licensed Compound or the Licensed Products in the Field in the Territory.

7.8.3. Notwithstanding Section 7.8.1 or Section 7.8.2, if a Party is subject to a Change of Control and, on the date of the closing of such Change of Control, the acquirer or any of its Affiliates prior to such Change of Control (collectively, the "**Acquiring Person**") is Developing, Manufacturing, or Commercializing a Competing Product for use in the Field (based on the applicable Regulatory Approval), then the Acquiring Person shall not be in breach of Section 7.8.1 or Section 7.8.2, as applicable, as a result of such Change of Control; provided, that, such Acquiring Person at all times Segregates the Competing Product and the Acquiring Person does not utilize or access the Licensed Technology for the Competing Product.

7.8.4. In case of a failure of either Party to comply with its covenants under this Section 7.8, the other Party shall have the right to terminate this Agreement for material breach [***]; provided that: (i) in the event the activity constituting non-compliance is carried out by such Third Party, then such other Party shall not have the right to terminate this Agreement if the non-compliant Party takes [***] action (in any event within [***] days after such non-compliant Party learns of such non-compliance) to terminate its agreement with such Third Party or to cause the cessation of such non-compliance activities and such termination or cessation occurs in such [***] day period; and (ii) in the event the activity constituting non-compliance is the conduct of research on compounds that the non-compliant Party was not aware are Competing Products, then such other Party shall not have the right to terminate this Agreement if the non-compliant Party takes [***] action to cease such research (in any event ceases such research within [***] days after such non-compliant Party learns that such compounds are Competing Products).

ARTICLE VIII
PAYMENTS AND RECORDS

In consideration of the rights granted by Licensor to Licensee on the Licensed Technology in accordance with Section 7.1 and the strong wish of the Licensor to have the commercialisation of the Licensed Product start as soon as possible in the Territory, the Licensee will make the below mentioned payments to the Licensor.

8.1. Upfront Payment. In partial consideration of the rights granted by Licensor to Licensee hereunder on the Licensed Technology as set out in Section 7.1, Licensee shall make a non-refundable, non-creditable payment of seventy five million Dollars ($75 million), which Licensor shall use to perform its investment obligations set out in the Share Issuance Agreement as attached hereto as **Schedule 8.1**. Upon the issuance and Delivery to the Subscriber of the Subscription Shares (each, as defined in the Share Issuance Agreement), Licensee's obligations under this Section 8.1 shall be satisfied in full.

8.2. Development Cost-Sharing Payment. In partial consideration of the rights granted by Licensor to Licensee hereunder on the Licensed Technology as set out in Section 7.1, Licensee shall make to Licensor a one-time, non-refundable and non-creditable payment of seventy five million Dollars ($75 million) in cash within [***] days after the Effective Date.

8.3. Development Milestone Payment. In partial consideration of the rights granted by Licensor to Licensee hereunder on the Licensed Technology as set out in Section 7.1, Licensee shall pay to Licensor a one-time milestone payment of twenty-five million Dollars ($25 million) in cash upon the first Regulatory Approval of a Licensed Product by the FDA for Myasthenia Gravis. Licensor will notify Licensee in writing upon the achievement of such milestone event. Licensee shall pay to Licensor the milestone payment within [***] days upon receipt of an invoice from Licensor.

8.4. Royalties.

8.4.1. Royalty Rates. As further consideration for the rights granted by Licensor to Licensee on the Licensed Technology in accordance with Section 7.1 hereunder, during the applicable Royalty Term, Licensee shall pay to Licensor royalties on Net Sales of all Licensed Products in the Territory, calculated as follows:

Net Sales of all Licensed Products in a Calendar Year	Royalty Rate
For that portion of aggregate net Sales of all Licensed products in the Territory during a Calendar Year less than [***]	[***]%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a calendar Year equal to or greater than [***]	[***]%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than [***]	[***]%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than [***]	[***]%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than [***]	[***]%

8.4.2. Royalty Term. On a Licensed Product-by-Licensed Product and jurisdiction-by-jurisdiction basis. Licensee's royalty obligations as set forth in this Section 8.4 shall begin with the First Commercial Sale of such Licensed Product in such jurisdiction in the Territory by Licensee, its Affiliates or sublicensees, and shall expire upon the last to occur of: (a) the expiry of the last to expire Valid Claim of any Licensed Patents (whether Controlled by Licensor alone or jointly with Licensee or a Third Party) that covers such Licensed Product, its Manufacture or its use in such jurisdiction in the Territory; (b) expiration of Regulatory Exclusivity in such jurisdiction in the Territory for such Licensed Product; or (c) twelve (12) years after the date of such First Commercial Sale of such Licensed Product in such jurisdiction in the Territory (the "**Royalty Term**").

8.4.3. Know-How Reduction. If, and for so long as, during the Royalty Term for a given Licensed Product in a jurisdiction in the Territory, there is both (i) no Valid Claim that claims or covers such Licensed Product or its method of use, and (ii) no Regulatory Exclusivity covering such Licensed Product, the royalty rate set forth in Section 8.4.1 with respect to such jurisdiction, shall be reduced to of the royalty rate set forth in Section 8.4.1 solely with respect to Net Sales of such Licensed Product in such jurisdiction.

8.4.4. Third Party Agreements.

(a) Existing Licensor Agreements. If and for so long as Licensor is obligated to pay royalties under the [***] Agreement with respect to sales of Licensed Product in the Territory, Licensee shall reimburse Licensor on a quarterly basis for an amount equal to [***] (as defined in the [***] Agreement) by Licensee, its Affiliates and sublicensees of Licensed Product (solely to the extent such Licensed Product constitutes a Product (as defined in the [***] Agreement)) in the Territory within [***] days after receipt of an invoice from Licensor. Except with respect to the [***] Agreement as set forth above, Licensor shall remain solely responsible for the payment of royalty, milestone, and other payment obligations if any, due to Third Parties under the In-licensing Agreements and any other agreement entered into by Licensor prior to the Effective Date. In relation to the aforementioned, Licensee shall provide Licensor with such reasonably detailed information as is required to determine the total of Net Sales as defined in the [***] Agreement insofar as relating to the Territory.

(b) Licensee Agreements. Licensee shall be solely responsible for the payment of royalty, milestone, and other payment obligations, if any, due to Third Parties under any Third Party license agreement that Licensee or its Affiliates enters into after the Effective Date in connection with this Agreement; provided, however, that on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis, if, during the Royalty Term, Licensee [***] a license under certain Third Party Patents [***] for the use or exploitation of the Licensed Technology as contemplated under this Agreement, then, for the calculation of royalty payments due under Section 8.4.1 for such Licensed Product in such jurisdiction, Licensee may deduct [***] of the amounts payable by Licensee to such Third Party under such license agreement in relation to the respective Licensed Product in such jurisdiction.

(c) New Licensor Agreements. Licensee shall be responsible for any payments agreed to pursuant to Section 7.7.3.

8.4.5. Biosimilar Competition. If with respect to a given Licensed Product, one or more Biosimilar Products is/are sold in a particular jurisdiction in the Territory during a particular Calendar Quarter, and during such Calendar Quarter (a) the [***] and (b) the [***], then the royalty rate for such Licensed Product in such jurisdiction will be reduced by [***] for [***], provided that this Section 8.4.5 [***].

8.4.6. Cumulative Deductions. Notwithstanding the above, any royalty reduction made pursuant to Section 8.4.3, Section 8.4.4 or Section 8.4.5 shall in no event reduce the applicable royalty rate for the respective Licensed Product in the respective jurisdiction to less than [***] of the amounts determined pursuant to Section 8.4.1.

8.4.7. Bundling Sale. If a Licensed Product is sold as part of a bundle including both (i) a Licensed Product, and (ii) other pharmaceutical products (a "**Bundling Sale**"), the Net Sales amount for the Licensed Product sold in such a Bundling Sale shall be adjusted to correspond to the price of the Licensed Product when sold separately in the Territory (if the Licensed Product is sold separately in the Territory) or (if the Licensed Product is not sold separately in the Territory) to the price reflecting the commercial value of the Licensed Product as compared to the other product included in the Bundling Sale. The factors to determine such price shall include the prices charged for the Licensed Product and the other product if sold separately in the Territory and the prices charged for products or corresponding market value and position in the Territory. Notwithstanding the foregoing, in the case of discounts on the Bundling Sale, such discount with respect to the bona fide list price of a Licensed Product shall not, for purposes of calculating Net Sales, exceed a percentage that is greater than the average percentage discount of all products of Licensee, its Affiliates, or sublicensees in a particular "bundle", calculated as follows: Average percentage discount on a particular' "bundle" = [1 - (X/Y)] x 100 where X equals the total discounted price of a particular "bundle" of products, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product in such "bundle".

8.4.8. Royalty' Payments and Reports.

(a) Commencing with the Calendar Quarter in which there is the First Commercial Sale of a Licensed Product, Licensee shall furnish to Licensor a written report showing in reasonably specific detail and to the extent reasonably possible, on a jurisdiction-by-jurisdiction basis: (a) the quantity, average sales price and aggregate gross sales of all Licensed Products sold by Licensee, its Affiliates and its sublicensee(s) during such Calendar Quarter in the Territory, and the calculation of Net Sales from such gross sales, specifically listing the deductions from such gross sales, disaggregated by type, as permitted by this Agreement; (b) the calculation of the royalties which shall have accrued based upon such Net Sales; (c) the withholding taxes, if any, required by law to be deducted with respect to such sales; and (d) the exchange rate used in determining the amount of Dollars. Licensee shall provide to Licensor the final report containing such information within [***] after the end of each Calendar Quarter. In addition, Licensee shall provide to Licensor a non-binding preliminary report containing estimates on Net Sales and estimated calculation of royalties for the Territory within [***] after the end of each Calendar Quarter.

(b) All sales of Licensed Products shall be expressed both in the currency in which the sale is invoiced and in the Dollar equivalent converted in accordance with Section 8.5.

(c) All royalties shown to have accrued by each royalty report provided under this Section 8.4.8 shall be payable [***] days after the delivery of such royalty report. Payment of royalties in whole or in part may be made in advance of such due date.

8.5. Mode of Payment; Offsets. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice in writing to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using the New York foreign exchange rate quoted in *The Wall Street Journal* (or, if *The Wall Street Journal* is no longer providing such exchange rate, a mutually agreed source) on the last Business Day of the Calendar Quarter to which such payment pertains. Except as provided in Section 8.7 or Section 3.7.3, Licensee shall have no right to offset, set off or deduct any amounts from or against the amounts due to Licensor. Except as provided in Section 8.10 and Section 8.7.4, all payments to Licensor under this Agreement will be irrevocable, non-refundable and non-creditable.

8.6. Forecasting. Throughout the Term, Licensee shall, no later than [***] of each Calendar- Year, provide Licensor with a guidance forecast setting out an estimate of royalty payments for such four (4) Calendar Quarters (broken out by each Calendar Quarter). It is understood by the Parties that the guidance forecast provided shall be non-binding but in good faith and the royalty information provided is not a performance commitment or guarantee.

8.7. Taxes.

8.7.1. All payments by Licensee to Licensor pursuant to this Agreement shall be paid free and clear of any and all taxes, assessments, fees, duties or other charges of any kind to governmental, regulatory, or other Third Party, except for any withholding taxes required by Applicable Law in the Territory as covered by Section 8.7.2.

8.7.2. If Licensee is required by Applicable Law in the Territory to withhold any withholding taxes in respect of the payments by Licensee to Licensor pursuant to this Agreement, other than VAT and Indirect Taxes ("**Withholding Income Taxes**" and together with VAT and Indirect Taxes, "**Withholding Taxes**"), Licensee shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant tax authorities in accordance with Applicable Law and, each such amount payable under this Agreement will be increased by an amount equal to [***] of the [***] Tax required by Applicable Law in the Territory to be withheld. If, however, the Withholding Taxes are imposed as a result of an assignment or transfer of this Agreement or any rights and/or obligations resulting from this Agreement by the Licensee, the Licensee will be obliged to increase the payments due as per ARTICLE 8 in such a manner that taking into account the Withholding Taxes, Licensor will receive, after the withholding of such taxes, the amount that would have been payable by Licensee had no such assignment or transfer occurred. Additionally, if, however, the Withholding Taxes are imposed as a result of an assignment or transfer of this Agreement or any rights and/or obligations resulting from this Agreement by the Licensor, Licensee will not be obliged to increase the payments due under ARTICLE 8 to account for such increased Withholding Taxes, and Licensee will only be obliged to increase the payments due as per ARTICLE 8 in such a manner that taking into account the Withholding Taxes, Licensor will receive, after the withholding of such taxes, the amount that would have been payable by Licensee had no such assignment or transfer occurred.

8.7.3. Notwithstanding anything to the contrary herein, Licensee shall not assign its rights or obligations hereunder to any Person located, established or residing in a Non- Cooperative Jurisdiction.

8.7.4. To the extent that Applicable Law in the Territory requires Licensee to withhold any Withholding Tax in respect of the payments by Licensee to Licensor pursuant to this Agreement and that obligation on Licensee can be relieved (or the amount to be withheld can be reduced to a lesser amount) on the basis of an application for relief by Licensor, Licensor shall, at Licensee's request, as soon as is reasonably practicable, make such application (including but not limited to seeking relief under any applicable double taxation treaty or convention), to enable Licensor to receive amounts payable under this Agreement without any Withholding Taxes being withheld (or to receive amounts at a reduced rate of withholding tax). If Licensor obtains a refund or credit of any such Withholding Taxes, Licensor shall remit or assign [***]% of any such refund or credit to Licensee by applying the refund or credit as credit against future amounts due under this Agreement.

8.7.5. All payments due to the terms of this Agreement are expressed to be exclusive of VAT and Indirect Taxes. The Parties will cooperate to minimize and to obtain all available exemptions from any VAT and Indirect Taxes. If Licensee is required to deduct or withhold any VAT and Indirect Taxes on any payments payable by Licensee under this Agreement, Licensee shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant tax authorities in accordance with Applicable Law and such amount payable under this Agreement will be increased by an amount equal to such VAT and Indirect Taxes required by Applicable Law in the Territory to be withheld.

8.8. Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then, without limiting any rights or remedies of the receiving Party, such paying Party shall pay interest thereon (before and after any judgment) at a rate of [***] above the [***] rate of the respective currency for the time period in which such amount is outstanding, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

8.9. Records.

8.9.1. Development and Commercialization Records. Licensee shall maintain records in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, and in compliance with Applicable Law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its Development and Commercialization activities by or on behalf of Licensee with respect to the any Licensed Product. Such records shall be retained by Licensee for at least [***] years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Upon request, Licensee shall provide copies of (and no more frequently than once per Calendar Year-, except for cause, allow Licensor, or its designee, to inspect) the records it has maintained pursuant to this Section 8.9.1 to Licensor.

8.9.2. Financial Records. Licensee shall, and shall cause its subbcontractors to, keep complete and accurate books and records pertaining to Net Sales of Licensed Products, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its payment obligations under this Agreement. Such books and records shall be retained by Licensee and its subcontractors until the later of (a) [***] years after the end of the Calendar Quarter to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

8.10. Audit. Subject to the other terms of this Section 8.10, at the request of Licensor, Licensee shall, and shall cause its Affiliates and subbcontractors to, permit an independent, certified public account designated by Licensor and reasonably acceptable to Licensee, its Affiliates and subcontractors at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 8.9 to ensure the accuracy of all reports and payments made hereunder for any Calendar Year ending not more than [***] months prior to the date of such request. These rights with respect to any Calendar Year shall be limited to once each Calendar Year (except for cause). The cost of this audit shall be borne by Licensor, unless the audit reveals a variance of more than [***]% from the reported amounts, in which case Licensee shall bear the cost of the audit. If such audit concludes that (a) additional amounts were owed by Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 8.8, or (b) excess payments were made by Licensee, Licensor shall reimburse such excess payments, in either case ((a) or (b)), within [***] days after the date on which such audit is completed. Licensor shall treat all financial information subject to review under this Section 8.10 as Confidential Information of Licensee and, prior to commencing such audit, shall cause its accounting firm to enter into a confidentiality agreement reasonably acceptable to Licensee. During the Term, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit the other Party to close its books periodically in a timely manner.

8.11. No Other Compensation. Each Party hereby agrees that the terms of this Agreement and the Share Issuance Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE IX
INTELLECTUAL PROPERTY

9.1. Ownership of Intellectual Property.

9.1.1. Background IP. Subject to the rights and licenses expressly granted under this Agreement, each Party shall retain all rights, title, and interests in, to and under any and all Patents and Information that are Controlled by such Party prior to the Effective Date or independent of this Agreement.

9.1.2. Program IP.

(a) As between the Parties, Licensor shall own all right, title, and interest in and to any and all Program IP that is an improvement, enhancement or modification to the Licensed Compound or Licensed Products or their method of use or manufacture ("**Product Improvement**"). Licensee will promptly disclose in writing to Licensor the conception, discovery, development or making of any Product Improvements. Licensee shall have no right to apply for Patents on any Product Improvements. Licensee shall, and hereby does (and shall cause its employees, agents, and subcontractors to, and shall cause its Affiliates and their respective employees, agents and subcontractors to), assign to Licensor all of its and their right, title and interest in and to Product Improvements. Upon Licensor's written request, Licensee shall, and shall cause its employees, agents, and subcontractors to, and shall cause its Affiliates and their respective employees, agents and subcontractors to, execute and deliver such instruments and do such acts and things as may be necessary under Applicable Law, or as Licensor may reasonably request to effectuate and confirm the vesting of all right, title and interest in and to Product Improvements in Licensor. Product Improvements shall be part of Licensor's Sole Program IP and will be included within the Licensed Technology.

(b) Subject to Section 3.5, Section 4.5 and Section 9.1.2(a), as between the Parties, each Party shall own all right, title, and interest in and to any and all Program IP that is conceived, discovered, developed, or otherwise made solely by or on behalf of such Party or its Affiliates or subcontractors ("**Sole Program IP**").

(c) Subject to Section 3.5, Section 4.5 and Section 9.1.2(a), as between the Parties, Licensor and Licensee shall jointly own any Program IP (other than Product Improvements) that is conceived, discovered, developed, or otherwise made jointly pursuant to a Development Plan by or on behalf of Licensor, its Affiliates or subcontractors, on the one hand, and Licensee, or its Affiliates on the other hand ("**Joint Program IP**"). Each Party will promptly disclose in writing to the other Party the conception, discovery, development or making of any Joint Program IP. Each Party will have an undivided one-half interest in and to the Joint Program IP and shall, and hereby does (and shall cause its employees, agents and subcontractors to, and shall cause its Affiliates and their respective employees, agents and subcontractors to), make such assignment to the other Party as is needed to effectuate such joint ownership. Each Party may exercise its ownership rights in and to such Joint Program IP, including the right to license and sublicense or otherwise to Exploit, transfer, or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the rights and licenses granted hereunder and the other terms and conditions of this Agreement. At the reasonable written request of a Party, the other Party will in writing giant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Program IP (but subject to the licenses granted under ARTICLE 7).

9.1.3. Employees and Agents. Prior to commencing any activities under this Agreement, each Party shall require all of its and its Affiliates' and subcontractors' employees and agents to assign all Program IP to such Party such that the Program IP can be assigned as set forth in Section 9.1.2 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions.

9.1.4. Ownership of Corporate Names. Each Party shall retain all right, title and interest in and to any corporate names. Trademarks and logos owned or otherwise used by such Party or any of its Affiliates.

9.2. Maintenance and Prosecution of Patents.

9.2.1. Patent Prosecution and Maintenance of Licensed Patents and Joint Patents.

(a) Subject to the remainder of this Section 9.2.1, Licensor shall, at its sole cost and expense, have the first right (but not the obligation) to prepare, file, prosecute, and maintain all of the Licensed Patents (other than Joint Patents) in Licensor's name and all Joint Patents in the name of both Parties in the Territory through the use of internal or external counsel. Licensor shall keep Licensee reasonably informed with regard to the preparation, filing, prosecution, and maintenance of all Licensed Patents and Joint Patents in the Territory and shall provide Licensee with copies of a draft of any proposed filings of Licensed Patents and Joint Patents in the Territory at least [***] days prior to any proposed filing. Licensee shall have an opportunity to review and comment upon prosecution and filing decisions of Licensed Patents and Joint Patents prior to the filing and submission of correspondences to the Patent authorities in connection with any Licensed Patents and Joint Patents in the Territory. Licensee shall provide to Licensor any comments at least [***] days prior to the proposed filing, and Licensor shall consider any comments timely received from Licensee in good faith, and implement as appropriate.

(b) If Licensor decides not to prepare, file, prosecute, or maintain a Licensed Patent or Joint Patent in a jurisdiction in the Territory, Licensor shall provide [***] days prior written notice to Licensee of such intention, and, Licensee shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Licensed Patent (other than a Joint Patent, in Licensor's name) or Joint Patent (in the name of both Parties) at its expense in such jurisdiction. In such event, Licensor shall promptly provide Licensee with the appropriate documents for transfer of responsibility for filing, prosecution and maintenance of such Licensed Patent or Joint Patent to Licensee or its designee and shall reasonably cooperate with Licensee or its designee as provided under Section 9.2.2. Thereafter, Licensee shall keep Licensor reasonably informed with regard to the preparation, filing, prosecution, and maintenance of such Patents and shall provide Licensor with copies of any proposed Patent filings at least [***] days prior to any proposed filing. Licensor shall have an opportunity to review and comment upon Patent prosecution and filing decisions prior to the submission of filing and correspondences to the Patent authorities in connection with any Licensed Patents and Joint Patents in the Territory. Licensor shall provide to Licensee any comments at least [***] days prior to the proposed filing, and Licensee shall consider any comments timely received from Licensor in good faith, and implement as appropriate.

9.2.2. Cooperation. The Parties agree to cooperate fully in the preparation, filing, prosecution, and maintenance of the Licensed Patents and Joint Patents in the Territory under this Agreement. Each Party's cooperation shall include executing all papers and instruments, or requiring its employees, consultants or contractors to execute such papers and instruments, so as to (a) effectuate the ownership of intellectual property set forth in Section 9.1.2; (b) enable the other Party to apply for and to prosecute Patent applications in the Territory; and (c) obtain and maintain any Patent extensions, supplementary protection certificates, and the like with respect to the Licensed Patents and Joint Patents in the Territory, in each case ((a), (b), and (c)) to the extent provided for in this Agreement.

9.2.3. Patent Prosecution and Maintenance of Sole Program Patents. Except as set forth in Section 9.2.1 with respect to any Sole Program Patents that are Licensed Patents, each Party, at its sole cost and expense and in its sole discretion, shall have the right (but not the obligation) to prepare, file, prosecute, and maintain all of the Sole Program Patents that it Controls.

9.2.4. Patent Term Extension and Supplementary Protection Certificate. Licensor shall have the right to make decisions regarding Patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, for Licensed Patents and Joint Patents that cover the Licensed Compound or Licensed Products in the Territory. Licensor shall consult with Licensee prior to such decisions and shall consider Licensee's comments in good faith and implement as appropriate. Licensor shall have the primary responsibility of applying for any extension or supplementary protection certificate with respect to such Patents in the Territory at its cost and expense. Licensee shall provide reasonable assistance, as requested by and at the sole cost of Licensor, including by taking such action as a joint owner of the Joint Patents as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

9.3. Enforcement of Patents.

9.3.1. Enforcement and Defense of Licensed Patents and Joint Patents.

(a) Each Party shall, promptly after becoming aware, notify the other Party in writing of any suspected or threatened infringement of the Licensed Patents or Joint Patents by a Third Party product in the Territory that is competitive with any Licensed Product, including suspected or threatened infringement based on the development, commercialization, or an application to market a generic or biosimilar product in the Territory (a "**Product Infringement**"). As between the Parties and subject to the In-licensing Agreements with respect to Patents in-licensed by Licensor under the In-licensing Agreements, Licensee shall have the first right, but not the obligation, to institute, prosecute and control any claim, suit or proceeding with respect to any Product Infringement of any Licensed Patent or Joint Patent in the Territory at its sole expense and Licensee shall retain control of the prosecution of such claim, suit or proceeding. If Licensee prosecutes any Product Infringement, Licensor shall have the right to join as a party to such claim, suit, or proceeding in the Territory and participate with its own counsel at its own expense; provided that Licensee shall retain control of the prosecution of such claim, suit, or proceeding.

(b) If Licensee does not undertake Commercially Reasonable Efforts to enforce or prosecute a Product Infringement (i) within [***] days following the first notice provided above with respect to the Product infringement, or (ii) [***] Business Days before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Licensor may (but shall have no obligation to) prosecute the Product Infringement of a Licensed Patent or Joint Patent in the Territory at its own expense and Licensor shall retain control of such prosecution. Licensor shall keep Licensee updated as to the steps it intends to take to prosecute a Product Infringement and shall otherwise provide Licensee with any information reasonably requested by Licensee.

(c) Licensor shall have the exclusive right (but not the obligation), in its sole discretion, to enforce Licensed Patents and Joint Patents for any infringement that is not a Product Infringement.

9.3.2. Cooperation. The Parties agree to cooperate fully in any Product Infringement action brought pursuant to Section 9.3.1. If a Party brings such an action, then the other Party shall, if necessary, either furnish a power of attorney solely for such purpose, join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any Product Infringement litigation in accordance with Section 9.3.1 shall have the right to settle such claim; *provided* that Licensee shall have no right to settle any Product Infringement litigation in a manner that would in effect be equivalent to granting a license of any Licensed Patent or Joint Patent to any Third Party, and neither Party shall have the right to settle any Product Infringement litigation in a manner that has a material adverse effect or meaningfully diminishes the rights or interests of the other Party (including in the case of settlement by Licensee, a material adverse effect on the Licensed Product outside the Territory or outside the Field), or in a manner that imposes any costs or liability on, or involves any admission of fault by, the other Party, without the express written consent of such other Party. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court and shall consider reasonable input from the other Party during the course of the proceedings.

9.3.3. Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 9.3.1 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if the recovery is insufficient to cover the totality of such expenses). Any remainder for enforcement of Product Infringement after such reimbursement is made shall be (a) [***] in the event [***]; provided, however, that any [***] and (b) [***] in the event [***]. Any remainder for infringement actions brought by Licensor pursuant to Section 9.3.1(c) that are not Product Infringements shall be retained by Licensor.

9.3.4. Enforcement of Sole Program Patents. Except as set forth in Section 9.3.1 with respect to any Sole Program Patents that are Licensed Patents, each Party, at its sole cost and expense and in its sole discretion, shall have the right (but not the obligation) to institute, prosecute, control and retain all recoveries from any claim, suit or proceeding with respect to suspected or threatened infringement of Sole Program Patents that it Controls.

9.4. Infringement Claims by Third Parties. If the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging Patent infringement by Licensee (or its Affiliates), Licensee shall promptly notify Licensor thereof in writing. Subject to the remainder of this Section 9.4 and Section 12.2, Licensee (or its Affiliates) shall have the right to defend any action which names Licensee (or its Affiliates) or claims the infringement, after the Effective Date, of any Third Party's Patent through the Development or Commercialization of the Licensed Product in the Field in the Territory. If necessary and at Licensee's expense. Licensor will reasonably assist and cooperate with Licensee in any such defense. Licensee shall keep Licensor reasonably informed of all material developments in connection with any such claim, suit, or proceeding, including by providing Licensor with copies of all pleadings filed in such action. Licensor shall have the right to (a) assume the defense of any claims that name Licensor or its Affiliates (and Licensee shall assist and cooperate in any such defense) or (b) participate in the defense of the claims in actions defended by Licensee. Neither Party may enter into any settlement that affects the other Party's rights or interests without such Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. Licensee will bear all costs and expenses (including attorneys' fees) and pay all damages and settlement amounts arising out of or in connection with any action described in this Section 9.4.

9.5. Invalidity or Unenforceability Defenses or Actions.

9.5.1. Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patents or Joint Patents by a Third Party, in each case in the Territory and of which such Party becomes aware.

9.5.2. Licensed Patents and Joint Patents. Licensor shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensed Patents and Joint Patents at its own expense in the Territory. Licensee may participate in any such claim, suit, or proceeding in the Territory applicable to the Field with counsel of its choice at its own expense; provided that Licensor shall retain control of the defense in such claim, suit, or proceeding. If Licensor elects not to defend or control the defense of any such Licensed Patents or Joint Patent in a suit brought in the Territory that is applicable to the Field, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then Licensee may conduct and control the defense of any such claim, suit, or proceeding of such Licensed Patents or Joint Patent at its own expense and Licensor may participate with counsel of its choice at its own expense.

9.5.3. Cooperation. Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with the defense of Licensed Patents and Joint Patents as set forth in Section 9.5.2, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its and its Affiliates' employees, subcontractors, agents and consultants available at reasonable business hours and for reasonable periods of time. In connection with any such defense or claim or counterclaim, the controlling Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim, or counterclaim. In connection with the activities set forth in this Section 9.5, each Party shall consult with the other as to the strategy for the defense of the Licensed Patents or Joint Patents in the Territory.

9.5.4. Sole Program Patents. Except as set forth in Section 9.5.2 with respect to any Sole Program Patents that are Licensed Patents, each Party, at its sole cost and expense and in its sole discretion, shall have the right (but not the obligation) to control the defense of the validity and enforceability of the Sole Program Patents that it Controls.

9.6. Product Trademarks. Licensor shall own all right, title, and interest to the Product Trademarks in the Territory, and shall have the sole right and responsibility for the registration, prosecution, maintenance and enforcement thereof. All costs and expenses of registering, prosecuting, maintaining and enforcing the Product Trademarks in the Territory shall be borne solely by Licensee. Licensee shall provide all assistance and documents reasonably requested by Licensor in support of its prosecution, registration, maintenance and enforcement of the Product Trademarks in the Territory. Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee a non-exclusive, sublicensable (subject to Section 7.2) license under the Product Trademarks for Licensee to Commercialize the Licensed Products in the Field in the Territory in compliance with Applicable Laws and this Agreement. Licensee shall comply with Licensor's guidelines on the use and display of the Product Trademarks and quality control instructions. The Parties acknowledge and agree that the consideration for the provision of any rights or services by Licensor under this Section 9.6 is included in the payments payable by Licensee to Licensor pursuant to this Agreement.

9.7. Inventor's Remuneration. Each Party shall be solely responsible for any remuneration that may be due such Party's inventors under any applicable inventor remuneration laws or by contract.

9.8. Licensor Technology. Notwithstanding any provision in this Agreement to the contrary, Licensor shall have the right to transfer or assign ownership of any Licensed Know-How and Licensed Patents (including Licensor's interest in Joint Program IP and Joint Patents) as long as any such transfer or assignment is made in connection with a permitted assignment or transfer of this Agreement in accordance with Section 15.2.

ARTICLE X
CONFIDENTIALITY AND NON-DISCLOSURE

10.1. Confidentiality Obligations. At all times during the Term and for a period of [***] years following termination or expiration of this Agreement, each Party shall, and shall cause its Affiliates, and such Party's and its Affiliates' officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party in connection with this Agreement, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is in connection with the performance of, or the exercise of such Party's rights or obligations under, this Agreement. Notwithstanding the foregoing, but to the extent the receiving Party can demonstrate by documentation or other competent proof, the confidentiality and non-use obligations under this Section 10.1 with respect to any Confidential Information shall not include any information that:

10.1.1. has been published by a Third Party or is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

10.1.2. has been in the receiving Party's possession prior to disclosure by the disclosing Party (as can be shown by competent written evidence) without any obligation of confidentiality with respect to such information;

10.1.3. is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

10.1.4. has been independently developed by or for the receiving Party without reference to, or use or disclose of the disclosing Party's Confidential Information, as evidenced by such Party's internal records documenting such independent development.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

10.2. Permitted Disclosures.

10.2.1. Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to law, regulation or made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction, including by reason of filing with securities regulators; *provided, however,* that the receiving Party shall first have given [***] written notice (and to the extent possible, at least [***] days' notice) to the disclosing Party and cooperates with the disclosing Party in taking whatever action the disclosing Party deems necessary to protect its Confidential Information (for example, to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or regulatory body or, if disclosed, be used only for the purposes for which the order was issued). If no protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Agreement, receiving Party shall furnish only that portion of Confidential Information which receiving Party is advised by counsel is legally required to be disclosed;

(b) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Agreement; *provided, however,* that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law; or

(c) made by Licensor to third parties to the extent required pursuant to the terms of agreements entered into prior to the date hereof, in any case with respect to the [***] as part of applicable royalty reports and as otherwise required.

10.2.2. In addition, the receiving Party may disclose Confidential Information of the disclosing Party to the extent that such disclosure is:

(a) made to a Patent authority as may be reasonably necessary or useful for purposes of obtaining, defending or enforcing a Patent in accordance with the terms of this Agreement; *provided, however,* that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or

(b) made to its or its Affiliates' financial and legal advisors who have a need to know such Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, or to potential investors, licensees or collaboration partners, in each case, at least as restrictive as those set forth in this Agreement; *provided, however,* that the receiving Party shall remain responsible for any failure by such financial and legal advisors or such investors, licensees or collaboration partners, to treat such Confidential Information as required under this ARTICLE 10.

10.3. Use of Name. Except as expressly provided herein, neither Party nor its Affiliates shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law; provided such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

10.4. Public Announcements. The Parties have agreed upon the content of a press release, which shall be issued promptly after the Effective Date substantially in the form attached as **Schedule 10.4**. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. If a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

10.5. Publications.

10.5.1. The JDC will develop, and submit to the JSC for approval, a strategy for Publications, including at major medical conferences.

10.5.2. Licensee will submit to the JDC for review and comment written copies of each proposed Publication no later than [***] days before submission for publication or presentation. The JDC will provide its comments with respect to such Publication within [***] after receipt of such written copy. Licensee shall incorporate any comments reasonably requested by the JDC in line with the Publication strategy. If the JDC cannot agree on a version of Licensee's Publication that is acceptable for both Parties, the matter shall be escalated to the JSC.

10.5.3. The JDC shall establish a process for efficient and rapid review and approval of Publications by Licensor that include Clinical Data generated by Licensee in the Territory.

10.5.4. Each Party shall remove any of the other Party's Confidential Information identified to the JDC from any such proposed Publication unless the other Party provides written consent. For clarity, Licensor shall be permitted to make Publications containing Licensor's Confidential Information, without any requirement of Licensee consent.

10.5.5. Any Publication under this Section 10.5 shall include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

10.6. Trade Secrets. Each acknowledges that the other Party may transfer trade secrets to such Party in connection with this Agreement. With respect to any such information so disclosed that is identified as a trade secret by the disclosing Party, the receiving Party shall take all steps necessary to maintain such information as a trade secret for as long as such information remains a trade secret under Applicable Law, notwithstanding Section 10.1. No trade secret information of either Party may be transferred by the receiving Party to a Third Party until the receiving Party has (a) received the disclosing Party's written approval and (b) entered into a confidentiality agreement at least as restrictive as the confidentiality terms of this Agreement, and which shall contain provisions protecting the confidentiality of trade secrets as set forth herein. In addition, the receiving Party shall take steps reasonably necessary to ensure that such Third Party maintains such information as a trade secret. Such trade secrets may only be used by the receiving Party or such Third Party as expressly set forth in this Agreement.

10.7. Notification of Breach. The receiving Party shall notify the disclosing Party within [***] after the receiving Party or its Affiliates becoming aware of any disclosure of the disclosing Party's Confidential Information in violation of this ARTICLE 10, or any other breach of this ARTICLE 10, by the receiving Party, its Affiliates or its subcontractors or their respective officers, directors, employees or agents.

10.8. Return of Confidential Information. Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which the other Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; *provided, however,* (i) the other Party shall be permitted to retain one copy of such Confidential Information for the sole purpose of performing any confirming obligations hereunder or for archival purposes and (ii) Licensor shall be permitted to retain Licensee's Confidential Information to the extent necessary or reasonably useful for Licensor to Exploit Licensed Product after termination as contemplated by Section 14.1.3. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

10.9. Survival. All Confidential Information shall continue to be subject to the terms of this Agreement for the applicable periods set forth in this ARTICLE 10 regardless of the termination or expiration of this Agreement.

ARTICLE XI
REPRESENTATIONS AND WARRANTIES

11.1. Mutual Representations and Warranties. Licensor and Licensee each represents and warrants to the other, as of the Effective Date, and covenants, as follows:

11.1.1. Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

11.1.2. Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

11.1.3. Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

11.1.4. No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement.

11.2. Additional Representations and Warranties of Licensor. Licensor further represents and warrants to Licensee, as of the Effective Date as follows:

11.2.1. Licensor or one of its Affiliates Controls the Licensed Patents listed in **Schedule 1.69** and the Licensed Know-How described in **Schedule 1.68**. Other than Patents or Information in-licensed under the In-licensing Agreements, there exists no Patent or Information that is owned or in-licensed by Licensor or any of its Affiliates that is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Product in the Field in the Territory that is not Controlled by Licensor or such Affiliate;

11.2.2. Schedule 1.69 sets forth a complete and accurate list of all Licensed Patents in the Territory;

11.2.3. Licensor has the right to grant to Licensee the licenses under the Licensed Technology in Section 7.1 and has not granted to any Third Party any license or other right with respect to Licensed Compounds, Licensed Products or Licensed Technology that conflicts with the licenses granted to Licensee hereunder;

11.2.4. to Licensor's knowledge, the Development of the Licensed Products in the Territory prior to the Effective Date did not infringe any valid claims of Patents owned or possessed by any Third Party and did not breach any obligation of confidentiality or non-use owed by Licensor or its Affiliates to a Third Party with respect to Information related to the Licensed Products;

11.2.5. to Licensor's knowledge, Licensor has provided to Licensee all material pre-clinical data and clinical data relating to Licensed Products that has been requested by Licensee; and

11.2.6. Licensor has received no written notice that a claim or action has been brought against Licensor, and Licensor has not received any written claim or demand as of the Effective Date alleging (a) that the Licensed Patents are invalid or unenforceable or (b) that the use of the Licensed Patents by Licensor in the Territory infringes or misappropriates the intellectual property rights of any Third Party. Licensor has received no written notice that an interference, opposition, cancellation or other protest proceeding has been filed against a Licensed Patent owned by Licensor.

11.3. Additional Representations and Warranties. Each Party further represents and warrants to the other Party, as of the Effective Date, and covenants during the Term, as follows:

11.3.1. it and its Affiliates have not ever been, are not currently, nor are they the subject of a proceeding that could lead to it or its Affiliates becoming a Debarred Entity, Excluded Entity or Convicted Entity and it and its Affiliates will not use in any capacity, in connection with the obligations to be performed under this Agreement, any person who is a Debarred Individual, Excluded Individual or a Convicted Individual. Such Party further covenants that if, during the Term, it or its Affiliates become a Debarred Entity, Excluded Entity or Convicted Entity, or listed on the FDA's Disqualified/Restricted List or if any employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual or a Convicted Individual, or added to the FDA's Disqualified/Restricted List, such Party shall immediately notify the other Party. If Licensee is the notifying Party (or Licensor otherwise becomes aware that Licensee is in breach of this Section 11.3.1 and provides written notice thereof to Licensee), and if Licensee has not prevented such person from performing work under this Agreement within [***] of becoming aware of such breach, then Licensor may terminate this Agreement immediately upon written notice to Licensee. This provision shall survive expiration of this Agreement. For purposes of this provision, the following definitions shall apply:

(a) a "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application;

(b) a "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity;

(c) an "**Excluded Individual**" or "**Excluded Entity**" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) a "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a—7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible; and

(e) "**FDA's Disqualified/Restricted List**" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if the FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false Information to the study sponsor or the FDA.

11.3.2. Sanctioned Party Prohibition. The Parties acknowledge and agree that governmental authorities, including the U.S. federal government prohibits trade with certain sanctioned or blocked parties and publishes and maintains lists of Persons with whom trade is prohibited (each such governmental authority's list, a "**Sanctioned Party List**"). Each Party represents and warrants that it (a) is not on any Sanctioned Party List maintained by any governmental authority, (b) has no reason to believe it will be placed on any Sanctioned Party List, and (c) will not deal with, conduct any business with or otherwise transact in any manner related to the rights and obligations contained in this Agreement with any Person on any global Sanctioned Party List.

11.3.3. Anti-Corruption. Each Party and its Affiliates and their respective directors, officers, employees, agents or other persons or entities acting on its behalf have conducted and will conduct their activities under this Agreement in compliance with the US Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and any other applicable anti-corruption laws, rules or regulations (collectively, "**Anti-Corruption Laws**"). Without limiting the foregoing, each Party shall ensure that neither it, nor any of the foregoing Persons, shall offer, pay, promise, solicit or receive, directly or indirectly, any remuneration, benefit or advantage to or from any physician or other health care practitioner, governmental or political official, political party, candidate for public office, hospital, medical insurance company or similar provider organization, customer or other person in order to induce or encourage approval, referrals, purchase, or reimbursement or to obtain any other improper business advantage in violation of any Anti-Corruption Laws.

11.3.4. The Parties shall comply with all applicable data protection laws, including the General Data Protection Regulation (EU) 2016/679 of May 25, 2018, and those concerning medical confidentiality and privacy in relation to human subjects. The Parties acknowledge that they do not intend that one Party processes personal information for and on behalf of the other Party. If personal information is transferred between the Parties (as between controllers) pursuant to the performance of this Agreement, the Parties shall enter into a data processing agreement as is required by Applicable Laws. The Parties will enter into further data protection agreements if required by Applicable Laws. No personal data shall be shared by either Party if this would be in breach of Applicable Laws.

11.4. Diligence of Licensee. In accordance with the terms of this Agreement, Licensee acknowledges and agrees that to its best knowledge, it has received access to all Information relating to [***] that Licensee deemed necessary to conduct and complete its due diligence to its satisfaction, including [***]. Licensee acknowledges and agrees it had the opportunity to ask questions and request additional information, data and documents, and that [***], and to Licensee's best knowledge, Licensor has provided all information, data and documents requested by Licensee.

11.5. DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE LICENSES GRANTED HEREIN ARE MADE "AS IS, WHERE IS" WITH ALL FAULTS. ANY INFORMATION PROVIDED BY LICENSOR OR ITS AFFILIATES TO LICENSEE IS OR HAS BEEN MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

ARTICLE XII
INDEMNITY

12.1. Indemnification of Licensor. Licensee shall indemnify Licensor and its directors, officers, employees, and agents (the "**Licensor Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Par ties (collectively, "**Third Party Claims**") incurred by or rendered against the Licensor Indemnitees arising from or occurring as a result of: (a) the breach by Licensee or its Affiliates of this Agreement or any of its representations, warranties or obligations herein, (b) the negligence, reckless conduct or willful misconduct on the part of Licensee or its Affiliates, sublicensees or subcontractors or its or their respective directors, officers, employees, and agents in performing its or their- obligations under this Agreement, or (c) the Exploitation by Licensee, or its Affiliates, sublicensees or subcontractors of the Licensed Technology, the Licensed Compound or any Licensed Products in the Territory, provided that the foregoing obligations of indemnification and saving harmless, in each case (a)-(c), shall not apply to the extent Licensor has an obligation to indemnify Licensee pursuant to Section 12.2.

12.2. Indemnification of Licensee. Licensor shall indemnify Licensee and its directors, officers, employees, and agents (the "**Licensee Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims inclined by or rendered against the Licensee Indemnitees arising from or coming as a result of: (a) the breach by Licensor or its Affiliates of this Agreement or any of its representations, warranties or obligations herein, (b) the negligence, reckless conduct or willful misconduct on the part of Licensor or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Agreement or (c) the Exploitation by Licensor, or its Affiliates, licensees or subcontractors (other than Licensee, its Affiliates, sublicensees or subcontractors) of the Licensed Technology, the Licensed Compound or any Licensed Products inside or outside the Territory, provided that the foregoing obligations of indemnification and saving harmless, in each case (a)-(c), shall not apply to the extent Licensee has an obligation to indemnify Licensor pursuant to Section 12.1.

12.3. Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or their- respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this ARTICLE 12, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Losses (to the extent that the nature and amount of such Losses are known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

12.4. Control of Defense.

12.4.1. In General. At its option and sole expense, the indemnifying Party may assume the control of the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party's receipt of an Indemnification Claim Notice provided that the indemnifying Party has agreed to be fully responsible for all Losses relating to such claims to the extent provided in Section 12.1 or Section 12.2, as applicable. Upon assuming the defense of a Third Party Claim, the indemnifying Party shall have sole power to control the defense and, subject to Section 12.4.3, settlement of such Third Party Claim and sole power to appoint and control the retention of lead counsel for the defense of such Third Party Claim. If the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 12.4.2, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless the incurring of those expenses were specifically requested in writing by the indemnifying Party.

12.4.2. Right to Participate in Defense. Without limiting Section 12.4.1, any Indemnified Party shall be entitled to participate in, but, subject to Section 12.4.1, not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided, however,* that such participation shall be at the Indemnified Party's own expense unless (a) the employment and control thereof has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.4.1 (in which case the Indemnified Party shall control the defense), or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

12.4.3. Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that do not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.4.1, the indemnifying Party shall have authority to consent to the entry of any judgment, make any admissions that would adversely affect the Indemnified Party, enter into any settlement or otherwise dispose of such Loss; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), unless such compromise or settlement involves (a) any admission of legal wrongdoing by the Indemnified Party, (b) any payment by the Indemnified Party that is not indemnified under this Agreement, or (c) the imposition of any equitable relief against the Indemnified Party (in which case, (a) through (c), the Indemnified Party may withhold its consent to such settlement in its sole discretion). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided in Section 12.4.1, the Indemnified Party may defend against such Third Party Claim in accordance with Section 13.2.4 *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party, not to be unreasonably withheld, conditioned or delayed.

12.4.4. Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business horns afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Patties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

12.4.5. Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund if the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

12.4.6. Subrogation. All rights an Indemnified Party may have against any Third Party who asserts a Third Party Claim that is paid by the indemnifying Party under this ARTICLE 12 shall be subrogated to the indemnifying Party.

12.5. Special, Indirect, and Other Losses. EXCEPT (A) FOR NEGLIGENCE OR WILLFUL MISCONDUCT, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 9 OR ARTICLE 10, OR (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12 OR AT LAW OR IN EQUITY, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED, IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE BREACH OF THE TERMS OF THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

ARTICLE XIII
TERM AND TERMINATION

13.1. Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall expire on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis upon the date of expiration of the Royalty Term for such Licensed Product and jurisdiction (such period, the "**Term**"). Following the expiration of the Term (but not the termination of this Agreement), the grants in Section 7.1 shall survive and become fully-paid [***] royalty-free and perpetual. Licensor shall upon expiration of the Term (but not the termination of this Agreement) endeavor to continue any supply of Licensed Products to Licensee in accordance with its ongoing supply obligations under the Commercial Supply Agreement, all as to be further specified in the Commercial Supply Agreement.

13.2. Termination for Cause.

13.2.1. Material Breach.

(a) Subject to Section 13.2.1(b), either Party (the "**Non- Breaching Party**") shall have the right to terminate this Agreement in its entirety immediately upon written notice if the other Party (the "**Breaching Party**") has materially breached this Agreement and the Breaching Party has not cured such breach within [***] days (or [***] days for breach of payment obligations) after receiving written notice from the Non-Breaching Party identifying such material breach with particularity (a "**Default Notice**").

(b) If the alleged Breaching Party disputes in good faith the existence or materiality of a breach specified in a Default Notice provided in accordance with Section 13.2.1(a), and such alleged Breaching Party provides the other Party notice of such dispute and submits such dispute for resolution in accordance with Section 15.5.2 within [***] after receipt of the Default Notice, the Non-Breaching Party shall not have the right to terminate this Agreement under Section 13.2.1(a) unless and until (i) the arbitrator(s), in accordance with Section 15.5.2, has determined that the alleged Breaching Party has materially breached this Agreement and the Breaching Party fails to cure such breach within [***] days following such arbitrators' decision, or (ii) if the alleged breach is in regards to a Party's diligence obligations under this Agreement, the Breaching Party fails to implement the measures contemplated in the last sentence of this Section 13.2.1(b). It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of then respective obligations hereunder. In the event the alleged breach is in regards to a Party's diligence obligations under this Agreement, then, concurrent with such dispute resolution process, the Parties shall discuss in good faith and implement appropriate measures that would improve the diligence level of such Party to address the other Party's concerns.

13.2.2. Termination for Bankruptcy, Insolvency or Similar Event. If either Party (a) becomes the subject, whether voluntarily or involuntarily, of any bankruptcy, insolvency, receivership or similar proceeding, and, in the event of an involuntary case under the bankruptcy code, such case is not dismissed within [***] days upon filing for such proceeding; (b) makes an assignment for the benefit of creditors; (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property; (d) files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings; (e) admits in writing its inability to meet its obligations as they fall due in the general course; or (f) becomes subject to a warrant of attachment, execution, or distraint or similar process against substantially all of its property, then the other Party may terminate this Agreement in its entirety, effective immediately upon written notice to the other Party. The licenses and other rights granted pursuant to this Agreement shall be deemed to be grants of licenses to intellectual property for purposes of Section 365(n) of the United States Bankruptcy Code.

13.2.3. Additional Termination Right by Licensee. Licensee may terminate this Agreement in its entirety for any or no reason, upon [***] days' prior written notice to Licensor.

13.2.4. Termination for Patent Challenge. If Licensee or any of its Affiliates or sublicensees, anywhere in the Territory, challenges, or otherwise aides any Third Party to challenge, any claim in a Licensed Patent (or any corresponding worldwide family member) as invalid, unenforceable or otherwise not patentable or as not being infringed by Licensee's, its Affiliates' or sublicensees' activities absent the rights and licenses granted hereunder, then Licensor shall have the right to immediately terminate this Agreement upon written notice to Licensee; provided that (a) if such action is brought by Licensee's or its Affiliate's sublicensee and Licensee terminates the sublicense agreement with such sublicensee within [***] after such written notice, then Licensor shall not have the right to terminate this Agreement pursuant to this Section 13.2.4 and (b) this Section 13.2.4 will not apply to, and Licensor may not terminate this Agreement with respect to, any affirmative defense or other validity, enforceability, or non-infringement challenge, advanced by Licensee, any of its Affiliates or sublicensees in direct response to any claim or action brought in the first instance by, or on behalf of, Licensor against Licensee, its Affiliates or sublicensees.

ARTICLE XIV
EFFECTS OF TERMINATION.

14.1. In the event of a termination of this Agreement, the following shall apply:

14.1.1. All rights and licenses granted by Licensor hereunder shall immediately terminate.

14.1.2. All payments accrued or paid to Licensor under this Agreement shall be irrevocable, non-refundable and non-creditable regardless of the cause for termination.

14.1.3. Licensee shall, at Licensor's written request, perform any or all of the following and agree upon a transition plan with Licensor that shall address the tuning and logistics of the transition of the Licensed Products in the Field in the Territory to Licensor:

(a) effective upon Licensor's written request, Licensee shall, and hereby does grant (without any further action required on the part of Licensor) to Licensor and its Affiliates, an exclusive, royalty-free, fully paid, worldwide, irrevocable, perpetual license, with the right to grant sublicenses through multiple tiers, under any Patents or Information Controlled by Licensee that is necessary or reasonably useful to Exploit Licensed Products in the Territory;

(b) Licensee shall, unless expressly prohibited by any Regulatory Authority, transfer control to Licensor of all clinical studies being conducted by Licensee as of the effective date of termination and, at Licensor's request, continue to conduct such clinical studies, [***], for up to [***] to enable such transfer to be completed without interruption of any such Clinical Trial; *provided* that (i) Licensor shall not have any obligation to continue any Clinical Trial unless required by Applicable Law or (ii) with respect to each Clinical Trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, if any, Licensee shall continue to conduct such Clinical Trial to completion at Licensee's cost if [***] or, if [***] and Licensor requests that Licensee continue such Clinical Trial, at Licensor's cost (including costs associated with any liabilities incurred after the effective date of such termination);

(c) Licensee shall assign (or cause its Affiliates to assign) to Licensor or its Affiliates any and all agreements with any Third Party with respect to the conduct of pre-clinical development activities or clinical studies for the Licensed Products, including agreements with contract research organizations, clinical sites, and investigators, unless, with respect to any such agreement, such agreement expressly prohibits such assignment or such agreement relates to products other than Licensed Products, in which case Licensee shall cooperate with Licensor in reasonable respects to secure the consent of the applicable Third Party to such assignment or to facilitate assignment in part of such agreement;

(d) Licensee shall assign (or cause its Affiliates to assign) to Licensor or its Affiliates any and all agreements with any Third Party that subcontracts or sublicenses any rights, obligations or activities related to the Licensed Products, including agreements with distributors, unless, with respect to any such agreement, such agreement expressly prohibits such assignment or such agreement relates to products other than Licensed Products, in which case Licensee shall cooperate with Licensor in reasonable respects to secure the consent of the applicable Third Party to such assignment or to facilitate assignment in part of such agreement;

(e) Licensee shall notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect the transfers set forth in this Section 14.1.3;

(f) effective upon Licensor's written request, Licensee shall, and hereby does, assign to Licensor all right, title, and interest of Licensee and its Affiliates, if any, in each Product Trademark;

(g) Licensee shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as Licensor may reasonably request in connection with, or to carry out more effectively the purpose of, or to better assure and confirm unto Licensor its rights under, and to effectuate and facilitate the transfer to Licensor of the Licensed Products in the Field in the Territory contemplated by, this Section 14.1.3; and

(h) Licensor shall have the right to obtain Licensee's inventory of Licensed Products at a price equal to the price paid by Licensee to Licensor under Section 5.2 or the Commercial Supply Agreement, respectively, provided that Licensee shall destroy the remaining inventory of Licensed Products at its sole cost and expense if Licensee does not exercise its right under this Section 14.1.3(h) within [***] months following the effective date of termination.

14.2. Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

14.3. Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, ARTICLE 1 (to the extent the definitions are used in any surviving provisions), the first sentence of Section 3.5, Section 3.7.3 (with respect to any payment obligations accrued before termination or expiration of this Agreement), Sections 7.4, 7.5, 7.8.1 and 7.8.3, Sections 8.4.8 and 8.5 (with respect to any payment obligations accrued before termination or expiration of this Agreement), Sections 8.7, 8.8, 8.9, 8.10, Sections 9.1.1, 9.1.2, 9.1.4, 9.2.2, the first sentence of Section 9.6, Section 9.7, ARTICLE 10 (other than Section 10.5), Section 11.3.1, Section 11.5, ARTICLE 12, Section 13.1, ARTICLE 14 and ARTICLE 15 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE XV
MISCELLANEOUS

15.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including files, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the nonperforming Party or any of its Affiliates of any term or condition of this Agreement). The nonperforming Party shall notify the other Party of such force majeure within [***] days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. Following this notification, the Parties shall enter into good faith discussions on how to limit the negative impact of any such force majeure to the extent possible. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Without limitation to the foregoing, if Licensee is the non-performing Party and the force majeure event specifically impacts Licensee (i.e., it does not also impact all or substantially all competitors of Licensee in the Territory), and if the suspension of performance continues for a consecutive period of [***] after the date of the occurrence, Licensor shall have the right to terminate this Agreement [***] upon written notice to Licensee, in its sole discretion, and [***]. In the event that Licensor terminates this Agreement in accordance with the aforementioned sentence, the Parties shall enter into discussions on any compensation to be paid by Licensor to Licensee for such termination taking into account the harm/costs to the Parties as a result of such termination and force majeure, to the extent agreed between the Parties and for which agreement the Parties shall make reasonable good faith efforts.

15.2. Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided that each of the Parties may, without such consent, but with notification, assign this Agreement and its rights and obligations hereunder to any of its Affiliates or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all of the portion of its business to which this Agreement relates. In case of an assignment by Licensee to an Affiliate, such Affiliate must agree in writing that in case such Affiliates ceases to be an Affiliate of Licensee, the Agreement, or in case of an assignment of rights or obligations, such assigned rights shall automatically be re-assigned and transfer back to Licensee, and that the parties to such assignment agreement will do all acts that are required to effectuate such re-assignment and transfer back to Licensee. Any attempted assignment or delegation in violation of this Section 15.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Licensor or Licensee, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

15.3. Change of Control.

15.3.1. Change in Control of Licensee. If Licensee enters into an agreement that results or that, if the transaction contemplated thereby is completed would result, in a Change of Control of Licensee, Licensee shall provide Licensor with prompt written notice describing such Change of Control in reasonable detail. Licensee shall provide such notice prior to the execution of such agreement, or, if not permitted by Applicable Law or third party confidentiality obligations, as soon as practicable thereafter and in any event not later than [***] following the consummation of the transaction contemplated by such agreement.

15.3.2. Change in Control of Licensor. Patents and Information that are Controlled by an Acquiring Person prior to a Change of Control of Licensor or that become Controlled by an Acquiring Person after a Change of Control of Licensor (without use of any Licensed Technology existing prior to such Change of Control) shall not be included within the Licensed Patents or Licensed Know-How except to the extent (a) such Patents or Information cover technology used by Licensor or its Affiliates or then respective (sub)licensees in the Development, Manufacture or Commercialization of Licensed Compounds or Licensed Products and (b) such Patents or Information are necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or the Licensed Products in the Field in the Territory.

15.4. Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

15.5. Governing Law, Jurisdiction and Service.

15.5.1. Governing Law. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, however, that all questions concerning the construction or effect of Patent applications and Patents shall be determined in accordance with the laws of the jurisdiction in which the particular Patent application or Patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

15.5.2. Dispute Resolution. Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration administered by the International Centre for Dispute Resolution in accordance with the provisions of its International Arbitration Rules for the time being in force, which rules are deemed to be incorporated by reference in this Section 15.5.2. The seat of the arbitration shall be New York, New York. The tribunal shall consist of three (3) arbitrators. The language of the arbitration shall be English.

15.5.3. Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 15.6.2 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

15.6. Notices.

15.6.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (a) delivered by hand, (b) by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 15.6.2 or (c) to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 15.6.1. Such notice shall be deemed to have been given as of the date delivered by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 15.6.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

15.6.2. Address for Notice.

If to **Licensor**, to:

argenx BV
Industriepark Zwijnaarde 7
9052 Zwijnaarde (Ghent)
Belgium
Attention: Tim van Hauwenneiren (CEO)

with an electronic copy by email to:
[***]

If to **Licensee**, to:

Zai Auto Immune (Hong Kong) Limited
4F, Bldg 1, Jinchuang Plaza
4560 Jinke Rd
Shanghai, China, 201210
Attention: Samantha Du (CEO)
with an electronic copy to
[***]

With a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94303
USA
Attention: [***]
with an electronic copy to: [***]

If to **Parent**, to:

Zai Lab Limited
4F, Bldg 1, Jinchuang Plaza
4560 Jinke Rd
Shanghai, China, 201210
Attention: Samantha Du (CEO)
With an electronic copy to
[***]

With a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94303
USA
Attention: [***]
with an electronic copy to [***]

15.7. Entire Agreement; Amendments. This Agreement and Schedules attached hereto (including the Share Issuance Agreement) sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including the Confidentiality Agreement between the Parties dated 14 September 2020). No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.8. English Language. This Agreement shall be written and executed in, and all reports and other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.9. No Benefit to Third Parties. Except as provided in ARTICLE 12, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

15.10. Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

15.11. Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12. Relationship of the Parties. It is expressly agreed that Licensor, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency. Neither Licensor, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15.13. Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

15.14. References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

15.15. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. Any reference to "demonstrable" costs and expenses means those costs and expenses can be evidenced in writing. Whenever this Agreement refers to a "jurisdiction", (a) the PRC, (b) Hong Kong, (c) Macau, and (d) Taiwan shall each be deemed a separate jurisdiction and any part of (a), (b), (c) or (d) shall not be deemed a separate jurisdiction. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

15.16. Parent Guarantee. Parent (a) hereby unconditionally guarantees the due and punctual payment and performance of all of Licensee's obligations and commitments under this Agreement, and (b) without limiting the foregoing, hereby covenants to procure and cause Licensee and its Affiliates to take such actions that may be necessary to support and duly complete the performance of Licensee's obligations and commitments under this Agreement. Parent agrees that such obligations of Licensee and this Agreement may be extended, modified or renewed, in whole or in part, in accordance with the terms of this Agreement (without notice or further assent from Parent). This guaranty is an irrevocable guaranty of payment and performance (and not just of collection) by Licensee and shall continue in effect until [***], notwithstanding any extension, modification or renewal of the terms of this Agreement. This guarantee is primary and is in no way conditioned upon any requirement that Licensor first attempt to collect or enforce any guaranteed obligation from or against Licensee. The obligations of Parent hereunder shall be absolute and unconditional, and shall not be affected by or contingent upon (i) the liquidation or dissolution of, or the merger or consolidation of Licensee with or into any corporation, any sale or transfer by Licensee or all or any part of its or their property or assets, or any assignment of this Agreement, (ii) the bankruptcy, receivership, insolvency, reorganization or similar proceedings involving or affecting Licensee, or (iii) any modification, alteration, amendment or addition of or to the Agreement; provided that, if Licensee is no longer an Affiliate of Parent, Parent has approved any such alteration, amendment or addition which would materially impact Parent's obligations hereunder. Parent's obligations under this Section 15.16 shall terminate upon [***]. Parent acknowledges that each of the waivers set forth in this Section 15.16 is made with full knowledge of its significance and consequences and under the circumstances the waivers are reasonable and not contrary to public policy. If any of said waivers is determined to be contrary to any applicable law or public policy, such waivers shall be effective only to the extent permitted by law.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date, 6 January 2020.

ZAI AUTO IMMUNE (HONG KONG) LIMITED

By: /s/ SAMANTHA DU
Name: Samantha Du
Title: Chief Executive Officer

ARGENX BV

By: /s/ TIM VAN HAUWERMEIREN
Name: Tim Van Hauwermeiren
Title: Chief Executive Officer

ARGENX BV

By: /s/ DIRK BEEUSAERT
Name: Dirk Beeusaert
Title: General Counsel

Soley with respect to Section 15.16:

ZAI LAB LIMITED

By: /s/ SAMANTHA DU
Name: Samantha Du
Title: Chief Executive Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.2
Execution Version

LICENSE AGREEMENT

This **License Agreement** (this "**Agreement**") is made as of January 10, 2021 (the "**Effective Date**"), by and between **Turning Point Therapeutics**, **Inc**., a corporation organized and existing under the laws of Delaware ("**TPTX**"), located at 10628 Science Center Drive, Suite 200, San Diego, California 92121, United States of America, and **Zai Lab** (**Shanghai**) **Co., Ltd.**, an exempted company organized and existing under the laws of P.R. of China, located at 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210 ("**Zai**"). TPTX and Zai are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, TPTX is a biopharmaceutical company designing and developing novel small molecule, targeted oncology therapies, and TPTX owns or controls rights to the Licensed Compounds and Products (as defined herein);

WHEREAS, Zai is a pharmaceutical company having experience in the development and commercialization of pharmaceutical products in the Territory (as defined herein);

WHEREAS, TPTX and Zai are parties to the License Agreement, dated July 6, 2020, regarding TPTX's development candidate repotrectinib, pursuant to which, among other terms, TPTX granted Zai a right of first negotiation for a license to certain additional development candidates of TPTX in the Territory, and this Agreement has been negotiated following Zai's exercise of such right of first negotiation with respect to TPX-0022;

WHEREAS, Zai wishes to develop and commercialize the Products in the Territory; and

WHEREAS, TPTX wishes to grant to Zai, and Zai wishes to be granted, an exclusive license to Develop and Commercialize (each as defined herein) Products in the Field in the Territory (each as defined herein) in accordance with the terms and conditions set forth below.

AGREEMENT

NOW, **THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

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

1.1. "**Acquired Party**" shall have the meaning set forth in Section 2.6(b)(ii).

1.2. "**Acquirer**" shall have the meaning set forth in Section 2.6(b)(i).

1.3. "**Additional Indication**" means [***].

1.4. "**Adverse Event**" means any unwanted or harmful medical occurrence in a patient or subject who is administered a Product, whether or not considered related to such Product, including any undesirable sign (including abnormal laboratory findings of clinical concern).

1.5. "**Affiliate**" means, with respect to a specified Person, any entity that directly or indirectly controls, is controlled by or is under common control with such Person. As used in this Section 1.5, "control" (and, with correlative meanings, the terms "controlled by" and "under common control with") means, in the case of a corporation, the ownership of more than fifty percent (50%) of the outstanding voting securities thereof or, in the case of any other type of entity, an interest that results in the ability to direct or cause the direction of the management and policies of such entity or the power to appoint more than fifty percent (50%) of the members of the governing body of the entity or, where ownership of more than fifty percent (50%) of such securities or interest is prohibited by law, ownership of the maximum amount legally permitted.

1.6. "**Agreement**" shall have the meaning set forth in the preamble to this agreement.

1.7. "**Alliance Manager**" shall have the meaning set forth in Section 3.1.

1.8. "**Anti-Corruption Laws**" shall have the meaning set forth in Section 11.5(a)(i).

1.9. "**Applicable Laws**" means all statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority that may be in effect from time to time and applicable to the relevant activities contemplated by this Agreement.

1.10. "**Authorized Regulatory Agent**" means a local entity (a) authorized by TPTX or any of its Affiliates, where TPTX, its Affiliate or its third party contractor research organization is the license holder of imported drug product, to exclusively (even as to TPTX and its Affiliates but in accordance with terms and conditions hereunder) manage the work associated with obtaining any Regulatory Approval or product registration in the Territory; and (b) which possesses and maintains valid licenses or permits in the Territory if such licenses or permits are required for such local entity to engage in the relevant activities in the Territory.

1.11. "**Business Day**" means a day other than Saturday, Sunday or any day on which banks located in the state of California or Shanghai, the PRC are authorized or obligated to close. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

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

1.13. "**Calendar Year**" means each twelve (12) month period commencing on January 1st.

1.14. "**cGMP**" means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the ICH Q7 guidelines, and (d) the equivalent Applicable Laws in any relevant country or region, each as may be amended and applicable from time to time.

1.15. "**Claims**" shall have the meaning set forth in Section 12.1.

1.16. "**Clinical Development Plan**" shall have the meaning set forth in Section 5.2.

1.17. "**Clinical Trial**" means any clinical testing of a Product in human subjects.

1.18. "**CMOs**" means Third Party contractor manufacture organizations.

1.19. "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which results in shareholders or equity holders of such Party immediately prior to such transaction, no longer owning at least fifty (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole, through one or more related transactions.

1.20. "**Combination Product**" means a Product that combines a Licensed Compound with one (1) or more other clinically or pharmacologically active ingredients (which term excludes, for clarity excipients, controlled-release compositions, materials to increase bioavailability, solubility or stability, or delivery means) in a single formulation or final package presentation for sale as a single unit (including separate unit doses so configured). The Licensed Compound portion of any Combination Product shall be deemed the "**Licensed Component**" and the other clinically or pharmacologically active ingredients of such Combination Product the "**Other Component**".

1.21. "**Combination Therapy**" means the use or method of using a product comprising one (1) or more clinically or pharmacologically active ingredients and a different product comprising one (1) or more other clinically or pharmacologically active ingredients, in concomitant or sequential administration.

1.22. "**Commercialization**" or "**Commercialize**" means all activities directed to marketing, distribution, promoting or selling of pharmaceutical products (including importing and exporting activities in connection therewith), but excluding activities directed to Manufacturing.

1.23. "**Commercialization Plan**" means the written plan for the Commercialization of the Product in the Territory, as updated in accordance with this Agreement.

1.24. "**Commercially Reasonable Efforts**" means with respect to a Party, the use of diligent, good faith efforts and resources, in an active and ongoing program, as normally used by such Party for a product discovered or identified internally or in-licensed from a Third Party that is important to such Party's overall strategy or objectives, which product is at a similar stage in its development or product life and is of similar market potential and intellectual property protection but in the event such Party is Zai, not considering the obligations (including financial) to TPTX or the rights of TPTX hereunder; provided, however, that in no event shall such efforts and resources be less than those a similarly situated biopharmaceutical company would apply to the development, manufacture, or commercialization of a similarly situated product. Commercially Reasonable Efforts requires that a Party, at a minimum, [***].

1.25. "**Competing Activities**" shall have the meaning set forth in Section 2.6(b)(i).

1.26. "**Competing Product**" means any product that [***].

1.27. "**Confidential Information**" means all confidential information of the Disclosing Party or its Affiliates, regardless of its form or medium as provided to the Receiving Party or its Affiliates in connection with this Agreement; provided that, Confidential Information shall not include any information that the Receiving Party can show by competent written evidence: (a) was already known to the Receiving Party at the time it was disclosed to the Receiving Party by the Disclosing Party without an obligation of confidentiality and not through a prior disclosure by the Disclosing Party, (b) was or becomes generally known to the public through no act or omission of the Receiving Party in violation of the terms of this Agreement, (c) was lawfully received by the Receiving Party from a Third Party without restriction on its disclosure and without, to the reasonable knowledge of the Receiving Party, a breach by such Third Party of an obligation of confidentiality to the Disclosing Party, or (d) was independently developed by the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party. All Improvements shall be the Confidential Information of TPTX, and TPTX shall be the Disclosing Party and Zai shall be the Receiving Party with respect thereto. The terms of this Agreement that are not publicly disclosed through a press release or by filings to financial regulatory authorities and all Joint Inventions and Joint Patents shall be the Confidential Information of both Parties.

1.28. "**Control**" or "**Controlled**" means, with respect to any Know-How, Patents or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license or otherwise, after taking into account the provisions of this Agreement regarding ownership of Improvements, but without taking into account any license granted by one Party to the other Party pursuant to this Agreement) to grant a license, sublicense, access or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.29. "**Deficient Site**" shall have the meaning set forth in Section 5.7.

1.30. "**Develop**" or "**Development**" or "**Developing**" means preclinical and clinical drug or biological development activities, including test method development, toxicology, formulation, quality assurance/quality control development, statistical analysis, preclinical and clinical studies and regulatory affairs, and regulatory activities, including filing for, obtaining and maintaining approval and registration, but excluding activities directed to Manufacturing.

1.31. "**Development Milestone Event**" shall have the meaning set forth in Section 9.2(a).

1.32. "**Development Milestone Payment**" shall have the meaning set forth in Section 9.2(a).

1.33. "**Disclosing Party**" shall have the meaning set forth in Section 10.1(a).

1.34. "**Dispute**" shall have the meaning set forth in Section 15.1.

1.35. "**Effective Date**" shall have the meaning set forth in the preamble in this Agreement.

1.36. "**Executive Officers**" shall have the meaning set forth in Section 3.2(f).

1.37. [***]

1.38. "**Existing Global Studies**" shall have the meaning set forth in Section 5.4(a).

1.39. "**Expiration Date**" shall have the meaning set forth in Section 14.1(a).

1.40. "**Field**" means all human therapeutic indications.

1.41. "**First Commercial Sale**" means, with respect to any Product, the first arm's length sale of such Product to a Third Party in a region of the Territory by Zai, its Affiliate(s) or Sublicensee(s) for use or consumption in such region following Regulatory Approval. Sales prior to receipt of marketing and pricing approvals, such as so-called "treatment IND sales," "named patient sales" and "compassionate use sales" and any sales to any government, foreign or domestic, including purchases for immediate sale or stockpiling purposes, are not a First Commercial Sale in that region.

1.42. "**FTE**" means the equivalent of the work of a full-time individual for a twelve (12) month period.

1.43. "**FTE Rate**" means a rate of US$[***] per FTE per year, to be pro-rated on an hourly basis of US$[***] per FTE per hour, based on [***] hours per year for an FTE and is subject to adjustments [***]. For clarity, the FTE rate of $[***] per FTE per year described above will be [***].

1.44. "**Fully Burdened Manufacturing Costs**" means the cost of Manufacturing the Product. Fully Burdened Manufacturing Costs shall be a "standard cost" per unit (calculated annually), comprised of the following elements calculated in accordance with GAAP: [***]; provided, however, that [***] and [***]. To the extent that Products are sourced from one or more CMOs by TPTX, Fully Burdened Manufacturing Costs shall be the actual invoiced price paid by a Party to such CMO(s) for the manufacture and supply of a Product [***].

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

1.46. "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.47. "**Generic Product**" means, with respect to a Product in a region in the Territory, after Regulatory Approval of such Product in such region, any other therapeutic drug product designated for human use which (a) contains the same active ingredient as such Product, (b) is approved for use pursuant to a Regulatory Approval process in such country that is based on the indications and conditions of use on a product meeting the standards set forth in the foregoing (a), whether or not such Regulatory Approval was based upon data generated by the Party independently or was obtained using an abbreviated, expedited or other process, and (c) is authorized for sale or sold in the region (or is commercially available in the same region via import from another region) as the Product by or on behalf of a Third Party that has not obtained rights to, and did not purchase, such product or its active pharmaceutical ingredients from Zai or any of its Affiliates or Sublicensees.

1.48. "**Generic Competition**" means, with respect to a particular Product in a region in the Territory, after a Generic Product is first launched in such region, [***].

1.49. "**Global Development Plan**" shall have the meaning set forth in Section 5.4(a).

1.50. "**Global Study**" means a clinical study designed to obtain Regulatory Approvals for the Products in multiple jurisdictions through the conduct of a Clinical Trial in multiple medical institutions, countries, regions, territories and conducted as part of one (1) unified Clinical Trial or separately but concurrently in accordance with a common Clinical Trial protocol.

1.51. "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.52. "**Governmental Authority**" means any court, commission, authority, department, ministry, official or other instrumentality of, or being vested with public authority under any law of, any country, region, state or local authority or any political subdivision thereof, or any association of countries.

1.53. "**GSP**" means all applicable Good Supply Practice standards, including, as applicable, as set forth in the then current good supply practice standards promulgated or endorsed by the FDA as defined in Good Supply Practice for Pharmaceutical Products or the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time.

1.54. "**ICC Rules**" shall have the meaning set forth in Section 15.4(a).

1.55. "**Improvement**" means any improvement, modification, or enhancement to any Licensed Technology invented, discovered, generated or made (a) solely by either Party, its Affiliates or its or its Affiliates' employees, agents or independent contractors or (b) jointly by both Parties, their Affiliates or their and their Affiliates' employees, agents or independent contractors, in each case, during the Term in the performance of any activity contemplated under this Agreement (including Global Studies and Local Studies) or otherwise in the exercise of its (their) rights or the carrying out of its (their) obligations under this Agreement, including all rights, title and interest in and to the intellectual property rights therein.

1.56. "**IND**" means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence Clinical Trials in the applicable jurisdiction.

1.57. "**Indemnifying Party**" shall have the meaning set forth in Section 12.3.

1.58. "**Indemnitee**" shall have the meaning set forth in Section 12.3.

1.59. "**Indication**" means a separate and distinct disease or condition, or sign or symptom of a disease or medical condition. For clarity [***].

1.60. "**Invention**" means any process, method, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented, discovered or generated as a result of a Party (or the Parties jointly) exercising its (their) rights or carrying out its (their) obligations under this Agreement, including all rights, title and interest in and to the intellectual property rights therein.

1.61. "**JDC**" shall have the meaning set forth in Section 3.3(a).

1.62. "**Joint Global Study**" shall have the meaning set forth in Section 5.4(b).

1.63. "**Joint Invention**" shall have the meaning set forth in Section 13.1(b).

1.64. "**Joint Patent**" shall have the meaning set forth in Section 13.1(b).

1.65. "**JSC**" shall have the meaning set forth in Section 3.2(a).

1.66. "**Know-How**" means any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, safety information, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data.

1.67. "**Licensed Component**" shall have the meaning set forth in Section 1.20.

1.68. "**Licensed Compound**" means TPX-0022, a small, macrocyclic TKI of MET, CSF1R and SRC, including any salt, metabolite, prodrugs, free-base, hydrate, solvate, polymorph, racemate, isotope, stereoisomer enantiomer thereof.

1.69. "**Licensed Know-How**" means any and all Know-How Controlled by TPTX or its Affiliates as of the Effective Date or during the Term, including TPTX's joint ownership interest in any Know-How within the Joint Inventions, that is necessary or reasonable useful for the Development, packaging or labelling, or Commercialization of the Product in the Field in the Territory, except to the extent excluded pursuant to Section 5.4(d). Notwithstanding the foregoing, in the event a Change of Control of TPTX occurs after the Effective Date, Know-How Controlled by any Affiliate of TPTX that was not an Affiliate of TPTX immediately prior to such Change of Control transaction shall not be Licensed Know-How except to the extent such Know-How falls within the definition of Licensed Know-How in the immediately preceding sentence and (a) is also Controlled by TPTX or its Affiliate existing immediately prior to such transaction or (b) is generated or used by such Affiliate in the Development, packaging or labelling or Commercialization of the Licensed Compound or Product after such transaction.

1.70. "**Licensed Patents**" means the Patents in the Territory Controlled by TPTX or its Affiliates as of the Effective Date or during the Term, including TPTX's joint ownership interest in any Joint Patents in the Territory, that (a) claim the Licensed Compound or the Product (including the composition of matter, formulation, or method of packaging or labelling or use thereof); and (b) are necessary or reasonably useful for the Development, packaging or labelling, or Commercialization of the Product in the Field in the Territory, except to the extent excluded pursuant to Section 5.4(d). Schedule 1.70 contains a list of all Licensed Patents as of the Effective Date. Notwithstanding the foregoing, in the event a Change of Control of TPTX occurs after the Effective Date, Patents Controlled by any Affiliate of TPTX that was not an Affiliate of TPTX immediately prior to such Change of Control transaction shall not be Licensed Patents except to the extent any such Patent falls within the definition of Licensed Patents in the immediately preceding sentence and (i) is also Controlled by TPTX or its Affiliate existing immediately prior to such transaction or (ii) claims any Invention generated or used by such Affiliate in the Development, packaging or labelling or Commercialization of the Product after such transaction.

1.71. "**Licensed Technology**" means the Licensed Know-How and Licensed Patents.

1.72. "**Local Study**" means any Clinical Trial for any Product in the Field and which (a) Zai determines to conduct and is conducted by or on behalf of Zai in the Territory, and (b) does not include clinical sites in any country or jurisdiction outside the Territory.

1.73. "**Losses**" shall have the meaning set forth in Section 12.1.

1.74. "**Manufacture**" or "**Manufacturing**" or "**Manufactured**" means all operations involved in the manufacturing, filling and finishing, quality control testing (including in-process, release and stability testing, if applicable), storage, releasing, packaging and labeling.

1.75. "**Manufacturing Technology**" shall have the meaning set forth in Section 7.3.

1.76. "**Manufacturing Technology Transfer**" shall have the meaning set forth in Section 7.3.

1.77. "**Milestone Events**" means Development Milestone Events and Net Sales Milestone Events.

1.78. "**Milestone Payments**" means Development Milestone Payments and Net Sales Milestone Payments.

1.79. "**Monotherapy**" means the use or method of using a product comprising one (1) clinically or pharmacologically active ingredient as its sole active ingredient, and not in concomitant or sequential administration with any other product.

1.80. "**Net Sales**" means the gross price billed or invoiced on sales of the Product by Zai, its Affiliates, or Sublicensees to a Third Party that is not a Sublicensee in the Territory, less (without duplication) usual and customary:

(a) cash, trade or quantity discounts actually granted and deducted solely on account of sales of the Product, but excluding early payment discounts;

(b) rebates actually paid to individual or group purchasers of the Product that are solely on account of the purchase of such Product;

(c) credits issued for the Product recalled or not accepted by customers or other refunds, allowances and chargebacks actually granted and related to the Product;

(d) (i) freight expense (actual), including insurance, to the extent it is not charged to or reimbursed by the customer, (ii) early payment discounts, (iii) bad debt written off under GAAP, with reasonable collection efforts and added back if collected; and

(e) Taxes (including, but not limited to sales, value added, consumption and similar taxes; but excluding income taxes) actually incurred, paid or collected and remitted to the relevant tax authority for the sale of the Product; provided that any amount of such taxes refunded, recovered or credited back by the relevant tax authority shall be included in Net Sales.

Each of the amounts set forth above shall be determined from the books and records of Zai, its Affiliate or Sublicensee, maintained in accordance with GAAP or in the case of Sublicensees, such similar accounting principles, consistently applied, and any amounts that are deducted from Net Sales pursuant to one subsection may not be deducted pursuant to another subsection (i.e., a deduction may only be taken once).

The transfer of a Product to an Affiliate, Sublicensee, or other Third Party (i) in connection with the Development or testing of a Product (including the conduct of clinical studies), (ii) for purposes of distribution as promotional samples, (iii) for indigent or similar public support or compassionate use programs, or (iv) by and between Zai and its Affiliates or Sublicensees shall not, in any case, be considered a Net Sale of a Product under this Agreement. Subject to the foregoing, any sales income received by Zai, its Affiliates or Sublicensees for Products prior to or after Regulatory Approval shall be Net Sales and subject to the Royalty Payments under Section 9.4(a).

Net Sales shall also include and be deemed to have been made with respect to any Products used by Zai or any Affiliate, for its own commercial purposes, or transferred to any Third Party for less than what the transferee is then charging in normal arms-length sales transactions; and Net Sales in all such cases shall be deemed to have been made at the prices therefor at which such Products are then being sold to the customers of such user or transferor (or of Zai, if an Affiliate is a user but not a seller) in arms-length sales transactions. For clarity, in the event the Product is sold in an arms-length transaction to a governmental agency, a group purchase entity or any other entity having the bargaining power to negotiate the purchase price below normal retail price in transactions of lesser volume, Net Sales shall be calculated based on the actual price negotiated and agreed to for such agency or entity and not be based on the price charged in other arms-length sales transactions.

To the extent that Zai or any of its Affiliates, or Sublicensees, provides to the purchasing Third Party discounts or allowances that are applicable to purchases of the Product and one or more other products (such as in a "bundled sale" arrangement), such discounts and allowances shall be allocated between the Product (for purposes of the deductions used in calculating Net Sales as above) and such other products in an equitable and commercially reasonable manner that does not unfairly or inappropriately bias the level of discounting against the Product (as compared to the other products).

If Zai or any of its Affiliates, or Sublicensees, sells a Product as a Licensed Component of a Combination Product in the Territory in any Calendar Quarter, then Net Sales shall be calculated by multiplying the Net Sales of the Combination Product during such Calendar Quarter by the fraction A/(A+B), where A is the average Net Sales per unit sold of the Licensed Component when sold separately in the Territory during such Calendar Year (calculated by determining the Net Sales of the Licensed Component during such Calendar Quarter in accordance with the definition of Net Sales set forth herein and dividing such Net Sales by the number of units of the Licensed Component during such Calendar Quarter) and B is the average Net Sales per unit sold of the Other Component(s) included in the Combination Product when sold separately during such Calendar Quarter (calculated by determining the Net Sales of such Other Component(s) sold during such Calendar Quarter by applying the definition of Net Sales set forth herein as if it applied to sales of such Other Component(s) and dividing such Net Sales by the number of units of such Other Component(s) sold during such Calendar Quarter). In each case, A and B shall be adjusted on a pro rata basis to account for dosing differences between the amounts of Licensed Component and Other Component(s) included in the Combination Product relative to the amounts of Licensed Component and Other Component(s) included in the separately sold product.

For purposes of calculating the average Net Sales per unit sold of a Licensed Component and Other Component(s) of a Combination Product, any of the deductions described herein that apply to such Combination Product shall be allocated among sales of the Licensed Component and sales of the Other Component(s) included in such Combination Product as follows: (1) deductions that are attributable solely to the Licensed Component or one of the Other Component(s) shall be allocated solely to Net Sales of the Licensed Component or such Other Component, as applicable, and (2) all other deductions shall be allocated among sales of the Licensed Component and sales of the Other Component(s) in proportion to Zai's and TPTX's mutual agreement of the fair market value of the Licensed Component and the Other Component(s).

In the event that no separate sales of the Licensed Component or any Other Component(s) included in a Combination Product are made by Zai or its Affiliates, or Sublicensees, during a Calendar Quarter in which such Combination Product is sold, the average Net Sales per unit sold in the above described equation shall be replaced with Zai's and TPTX's mutual written agreement of the fair market value of the Licensed Component and each of the Other Component(s) included in such Combination Product.

1.81. "**Net Sales Milestone Event**" shall have the meaning set forth in Section 9.3(a).

1.82. "**Net Sales Milestone Payment**" shall have the meaning set forth in Section 9.3(a).

1.83. "**NMPA**" means the National Medical Products Administration, formerly known as the China Food and Drug Administration, and local or provincial counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

1.84. [***]

1.85. "**NSCLC**" shall have the meaning set forth in Section 9.2(a).

1.86. "**Other Component**" shall have the meaning set forth in Section 1.20.

1.87. "**Party**" or "**Parties**" shall have the meaning set forth in the preamble to this Agreement.

1.88. "**Patent Prosecution**" means the responsibility and authority for (a) preparing, filing and prosecuting applications (of all types) for any Patent (including any decision whether to file a further divisional application), (b) managing any interference, opposition, re-issue, reexamination, invalidation proceedings, revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding to abandon Patent(s), (d) listing in regulatory publications (as applicable), (e) patent term extension, and (f) settling any interference, opposition, revocation, nullification or cancellation proceeding.

1.89. "**Patents**" means (a) all national, regional and international patents and patent applications, including any provisional patent application, (b) any patent application claiming priority from such patent application or provisional patent applications, including divisions, continuations, continuations-in-part, additions, (c) any patent that has issued or in the future issues from any of the foregoing patent applications, including any utility or design patent or certificate of invention, and (d) re-issues, renewals, extensions, substitutions, re-examinations or restorations, registrations and revalidations, and supplementary protection certificates and equivalents to any of the foregoing.

1.90. "**Person**" means any individual, sole proprietorship, corporation, joint venture, limited liability company, partnership, limited partnership, limited liability partnership, trust or any other private, public or governmental entity.

1.91. "**Pharmacovigilance Agreement**" shall have the meaning set forth in Section 6.9(a).

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

1.93. "**Primary Indication**" means any of the following Indications: [***].

1.94. "**Prime Rate**" means for any day a per annum rate of interest equal to the "prime rate," as published in the "Money Rates" column of The Wall Street Journal, from time to time, or if for any reason such rate is no longer available, a rate equivalent to the base rate on corporate loans posted by at least percent (70%) of the ten largest U.S. banks.

1.95. "**Product**" means any pharmaceutical preparation containing the Licensed Compound as an active ingredient, in any formulation or dosage form.

1.96. "**Product Infringement**" shall have the meaning set forth in Section 13.4(a).

1.97. "**Product Marks**" shall have the meaning set forth in Section 8.4.

1.98. "**Product Specifications**" means the specifications of the Product to be agreed by the Parties in the Supply Agreement.

1.99. "**Public Official**" shall have the meaning set forth in Section 11.5(d).

1.100. "**Quality Agreement**" shall have the meaning set forth in Section 7.2.

1.101. "**Receiving Party**" shall have the meaning set forth in Section 10.1(a).

1.102. "**Regulatory Approval**" means, with respect to a Product in a region or a country, the approvals from the necessary Governmental Authority to import, market and sell such Product in such region (but excluding pricing approvals and reimbursement approvals).

1.103. "**Regulatory Approval Application**" means a New Drug Approval Application or Biologics License Application (each, as defined in the U.S. Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.), as amended from time to time) in the U.S., or any corresponding application for approval to market or sell a product in any country, region or jurisdiction in the Territory.

1.104. "**Regulatory Authority**" means any applicable Governmental Authority responsible for granting Regulatory Approvals for Products, including the NMPA, and any corresponding national or regional regulatory authorities.

1.105. "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to a Product.

1.106. "**Remedial Action**" shall have the meaning set forth in Section 6.11.

1.107. "**Replacement Site**" shall have the meaning set forth in Section 5.7.

1.108. "**Retained Rights**" shall have the meaning set forth in Section 2.2.

1.109. "**Royalty Payment**" shall have the meaning set forth in Section 9.4(a).

1.110. "**Royalty Term**" shall have the meaning set forth in Section 9.4(b).

1.111. "**Sole Invention**" shall have the meaning set forth in Section 13.1(b).

1.112. "**Sublicensee**" means a Third Party or Zai's Affiliate who was granted a sublicense by Zai under the licenses granted in Section 2.1. For clarity, a Third Party who was granted a sublicensee by a Sublicensee shall also be deemed a Sublicensee.

1.113. "**Supply Agreement**" shall have the meaning set forth in Section 7.2.

1.114. "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon). For the avoidance of doubt, Taxes includes VAT.

1.115. "**Term**" shall have the meaning set forth in Section 14.1(a).

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

1.117. "**Third Party**" means an entity other than (a) Zai and its Affiliates or (b) TPTX and its Affiliates.

1.118. [***]

1.119. [***]

1.120. "**TPTX**" shall have the meaning set forth in the preamble of this Agreement.

1.121. "**TPTX Acquirer**" shall have the meaning set forth in Section 8.7.

1.122. "**TPTX Acquirer ROFN**" shall have the meaning set forth in Section 8.7.

1.123. "**TPTX Acquirer ROFN Exercise Notice**" shall have the meaning set forth in Section 8.7.

1.124. "**TPTX Acquirer ROFN Negotiation Period**" shall have the meaning set forth in Section 8.7.

1.125. "**TPTX Indemnitee**(**s**)" shall have the meaning set forth in Section 12.1.

1.126. "**TPTX Product Marks**" shall have the meaning set forth in Section 8.4.

1.127. "**TPTX ROFN**" shall have the meaning set forth in Section 2.7.

**1.128. [*****]

1.129. "**TPTX ROFN Exercise Notice**" shall have the meaning set forth in Section 2.7.

1.130. "**TPTX ROFN Exercise Period**" shall have the meaning set forth in Section 2.7.

1.131. "**TPTX ROFN Expiration**" shall have the meaning set forth in Section 2.7.

1.132. "**TPTX ROFN Negotiation Period**" shall have the meaning set forth in Section 2.7.

1.133. "**TPTX ROFN Offer Notice**" shall have the meaning set forth in Section 2.7.

1.134. [***]

1.135. "**Transition Period**" shall have the meaning set forth in Section 14.9(b)(iv).

1.136. "**U**.**S**. **Dollars**" or "**$**" means United States dollars, the lawful currency of the United States.

1.137. "**Upfront Payment**" shall have the meaning set forth in Section 9.1.

1.138. "**Valid Claim**" means (a) a claim of an issued and unexpired Patent included within the Licensed Patents (including any Patent covering an Improvement and any Joint Patents in the Territory) that (i) covers the Licensed Compound or the Product (including the composition of matter, formulation, or method of packaging or labelling or use thereof) in the Territory that (ii) has not been permanently revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, which decision is not appealable or is not appealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) a claim of a pending patent application included within the Licensed Patents (including any Patent covering an Improvement and any Joint Patent) in the Territory that (1) would cover the Licensed Compound or Product (including the composition of matter, formulation, or method of packaging or labelling or use thereof) in the Territory if such claim was to issue, (2) has not been pending for more than [***] years from its earliest priority date, and (3) (A) has not been cancelled, withdrawn or abandoned or (B) finally rejected by an administrative agency action from which no appeal can be taken or that has not been appealed within the time allowed for appeal.

1.139. "**VAT**" means value-added taxes or other similar taxes.

1.140. "**Withholding Income Taxes**" shall have the meaning set forth in Section 9.8(b).

1.141. "**Withholding Taxes**" shall have the meaning set forth in Section 9.8(b).

1.142. "**Withholding VAT Taxes**" shall have the meaning set forth in Section 9.8(a).

1.143. "**Zai**" shall have the meaning set forth in the preamble of this Agreement.

1.144. "**Zai Indemnitee**(**s**)" shall have the meaning set forth in Section 12.2.

1.145. "**Zai IP**" means any and all Know-How and Patents Controlled by Zai or its Affiliates (a) as of the Effective Date or (b) at any time during the Term that are, in each case, (i) not Improvements and (ii) necessary or reasonably useful for the Development, Manufacture, use or Commercialization of the Licensed Compound or any Product.

1.146. "**Zai Patents**" shall have the meaning set forth in Section 13.3(b).

1.147. "**Zai Pipeline Product**" shall have the meaning set forth in Section 2.7.

ARTICLE 2

LICENSES; NON-COMPETE; TPTX ROFN

2.1. License Grant to Zai. Subject to the terms and conditions of this Agreement, TPTX hereby grants to Zai, during the Term, (a) an exclusive, royalty-bearing license, with the right to grant sublicenses (solely in accordance with Section 2.3), under the Licensed Technology to Develop, register, use, sell, offer for sale, import and otherwise Commercialize the Products in the Field in the Territory; and (b) a non-exclusive, royalty-bearing license, with the right to grant sublicenses (solely in accordance with Section 2.3), under the Licensed Technology to package or have packaged, and label or have labeled the Products in the Field in and outside the Territory, solely to support the Development, use, sale, offer for sale, import or other Commercialization of the Products in the Field in the Territory. For clarity, (i) the licenses granted by TPTX to Zai under this Section 2.1 shall not include any right or license to any product containing any of TPTX's proprietary compounds other than the Licensed Compound, and (ii) the licenses granted under this Section 2.1 do not include any right to Manufacture or to have Manufactured the Licensed Compound or Products, except for Zai's non-exclusive right to package and label the Licensed Compound and Product in accordance with Section 2.1(b).

2.2. TPTX Retained Rights. Notwithstanding anything to the contrary in this Agreement, TPTX hereby expressly retains, on behalf of itself (and its Affiliates, other licensees, and sublicensees) (a) all rights under the Licensed Technology to fulfill, either itself, its Affiliates or through subcontractors, TPTX's obligations under this Agreement; (b) the exclusive rights to Develop, Manufacture or have Manufactured (subject to Zai's non-exclusive right to package and label the Licensed Compound and Product outside the Territory in accordance with Section 2.1(b)), use, sell, offer for sale, import and otherwise Commercialize the Licensed Compound and Products outside the Territory; and (c) (i) subject to and in accordance with Section 5.4, [***] (including through the conduct of Global Studies by TPTX pursuant to Section 5.4) (the "**Retained Rights**"); provided that upon Zai's reasonable request, TPTX shall perform any research activity that is necessary or reasonably useful for the Development of or obtaining the Regulatory Approval for the Product in the Territory in accordance with the Clinical Development Plan or as otherwise proposed by Zai and thereafter approved by the JDC at Zai's cost. In the event that TPTX wishes to exercise its Retained Rights [***]. For the avoidance of doubt, the Retained Rights shall exclude the right under the Licensed Technology to Commercialize the Licensed Compound or Products in the Field in the Territory during the Term, and TPTX, its Affiliates and licensees of rights to the Licensed Compound or Products (other than Zai and its Affiliates and Sublicensees) shall not undertake such Commercialization of the Licensed Compound or Products in the Field in the Territory without Zai's express prior written consent.

2.3. Right to Sublicense.

(a) **General**. Zai shall have the right to grant sublicenses under the licenses granted in Section 2.1 to: (i) its Affiliates without TPTX's consent or approval; and (ii) any Third Party only with TPTX's prior written consent (not to be unreasonably withheld, delayed or conditioned). Zai shall remain primarily responsible for all of its obligations under this Agreement that have been delegated or sublicensed to any Sublicensee and shall be liable for (1) its Sublicensee's conduct that is prohibited under this Agreement, and (2) its Sublicensee's breach of this Agreement which shall be deemed a breach of this Agreement as if Zai had itself conducted the action or inaction that contributed to the breach of this Agreement; provided that Zai shall have the right to cure, if curable, such breach on behalf of such Sublicensee within [***] days following the receipt of notice of such breach.

(b) **Restrictions**. Zai shall not grant a sublicense to any Third Party that has been debarred or disqualified by any Governmental Authority or is subject to any proceedings, sanctions or fines under any Anti-Corruption Law. Zai shall ensure, prior to engaging any Third Party as a Sublicensee that such Third Party is subject to written agreements containing terms and conditions that: (i) require each such Sublicensee to protect and keep confidential any Confidential Information of the Parties, including in accordance with ARTICLE 10; (ii) provide TPTX with the right to audit (either by itself or through Zai or Zai's designee) the books and records of each such Sublicensee in accordance with this Agreement (including pursuant to Sections 6.10, 9.6(b), 9.6(d), and 11.5(a)(iv)); (iii) do not impose any payment obligations or liability on TPTX; and (iv) are otherwise consistent with the terms of this Agreement. Zai shall provide a copy of the complete executed agreement with each Sublicensee to TPTX; provided that Zai shall be permitted to redact commercially sensitive economic terms of any such agreement which terms are not necessary for TPTX to confirm Zai's compliance with its obligations hereunder.

2.4. License Grant to TPTX. Subject to the terms and conditions of this Agreement, Zai hereby grants to TPTX a perpetual, fully paid-up and royalty free, and sublicenseable (in multiple tiers) license under Zai IP to exercise its Retained Rights, which shall be exclusive with respect to the Retained Rights in Section 2.2(b) and (c)(ii) and non-exclusive with respect to all other Retained Rights.

2.5. No Implied Licenses; Negative Covenant. Except as set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Know-How, trademarks, Patents of the other Party. Each Party shall not, and shall not permit any of its Affiliates or sublicensees to, practice any Patent or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6. Exclusivity.

(a) **Non-Compete**.

(i) During the Term, except as provided in Section 2.6(b) below or otherwise expressly contemplated under this Agreement, Zai shall not, and shall cause its Affiliates, licensees, Sublicensees to not, engage in (independently or for or with any Third Party) any Development, Manufacture or Commercialization in or outside the Territory of any Competing Product other than the Licensed Compound and Products as permitted under this Agreement.

(ii) During the Term, except as provided in Section 2.6(b) below or otherwise expressly contemplated under this Agreement, TPTX shall not, and shall cause its Affiliates, and its licensees and sublicensees with respect to the Licensed Compound or Products to not, engage in (independently or for or with any Third Party) any Development, Manufacture or Commercialization in the Territory of any Competing Product other than the Licensed Compound and Products as permitted under the Retained Rights, except that TPTX may, and may allow its Affiliates and such licensees and sublicensees, to Manufacture or have Manufactured any Competing Product in the Territory solely to support the Development, Manufacture, use sale, offer for sale, import and other Commercialization of any Competing Product outside of the Territory.

(b) **Change of Control; Acquisition**.

(i) **Change of Control of a Party**. In the event that a Party or any of its Affiliates undergoes a Change of Control with a Third Party (an "**Acquirer**"), the restrictions set forth in Section 2.6(a) shall not apply to (1) any activities that would otherwise constitute a breach of Section 2.6(a), including a Competing Product that is being Developed, Manufactured, registered or Commercialized (collectively, "**Competing Activities**"), being performed by the Acquirer or its Affiliates at the closing of the applicable transaction, or (2) any Competing Activities undertaken after the closing of the Change of Control transaction by an Acquirer or its Affiliates (other than such Party or any of its Affiliates existing prior to the closing of such transaction), in each case of (1) and (2) as long as [***].

(ii) **Acquisition of a Third Party by a Party**. In the event that either Party or any of its Affiliates that is subject to the restrictions set forth in Section 2.6(a) merges or consolidates with, or otherwise acquires a Third Party (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction) (an "**Acquired Party**") that is performing any Competing Activities at the closing of such transaction, the other Party shall have the right to terminate this Agreement with immediate effect upon written notice to such Party at any time after [***] months following such closing unless by the end of such [***] month period, such Party or such Party's Acquired Party has (1) divested, or caused their respective Affiliate to have divested, whether by license or otherwise, its interest in the corresponding Competing Products or (2) terminated the corresponding performance of any Competing Activities with respect to the corresponding Competing Products, and provide the other Party with written confirmation of such divestment or termination. In the event such Party, after receiving such written notice from the other Party, in good faith disputes the existence of such Competing Activities, then such termination shall not become effective unless and until such dispute is resolved with a determination that such Competing Activities exist.

2.7. TPTX's Right of First Negotiation. During the [***] day period following the Effective Date, Zai will provide [***]. TPTX will [***], with such notice to be given [***,] the "**Zai Pipeline Product**"). For the avoidance of doubt, nothing contained herein shall obligate or require Zai to [***], and TPTX acknowledges and agrees that [***] and in such event, the Zai Pipeline Product will be [***]. Subject to the terms and conditions of this Agreement, Zai hereby grants to TPTX a right of first negotiation for an exclusive license to Develop and Commercialize the Zai Pipeline Product outside the Territory (the "**TPTX ROFN**") as follows: (a) [***]; (b) upon [***], Zai shall promptly provide TPTX with written notice [***] (the "**TPTX ROFN Offer Notice**"); (c) TPTX shall thereafter have [***] days following the date of TPTX's receipt of such TPTX ROFN Offer Notice (the "**TPTX ROFN Exercise Period**") to exercise the TPTX ROFN by providing Zai with written notice of its intent to obtain a license to the Zai Pipeline Product outside the Territory (the "**TPTX ROFN Exercise Notice**"); (d) if TPTX delivers such TPTX ROFN Exercise Notice prior to the expiration of the TPTX ROFN Exercise Period, TPTX shall have the exclusive right to negotiate with Zai, and the Parties shall negotiate in good faith, for a period of up to [***] days from the date of the TPTX ROFN Exercise Notice (or any additional period of time if mutually agreed in writing by the Parties) (the "**TPTX ROFN Negotiation Period**") the terms and conditions of such license; and (e) if (i) TPTX does not provide Zai with a TPTX ROFN Exercise Notice prior to the expiration of the TPTX ROFN Exercise Period or (ii) TPTX provides Zai with a TPTX ROFN Exercise Notice prior to the expiration of the TPTX ROFN Exercise Period and the Parties fail to enter into a definite agreement regarding the terms and conditions with respect to such license prior to the expiration of the TPTX ROFN Negotiation Period, (1) the TPTX ROFN shall automatically expire on the applicable expiration date (the "**TPTX ROFN Expiration**"), which, with respect to the TPTX ROFN Exercise Period, shall be the last day of the TPTX ROFN Exercise Period, and with respect to the TPTX ROFN Negotiation Period, shall be the last day of the TPTX ROFN Negotiation Period; and (2) Zai shall be free to enter into a license agreement with a Third Party for the Development and Commercialization of such Zai Pipeline Product and Zai shall not have any further obligations to TPTX under this Section 2.7. Notwithstanding anything to the contrary, (w) the TPTX ROFN shall automatically expire, and Zai shall not have any further obligations to TPTX under this Section 2.7, upon [***], (w) the TPTX ROFN shall only apply to [***] in accordance with the foregoing, and [***] shall not be subject to the TPTX ROFN and Zai shall not have any further obligations to TPTX under this Section 2.7 with respect thereto; (x) the TPTX ROFN shall automatically expire and Zai shall not have any further obligations to TPTX under this Section 2.7 if [***]; (y) the TPTX ROFN only applies to the Zai Pipeline Product and not to any other Zai compounds or products; and (z) nothing in this Section 2.7 shall prevent Zai from negotiating or completing any transaction for the sale of all or substantially all of Zai's business or assets (including the Zai Pipeline Product), whether by merger, sale of stock, sale of assets or otherwise, and the TPTX ROFN shall not apply to such transaction.

ARTICLE 3

GOVERNANCE

3.1. Alliance Managers. Within [***] days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications (including a general understanding of pharmaceutical Development and Commercialization issues) to act as its alliance manager regarding Development, Manufacture and Commercialization of the Products in the Territory under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall serve as the primary contact points between the Parties regarding the Product Development, Manufacture and Commercialization activities in the Territory contemplated under this Agreement. The Alliance Managers shall (a) facilitate the flow of information; (b) otherwise promote communication, coordination and collaboration between the Parties by providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party or cross-functional disputes in a timely manner; and (c) manage the JSC and JDC meetings by (i) calling meetings of the JSC and JDC; (ii) preparing and issuing minutes of each such meeting within ten (10) Business Days thereafter; and (iii) preparing and circulating an agenda for the upcoming meeting, in each case at the direction of and in consultation with the then-current chairperson. Each Party may replace its Alliance Manager by written notice to the other Party.

3.2. Joint Steering Committee.

(a) **Formation**. Within [***] days after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**") to cooperate, coordinate, integrate and monitor the Development and Commercialization of the Products in the Field in the Territory under this Agreement. Each Party shall appoint [***] representatives (or such other equal number of representatives as agreed by the Parties in writing) to the JSC, each of whom shall be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. Each Party may replace its JSC representatives upon written notice to the other Party; provided that the Parties shall use reasonable efforts not to make changes to such representatives during the first [***] months after establishment of the JSC. Upon the JSC's establishment, a representative from Zai shall act as the chairperson of the JSC. Once a year, the role of chairperson shall rotate between the Parties. The chairperson shall not have any greater authority than any other representative of the JSC.

(b) **Role**. The JSC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement; (ii) review and discuss the overall strategy for the Commercialization of the Product in the Field in the Territory; (iii) overseeing the activities of the JDC, resolving any matter as to which the JDC has authority but cannot reach agreement, including approving the Clinical Development Plan or any amendment thereto, as applicable, and reviewing, discussing and approving any changes in the scope or direction of the Development work with Products in the Territory to be performed by Zai under this Agreement that would be a material deviation from the Clinical Development Plan, whether or not approved by the JDC; (iv) review and discuss the Commercialization Plan and amendments thereto; (v) establish subcommittees as necessary or advisable to further the purpose of this Agreement; and (vi) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

(c) **Limitation of Authority**. The JSC shall only have the powers expressly assigned to it in this ARTICLE 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement; (iv) make any decisions related to, or determine, approve or oversee the initiation, suspension, cessation, conduct, strategy, implementation of or other matters related to, any Global Study; or (v) impose any other obligations on either Party without the prior written consent of such Party.

(d) **Meetings**. The JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every [***] months. Each Party may call additional ad hoc JSC meetings as the needs arise with reasonable advance notice to the other Party. Meetings of the JSC may be held in person, by audio or video teleconference; provided that at least [***] of the JSC shall be held in person unless otherwise agreed by the Parties. In-person JSC meetings shall be held at locations selected alternately by the Parties. Each Party shall be responsible for such Party's expenses of participating in the JSC meetings. No action taken at any JSC meeting shall be effective unless at least [***] are participating in such JSC meeting.

(e) **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants relevant to items on the issued agenda, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party. Such Party shall also ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(f) **Decision-Making**. All decisions of the JSC shall be made by unanimous vote, with TPTX's representatives collectively having one (1) vote and Zai's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach a decision as to such matter within [***] days after such matter was brought to the JSC for resolution, such matter shall be referred by the Parties' Alliance Managers to the Chief Executive Officer of TPTX (or a senior officer designated by the Chief Executive Officer of TPTX) and the Chief Executive Officer of Zai (or a senior officer designated by the Chief Executive Officer of Zai) (the "**Executive Officers**") for resolution. [***].

(g) **Exchange of Information**. The Parties shall cooperate to exchange information through the JSC with respect to Product Commercialization and medical affairs activities conducted by each Party and their Affiliates, in the case of Zai its Sublicensees, and in the case of TPTX its licensees of rights to Products outside the Territory to the extent permitted by such licensees.

3.3. Joint Development Committee.

(a) **Formation**. In accordance with Section 3.2(b)(v), the Parties shall establish a subcommittee to review and oversee the Development of the Product(s) in the Territory and to coordinate the Parties' activities under this Agreement with respect to the Development of such Product(s) (the "**JDC**") within [***] days after the establishment of the JSC by each Party appointing [***] representatives (or such other equal number of representatives as agreed by the Parties in writing) to the JDC, each of which shall have sufficient seniority and relevant expertise to make decisions within the scope of the JDC's responsibilities. The JDC may change its size from time to time by mutual consent of the Parties; provided that the JDC shall consist at all times of an equal number of representatives of each Party. Each Party may at any time replace any one or more of its JDC representatives upon written notice to the other Party; provided that the Parties shall use reasonable efforts not to make changes to such representatives during the first [***] months after establishment of the JDC. A member of the JDC may also be a member of the JSC or any other subcommittee established by the JSC if so desired by the Party who appoints such member.

(b) **Role**. The JDC shall (i) provide a forum for the discussion of the Parties' Product Development activities under this Agreement and status of Regulatory Submissions and Regulatory Approvals in the Territory; (ii) review, discuss and approve the Clinical Development Plan and amendments thereto; (iii) report safety issues of the Products to Regulatory Authorities; (iv) review data generated from the Clinical Trials of the Products in and outside the Territory; and (v) perform such other functions as expressly set forth in this Agreement or allocated to it by the Parties' written agreement.

(c) **Limitation of Authority**. The JDC shall only have the powers expressly assigned to it in this ARTICLE 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any such issue in a manner that would conflict with the express terms and conditions of this Agreement; (iv) make any decisions related to, or determine, approve or oversee the initiation, suspension, cessation, conduct, strategy, implementation of or other matters related to any Global Study; or (v) impose any other obligations on either Party without the prior written consent of such Party.

(d) **Meetings**. The JDC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than [***] until the date when Zai first receives a Regulatory Approval for the Product in the PRC. Thereafter, the JDC shall hold meeting no less frequently than once every [***] months. JDC meetings shall be held adjacently to JSC meetings to the extent possible. Each Party may call additional ad hoc JDC meetings as the needs arise with reasonable advance notice to the other Party. Meetings of the JDC may be held in person, by audio or video teleconference; provided that at least [***] of the JDC shall be held in person unless otherwise agreed by the Parties. In-person JDC meetings shall be held at locations selected alternately by the Parties. Each Party shall be responsible for such Party's expenses of participating in the JDC meetings. No action taken at any JDC meeting shall be effective unless at least [***] representatives of each Party are participating in such JDC meeting.

(e) **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants relevant to items on the issued agenda, in addition to its representatives, to attend the JDC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party. Such Party shall also ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(f) **Decision-Making**. All decisions of the JDC shall be made by unanimous vote, with TPTX's representatives collectively having one (1) vote and Zai's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JDC, the JDC cannot reach a decision as to such matter within [***] days after such matter was brought to the JSC for resolution, such matter shall be referred by the Parties' Alliance Managers to the JSC for resolution in accordance with Section 3.2(f).

(g) **Exchange of Information**. The Parties shall cooperate to exchange information through the JDC and otherwise as reasonably requested by the other Party with respect to Product Development activities conducted by each Party and their Affiliates, in the case of Zai its Sublicensees, and in the case of TPTX its licensees of rights to Products outside the Territory to the extent permitted by such licensees. Such exchange shall include summaries of information relating to Product Development activities of each Party, including all Clinical Trials of the Products, IND and Regulatory Approval Application filings for all indications for the Products. For Clinical Trials of a Product that may be used to support Regulatory Approval for such Product in the other Party's territory (including Global Studies), such exchange shall also include all data, results and analyses as reasonably requested by a Party, and the other Party shall have the right to use such data and results for the purpose of obtaining and maintaining Regulatory Approval for the Product in its territory.

3.4. Withdrawal. At any time during the Term and for any reason, TPTX shall have the right to withdraw from participation in the JSC or JDC upon written notice to Zai, which notice shall be effective immediately upon receipt. Following the issuance of a withdrawal notice and subject to this Section 3.4, TPTX's representatives to the applicable committee shall not participate in any meetings of such committee. If, at any time following the issuance of a withdrawal notice, TPTX wishes to resume participation in the applicable committee, TPTX shall notify Zai in writing, and thereafter, TPTX's representatives to such committee shall be entitled to attend any subsequent meeting of such committee and to participate in the activities of, and decision-making by, such committees as provided in this ARTICLE 3 as if a withdrawal notice had not been issued by TPTX. Following TPTX's issuance of a withdrawal notice, unless and until TPTX resumes participation in the applicable committee in accordance with this Section 3.4 (a) all meetings of the applicable committee will be held at Zai's facilities; and (b) TPTX shall have the right to continue to receive the minutes of such committee meetings, but shall not have the right to approve the minutes for any meeting of such committee held after TPTX's issuance of a withdrawal notice.

ARTICLE 4

DEVELOPMENT TECHNOLOGY TRANSFERS

4.1. Access to Licensed Know-How. TPTX shall provide or make available to Zai all Licensed Know-How which exists as of the Effective Date, which provision or access shall occur in a manner and following a reasonable schedule proposed by TPTX and agreed by the JDC (to be completed within [***] days after the Effective Date or such later time as agreed by the JDC). During the Term, TPTX shall provide or make available Zai with additional Licensed Know-How, to the extent that such Licensed Know-How comes to TPTX's attention (or is reasonably requested by Zai) and has not previously been provided or made available to Zai.

4.2. Assistance by TPTX. At Zai's reasonable request, TPTX shall cooperate with Zai to provide reasonable technical assistance in connection with (a) the transfer to Zai of the Development of Products in the Territory and (b) the seeking of Regulatory Approval for Products in the Territory. Upon Zai's request for any reasonable technical assistance, TPTX shall provide Zai with such reasonable technical assistance [***].

ARTICLE 5

DEVELOPMENT

5.1. Diligence and Responsibilities. Zai shall be primarily responsible for, and shall use Commercially Reasonable Efforts to conduct, all Development activities of the Products in the Field in the Territory in accordance with the Clinical Development Plan at Zai's sole cost subject to Section 5.4(b). Zai shall perform such obligations under the Clinical Development Plan in a professional manner, and in compliance in all respects with the Clinical Development Plan and the requirements of Applicable Laws, GCP and cGMP. Changes in the scope or direction of the Development work under this Agreement that would be a material deviation from the Clinical Development Plan must be approved by the JSC as set forth in Section 3.2(b); provided that any change with respect to Joint Global Studies shall be consistent with the Joint Global Studies as set forth in the Global Development Plan.

5.2. Clinical Development Plan. The Parties shall undertake the Development of the Products in a collaborative and efficient manner in accordance with this ARTICLE 5. The Development of the Products relating to the Territory under this Agreement shall be governed by a written clinical development plan, as revised from time to time in accordance with this Section 5.2 (the "**Clinical Development Plan**"). The Clinical Development Plan shall include (a) an outline of Clinical Trials to be conducted by Zai in the Territory, including the Local Studies and Joint Global Studies; and (b) the material activities to be performed by the Parties to obtain the Regulatory Approvals for the Products in the Territory and to support the Joint Global Studies. The Clinical Development Plan shall contain in reasonable detail the major Development activities and the projected timelines for conducting such activities, including activities designed to achieve Regulatory Approvals for the Products in the Territory. As of the Effective Date, the Parties have agreed to an initial Clinical Development Plan, which is attached hereto as Schedule 5.2. From time to time, [***,] Zai shall propose updates or amendments, if any, to the Clinical Development Plan in consultation with TPTX and submit such proposed updated or amended plan to the JDC for review, discussion and approval. In accordance with Section 3.3(b), the JDC shall review, discuss and approve any updates or amendments to the Clinical Development Plan; provided [***]. Zai may propose to [***]. For the avoidance of doubt, any proposed [***].

5.3. Local Study. Zai shall use Commercially Reasonable Efforts, be solely responsible for and have decision-making authority for performance of any Local Study (including handling relevant Regulatory Submissions for any Local Studies in the Territory at its own cost, as applicable, in accordance with ARTICLE 6); provided [***]. Each Local Study conducted in the Territory shall be conducted in accordance with the Clinical Development Plan, the study protocol approved by any relevant Regulatory Authority, and Applicable Laws in the Territory.

5.4. Global Study.

(a) **General**. TPTX may initiate, suspend, or cease a Global Study for any Product for any Indication. TPTX's global Development of Products will be conducted pursuant to a written development plan, as amended from time to time by TPTX, subject to this Section 5.4 with respect to participation by Zai (the "**Global Development Plan**"). The Global Development Plan in effect as of the Effective Date, a copy of which TPTX has provided to Zai and also attached hereto as Schedule 5.4(a), identifies Global Studies that are planned to include clinical sites for Clinical Trials in the Territory (the "**Existing Global Studies**"). [***.] If TPTX amends the Global Development Plan after the Effective Date, [***].

(b) Zai (i) shall participate in the Existing Global Studies by coordinating clinical trial sites in the Territory and enrolling the percentage of the subjects for such Existing Global Studies as specified in the Global Development Plan existing as of the Effective Date, and (ii) may, in its sole discretion, agree to participate in a Global Study presented by TPTX other than any Existing Global Study (each of the Existing Global Studies and any such agreed Global Studies, a "**Joint Global Study**"). The Joint Global Studies that are Existing Global Studies are listed in Schedule 5.4(b). Zai shall be responsible for all activities (if any) associated with conducting each Joint Global Study in the Territory set forth in the Global Development Plan existing as of the Effective Date and each additional Joint Global Study as outlined in the plan for such Joint Global Study as mutually agreed by the Parties and any additional Joint Global Study so agreed between the Parties shall be included in an amendment to the Global Development Plan. Zai shall use Commercially Reasonable Efforts to [***].

(c) Zai, itself or with or through any other of its Affiliates or Sublicensees, shall, in accordance with [***]. For any Joint Global Study, Zai shall be responsible for all costs incurred by or on behalf of Zai in the performance of such Joint Global Study in the Territory (except to the extent of assistance provided by TPTX without additional charge in accordance with Section 4.2), and TPTX shall be responsible for all other costs incurred for or in connection with such Joint Global Study.

(d) If Zai elects not to participate in any Global Study presented by TPTX (other than Existing Global Studies in which Zai will be participating) by notifying TPTX in writing of such election not to participate (or by failing to notify TPTX in writing of its election to participate) within [***] days after the date of TPTX's presentation of such Global Study to the JDC, TPTX may conduct such Global Study in the Territory at its sole cost, but in conducting such Global Study, the Parties shall coordinate the Parties' Development activities for the Product(s) in the Territory; provided, however, that [***].

5.5. Development Reports. The status, progress and results of Zai's Development activities under this Agreement shall be discussed at meetings of the JDC. At least [***] Business Days before each regularly scheduled JDC meeting, Zai shall provide the JDC with a written report detailing its Product Development activities and the results thereof, covering subject matter at a level of detail reasonably requested by TPTX and sufficient to enable TPTX to determine Zai's compliance with its obligations pursuant to Section 5.1 to Section 5.4. Through the JDC, each Party shall keep the other Party reasonably informed on the Development of the Product conducted by or on behalf of such Party. In addition, each Party shall make available to the other Party such additional information about its Development activities with Products as may be reasonably requested by the other Party from time to time. All updates and reports provided by a Party pursuant to this Section 5.5 shall be the Confidential Information of such Party.

5.6. Records. Each Party shall maintain appropriate records in either tangible or electronic form of all significant Development, packaging or labeling, Manufacture (in the case of Zai, after the Manufacturing Technology Transfer), regulatory or Commercialization of a Product, in each case in accordance with its usual documentation and record retention practices. Such records shall be in sufficient detail to properly reflect, in a good scientific manner, all significant work done, and the results of studies and trials undertaken and, further, shall be at a level of detail appropriate for patent and regulatory purposes. Each Party shall document all non-clinical studies and Clinical Trials in formal written study reports according to Applicable Laws and national and international guidelines. Upon a Party's reasonable request, the other Party shall, and shall cause its Affiliates and, in the case of Zai, Sublicensees, to provide to the first Party copies of such records of Development, packaging or labeling, Manufacture (in the case of Zai, after the Manufacturing Technology Transfer), regulatory and Commercialization activities to the extent necessary for the Development, packaging or labeling, Manufacture (in the case of Zai, after the Manufacturing Technology Transfer), and Commercialization of the Product in the other Party's territory, including for regulatory and patent purposes. All such records, reports, information and data of a Party provided to the other Party shall be the Confidential Information of the providing Party.

5.7. Clinical Trial Audits. TPTX or its representatives may conduct an audit of Zai, its Affiliates, or any Sublicensees or subcontractors, and all Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees or subcontractors to perform Zai's obligations under any Clinical Development Plan, in each case, to ensure that the applicable Clinical Trials are conducted in compliance with the Clinical Development Plan, GCP, and Applicable Laws; provided that in the event any such audit of Zai's subcontractors or Clinical Trial sites engaged by Zai or its Affiliates or Sublicensees or subcontractor requires Zai's assistance, Zai shall provide TPTX or its representatives with such assistance, to the extent reasonable, including providing personnel of Zai to be present for such audit and producing any documents or authorizations allowing TPTX or its representatives to conduct such audit, to the extent reasonable. TPTX may conduct such audit no more than [***] (unless an additional audit is warranted for cause) upon [***] days' prior written notice to Zai. No later than [***] days after the completion of such audit, TPTX shall provide Zai with a written summary of TPTX's findings of any deficiencies or other areas of remediation that TPTX identifies during any such audit. Zai shall use Commercially Reasonable Efforts to respond or remediate any such deficiencies within [***] days following TPTX's receipt of such report. Without limiting the foregoing, Zai shall have the right to be present at any such audit conducted by TPTX pursuant to this Section 5.7 of any Sublicensees, subcontractors or Clinical Trial sites. With respect to any Clinical Trial in a Joint Global Study in the Territory or Local Study, if the Parties acting reasonably and in good faith agree that any deficiencies with respect to a Clinical Trial site identified pursuant to an audit (each, a "**Deficient Site**") may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from the conduct of any such Clinical Trial at such Deficient Site, then TPTX shall notify Zai of such Deficient Site and the Parties shall discuss and attempt to agree upon a remediation plan for such Deficient Site. If the Parties cannot agree to such a remediation plan for a Deficient Site, then Zai shall promptly remove such Deficient Site from such Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") in the Territory, and Zai shall be solely responsible for the costs of such replacement (unless not permitted by Applicable Law or for ethical reasons). Any such Replacement Site shall be compliant in all respects with Applicable Law.

ARTICLE 6

REGULATORY

6.1. Zai's Responsibilities. Zai shall be responsible for (a) all regulatory activities leading up to and including the obtaining of the Regulatory Approval for a Product from the Regulatory Authority on a region-by-region basis in the Territory, at its sole cost and expense, except as set forth in the Global Development Plan and Clinical Development Plan; and (b) hold and maintain all Regulatory Approvals [***]. Subject to the terms and conditions of this Agreement, TPTX shall [***] and Zai shall use Commercially Reasonable Efforts to obtain Regulatory Approvals for Products in the Territory in accordance with the Clinical Development Plan and Zai shall be solely responsible for all costs and expenses incurred in connection with performing such activities in the Territory; provided that TPTX shall [***]. Zai shall keep TPTX promptly informed (and in any event within [***] hours for any significant matter) of regulatory developments related to the Products in the Territory and shall promptly notify TPTX in writing of any decision by any Regulatory Authority in the Territory regarding a Product.

6.2. Review of Regulatory Submissions. Zai shall provide to TPTX for review and comment drafts of all Regulatory Submissions in the Territory for the Products no later than [***] days prior to the planned submission. Zai shall incorporate any comments received from TPTX on such Regulatory Submissions where required under any Applicable Laws and shall consider in good faith any other comments received from TPTX on such Regulatory Submissions. In addition, Zai shall notify TPTX of any material Regulatory Submissions for the Products and any other material documents, comments or other correspondences related thereto submitted to or received from any Regulatory Authority in the Territory and shall provide TPTX with copies thereof as soon as reasonably practicable, but in all events within [***] days after submission or receipt thereof. If any such Regulatory Submission, comment, or correspondence is not in English, then, in addition to a copy thereof in its original language, (a) Zai shall also provide TPTX with an English summary thereof within the corresponding timelines as set forth in this ARTICLE 6 at Zai's cost; and (b) upon TPTX's reasonable request, provide TPTX with an English translation thereof at TPTX's cost.

6.3. Notice of Meetings. Zai shall provide TPTX with notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Product no later than [***] Business Days after receiving notice thereof. Zai shall lead any such meeting or discussion and TPTX or its designee shall have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Laws or Regulatory Authority. At Zai's request, TPTX shall reasonably cooperate with Zai in preparing for any such meeting or discussion. If TPTX elects not to attend such meeting or discussion, then Zai shall provide to TPTX a written summary thereof in English promptly following the issuance or approval of the corresponding official minutes by the applicable Regulatory Authority.

6.4. 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 Product, then Zai shall notify TPTX of such contact, inspection, or notice or action within [***] Business Days after receipt of such notice (or, if action is taken without notice, within [***] Business Days of Zai becoming aware of such action). TPTX shall have the right to review and comment on any responses to Regulatory Authority that pertain to a Product in the Territory.

6.5. TPTX's Responsibilities. TPTX shall reasonably cooperate with Zai in obtaining any Regulatory Approvals for a Product in the Territory by providing, to the extent reasonably requested by Zai, access to Regulatory Approvals, Regulatory Submissions, clinical data, and other data, information, and documentation for the Product outside of the Territory pursuant to ARTICLE 4. In addition, upon Zai's reasonable request, TPTX shall, and shall cause its Affiliates and sublicensees (to the extent permitted in such sublicensees' agreement with TPTX), to provide to Zai copies of such records of Development, Manufacturing, and Commercialization activities to the extent necessary or reasonably useful to obtain Regulatory Approval of the Product in the Territory. [***].

6.6. No Harmful Actions. If TPTX believes that Zai is taking or intends to take any action with respect to a Product that could have a material adverse impact upon the regulatory status of the Product outside the Territory, TPTX shall have the right to bring the matter to the attention of the JDC and the Parties shall discuss in good faith to resolve such concern. Without limiting the foregoing, unless the Parties otherwise agree: (a) Zai shall not communicate with any Regulatory Authority having jurisdiction outside the Territory, unless so ordered by such Regulatory Authority, in which case Zai shall immediately notify TPTX of such order; and (b) Zai shall not submit any Regulatory Submissions or seek Regulatory Approvals for the Product outside the Territory.

6.7. Notification of Threatened Action. Each Party shall within [***] notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by any Third Party, which would reasonably be expected to affect the safety or efficacy claims of any Product or the continued marketing of any Product (as to TPTX's notification obligation, only to the extent it would reasonably be expected to affect the Territory). Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action with respect to the Territory.

6.8. Right of Reference.

(a) Zai hereby grants to TPTX the right of reference to all Regulatory Submissions pertaining to the Product in the Field submitted by or on behalf of Zai or its Affiliates (and all data contained or referenced therein), with the right to grant further rights of reference to TPTX's licensees with respect to Products. TPTX and its Affiliates (and any licensee to whom it may grant a further right of reference) may use the right of reference to Zai's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining the Regulatory Approval of the Products outside the Territory.

(b) TPTX hereby grants to Zai the right of reference to all Regulatory Submissions pertaining to the Product in the Field submitted by or on behalf of TPTX or its Affiliates (to the extent included in the definition of Licensed Know-How) (and all data contained or referenced therein), subject to Section 5.4(d) as to the Licensed Know-How contained therein, with the right to grant further rights of reference to Sublicensees. Zai and its Affiliates (and any Sublicensee to whom it may grant a further right of reference) may use such right of reference to TPTX's Regulatory Submissions in the Field solely for the purpose of seeking, obtaining and maintaining the Regulatory Approval of the Products in Field in the Territory.

6.9. Adverse Events Reporting.

(a) Promptly following the Effective Date, but in no event later than [***] days thereafter, Zai and TPTX shall develop and agree to the worldwide safety and pharmacovigilance procedures for the Parties with respect to the Products, such as safety data sharing and exchange, Adverse Events reporting and prescription events monitoring in a written agreement (the "**Pharmacovigilance Agreement**"). Such agreement shall describe the coordination of collection, investigation, reporting, and exchange of information concerning Adverse Events or any other safety problem of any significance, and product quality and product complaints involving Adverse Events, sufficient to permit each Party, its Affiliates, licensees or sublicensees to comply with its legal obligations. The Pharmacovigilance Agreement shall be promptly updated if required by changes in legal requirements. Each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement and to cause its Affiliates, licensees and sublicensees to comply with such obligations. To the extent there is any disagreement between this Section 6.9, Section 6.10, or any related definitions and the Pharmacovigilance Agreement, the Pharmacovigilance Agreement shall control with respect to safety matters and this Agreement shall control with respect to all other matters.

(b) Zai shall be responsible for complying with all Applicable Laws governing Adverse Events in the Territory for all Clinical Trials performed by Zai, including the Local Studies and Joint Global Studies, and TPTX shall be responsible for complying with all Applicable Laws covering Adverse Events (i) in the Territory for all Clinical Trials performed by TPTX for the Global Studies that Zai does not participate in and (ii) outside the Territory for all Clinical Trials.

(c) TPTX shall hold and control the global safety database for all Products and for the exchange by the Parties in English of any information which a Party becomes aware of concerning any Adverse Event experienced by a subject or patient being administered any Product, including any such information received by either Party from any Third Party (subject to receipt of any required consents from such Third Party). It is understood that each Party and its Affiliates, licensees and sublicensees shall have the right to disclose such information if such disclosure is reasonably necessary to comply with Applicable Laws or requirements of any applicable Regulatory Authority.

6.10. Safety and Regulatory Audits. In addition to the audit rights under Section 5.7, upon reasonable notification, TPTX shall be entitled to conduct an audit of safety and regulatory systems, procedures and practices of Zai, including on-site evaluations to the extent permitting such on-site evaluations is in the control of Zai. TPTX may conduct such audit no more than [X***XX] (unless an additional audit is warranted for cause) upon [***] days' prior written notice to Zai. With respect to any inspection of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to any Product, Zai shall notify TPTX of such inspection (a) no later than [***] Business Days after Zai receives notice of such inspection or (b) within [***] Business Day after the completion of any such inspection of which Zai did not receive prior notice. Zai shall promptly provide TPTX with all information related to any such inspection. Zai shall also permit Governmental Authorities outside of the Territory to conduct inspections of Zai or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Product, and shall ensure that all such Affiliates or Sublicensees permit such inspections. TPTX shall have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection. Following any such regulatory inspection related to the Products, Zai shall provide TPTX with (i) an unredacted copy of any finding, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Product) within [***] days of Zai receiving the same, and (ii) in the event that such findings, notice, or report [***] of any material finding, notice, or report of a Governmental Authority related to such inspection (to the extent related to the Product) within [***] days after receiving the same. Further details including notification, timing, response and scope of such audits shall be included in the Pharmacovigilance Agreement.

6.11. Remedial Actions. Each Party shall notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (as to TPTX's notification obligation, only to the extent it would reasonably be expected to affect the Territory) (a "**Remedial Action**"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action with respect to the Territory. Zai shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action; provided that TPTX shall have sole discretion with respect to any matters relating to any Remedial Action in the Territory to the extent related to any Global Study. The cost and expenses of any Remedial Action in the Territory shall be borne solely by the Party with sole discretion; provided, however, that to the extent a Remedial Action in the Territory results primarily from the failure of the Product supplied by TPTX to comply with the Product Specifications, product warranties (as set forth in the Supply Agreement) or any Applicable Law, including cGMP requirements, then TPTX shall reimburse Zai for the reasonable cost and expense of such Remedial Action if this is required and after consultation with TPTX. Each Party shall, and shall ensure that its Affiliates and sublicensees shall, maintain adequate records to permit the Parties to trace the distribution and use of the Product in the Territory.

ARTICLE 7

MANUFACTURING

7.1. Packaging and Labeling. Subject to the terms and conditions of this Agreement, Zai shall (a) have the right to package or label the Products in or outside the Territory, and (b) upon its written notice to TPTX of its exercise of such right, for instances in which it exercises such right, be responsible for, and use Commercially Reasonable Efforts to package or label the Products in or outside the Territory solely for the Development and Commercialization of the Products in the Field in the Territory, at its sole cost and expense.

7.2. Manufacture; Supply of Products. Subject to Section 7.3, TPTX shall be solely responsible (itself or through its Affiliate or CMO) for the Manufacture of the Product for Development and Commercialization by Zai and its Affiliates and Sublicensees in the Territory. Customary terms of forecasting and ordering procedures, Product Specifications, and other operational matters relating to the supply of the Product under this Section 7.2 shall be set forth in a supply agreement to be mutually agreed upon by the Parties within [***] days following the Effective Date or such longer period as agreed by the Parties (the "**Supply Agreement**"). In connection with such Supply Agreement, the Parties shall enter into a quality agreement governing the Product Specifications and other technical aspects of the Product (the "**Quality Agreement**"). Subject to the terms of this ARTICLE 7, the Supply Agreement and Quality Agreement, TPTX shall, itself or through one or more CMOs, [***]. The Supply Agreement will include other customary terms for the clinical and commercial supply of pharmaceutical products, including (i) pro rata allocation of Products among TPTX and its Affiliates and licensees (including Zai and its Affiliates and Sublicensees) and (ii) other appropriate remedies, in each case of (i) and (ii), in a manner and under the circumstances mutually agreed by the Parties. Zai or its Affiliates shall (1) obtain and maintain all required export or import licenses or authorizations, and shall serve as importer of record for all Products delivered in or into any region in the Territory pursuant to this Agreement and the Supply Agreement; and (2) be responsible for shipment and insurance from TPTX's or its CMO's facility and all customs' duties, import tariffs, taxes, freight, insurance, inspection costs and the like attributed to or for the transport and importation of the Product in or into any region in the Territory.

7.3. Manufacturing Technology Transfer. If Zai [***]; and (b) [***], then (1) the Parties would enter into an amendment to this Agreement pursuant to which TPTX would grant to Zai a non-exclusive, sublicenseable (subject to the same terms as a sublicense under Licensed Technology pursuant to Section 2.3) license under Manufacturing Technology to Manufacture and have Manufactured (through a qualified CMO mutually acceptable to the Parties) the Product in the Territory solely for use in Development and Commercialization of the Product in the Field in the Territory, where "**Manufacturing Technology**" means any and all (i) Patents Controlled by TPTX or its Affiliates as of the date of grant of such license or thereafter during the Term that cover the method of manufacture of the Product in the Territory, and (ii) Know-How Controlled by TPTX or its Affiliates as of the date of grant of such license or thereafter during the Term that is used by or on behalf of TPTX for the Manufacture of the Products in the Field in the Territory; provided that, notwithstanding the foregoing, in the event a Change of Control of TPTX occurs after the Effective Date, Patents or Know-How Controlled by any Affiliate of TPTX that was not an Affiliate of TPTX immediately prior to such Change of Control transaction shall not be Manufacturing Technology except to the extent such Patent or Know-How falls within the definition of Manufacturing Technology and (A) is also Controlled by TPTX or its Affiliate existing immediately prior to such transaction or (B) is generated or used by such Affiliate in the Manufacture of the Licensed Compound or Product after such transaction; and (2) at Zai's sole cost, TPTX shall (A) transfer all Know-How within the Manufacturing Technology to Zai or its permitted CMO; and (B) provide any and all necessary assistance to Zai or such permitted CMO at Zai's cost (clauses (A) and (B), the "**Manufacturing Technology Transfer**").

ARTICLE 8

COMMERCIALIZATION; MEDICAL AFFAIRS

8.1. General. Zai shall be solely responsible for, and use Commercially Reasonable Efforts to Commercialize and obtain pricing and reimbursement approvals for the Products in the Field in the Territory in accordance with the Commercialization Plan, at its sole cost and expense. Upon Zai's reasonable request, TPTX shall reasonably assist Zai in such Commercialization of the Products [***].

8.2. Commercialization Plan. The Commercialization Plan shall contain in reasonable detail the significant Commercialization activities and the projected timelines for achieving such activities, including [***] in the Territories. Zai shall deliver an initial Commercialization Plan to the JSC for review and discussion no later than [***] of the first Regulatory Approval Application for a Product in the Territory. Thereafter, from time to time, but at least once every [***] months, Zai shall propose updates or amendments to the Commercialization Plan to reflect changes in such plans, including those in response to changes in the marketplace, relative success of the Products, and other relevant factors influencing such plan and activities, and submit such proposed updated or amended Commercialization Plan to the JSC. In preparing the initial Commercialization Plan and any updates or amendments thereto, Zai shall provide TPTX with an opportunity to comment and Zai shall consider any TPTX's comments in good faith in finalizing the initial Commercialization Plan and any updates or amendments thereto.

8.3. Commercialization Reports. Zai shall update the JSC at each regularly scheduled JSC meeting regarding Zai's Commercialization activities with respect to the Products in the Territory. Each such update shall be in a form to be agreed by the JSC and shall summarize Zai's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Products in the Territory, covering subject matter at a level of detail reasonably required by TPTX and sufficient to enable TPTX to determine Zai's compliance with its diligence obligations pursuant to Section 8.1. In addition, Zai shall make available to TPTX such additional information about its Commercialization activities as may be reasonably requested by TPTX from time to time. All updates and reports generated pursuant to this Section 8.3 shall be the Confidential Information of Zai.

8.4. Product Trademarks. Zai may use (pursuant to this Section 8.4) the trademarks Controlled by TPTX in the Territory as TPTX may provide to Zai in writing from time to time (the "**TPTX Product Marks**") and may use the English mark thereof with Chinese phonetic translation below. TPTX hereby grants to Zai, during the Term and subject to the terms and conditions of this Agreement, a royalty-free, exclusive license under TPTX's rights to use such TPTX Product Marks in connection with the Commercialization of the Products in the Field in the Territory in compliance with Applicable Laws and this Agreement. Zai shall comply with TPTX's brand usage guidelines provided to Zai in its use of the TPTX Product Marks. Zai may also brand the Products in the Territory using other trademarks, logos, and trade names specific for the Products that differ from the TPTX Product Marks and do not contain the name of TPTX; provided, however, that (a) prior to such use, Zai shall submit such trademarks, logos and trade names for TPTX's prior written approval (not to be unreasonably withheld, delayed or conditioned), and (b) such trademarks, logos and trademarks shall be deemed owned by Zai (the "**Product Marks**"). Zai shall own all rights in the Product Marks in the Territory and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary.

8.5. Commercialization Assistance. [***] provide assistance to Zai at Zai's request for the Commercialization activities, including assistance pursuant to Sections 8.1 and 8.4 as requested by Zai.

8.6. No Diversion. Each of TPTX and Zai hereby covenants and agrees that (a) it shall not, and shall ensure that its Affiliates and sublicensees shall not, directly or indirectly, promote, market, distribute, import, sell or have sold the Products, including via internet or mail order, outside its territory; (b) with respect to any country or region outside its territory, it shall not, and shall ensure that its Affiliates and their respective sublicensees shall not: (i) unless otherwise agreed by the Parties in writing, establish or maintain any branch, warehouse or distribution facility for Products in such countries (except, in the event such Party is Zai, Zai shall have the right to maintain one or more warehouses outside the Territory solely to support the packaging and labelling activities of the Products by Zai or its Affiliates outside the Territory and, in the event such Party is TPTX, TPTX shall have the right to maintain one or more warehouses in the Territory solely to support the Retained Rights), (ii) engage in any advertising or promotional activities relating to Products that are directed primarily to customers or other purchaser or users of Products located in such countries, (iii) solicit orders for Products from any prospective purchaser located in such countries, or (iv) sell or distribute Products to any Person in such Party's territory who intends to sell or has in the past sold Products in such countries; (c) if a Party receives any order for any Product from a prospective purchaser reasonably believed to be located in a region or country outside its territory, such Party shall promptly refer that order to the other Party, and such Party shall not accept any such orders; (d) neither Party shall deliver or tender (or cause to be delivered or tendered) Products into a country or region outside its territory; and (e) each Party shall not, and shall ensure that its Affiliates and their respective sublicensees shall not, knowingly restrict or impede in any manner the other Party's exercise of its exclusive rights to Commercialize the Products in the other Party's territory. For the purpose of this Agreement, Zai's territory shall mean the Territory and TPTX's territory shall mean all countries and regions outside the Territory.

8.7. TPTX Acquirer's Right of First Negotiation. Zai hereby grants to TPTX for the benefit of the Third Party that is the acquirer of TPTX in a Change of Control of TPTX (the "**TPTX Acquirer**") a right of first negotiation to co-Commercialize the Products in the Territory (the "**TPTX Acquirer ROFN**") in accordance with this Section 8.7. Following a Change of Control of TPTX, TPTX Acquirer may provide written notice to Zai of its interest in negotiating an agreement with Zai to co-Commercialize the Products in the Territory (the "**TPTX Acquirer ROFN Exercise Notice**"). If TPTX Acquirer delivers such TPTX Acquirer ROFN Exercise Notice, TPTX Acquirer shall have the exclusive right to negotiate with Zai for a period up to [***] days from the date of the TPTX Acquirer ROFN Exercise Notice (or any additional period of time if mutually agreed in writing by TPTX Acquirer and Zai) (the "**TPTX Acquirer ROFN Negotiation Period**") the terms and conditions of such agreement to co-Commercialize the Products in the Territory. If the TPTX Acquirer ROFN Exercise Notice has not been received by Zai on or prior to the date Zai files the first Regulatory Approval Application for the first Product in the Territory, the TPTX Acquirer ROFN shall automatically expire upon such date, and Zai shall thereafter be free to enter into an agreement with a Third Party for the co-Commercialization of any and all Products in the Territory. If TPTX Acquirer provides Zai with a TPTX Acquirer ROFN Exercise Notice prior to the expiration of the TPTX Acquirer ROFN and Zai and TPTX Acquirer fail to enter into a definitive agreement regarding the terms and conditions with respect to such co-Commercialization of Products in the Territory prior to the expiration of the TPTX Acquirer ROFN Negotiation Period, (i) the TPTX Acquirer ROFN shall automatically expire on the last day of the TPTX Acquirer ROFN Negotiation Period and (ii) Zai shall be free to enter into an agreement with a Third Party for the co-Commercialization of any and all Products in the Territory.

8.8. Medical Affairs. Zai shall be solely responsible, at its sole cost and expense, for conducting medical affairs activities with respect to the Products in the Territory, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), publications, congress presentations and posters, published manuscripts, activities performed in connection with patient registries and post-approval trials, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale, or other Commercialization of the Products, all of which shall be conducted in accordance with Applicable Law. Zai shall update the JSC at each regularly scheduled JSC meeting regarding Zai's medical affairs activities. Each such update shall be in a form to be agreed by the JSC and shall summarize Zai's, its Affiliates' and Sublicensees' significant Commercialization activities with respect to the Products in the Territory, covering subject matter at a level of detail reasonably required by TPTX and sufficient to enable TPTX to determine Zai's compliance with its diligence obligations pursuant to Section 8.1. In addition, Zai shall make available to TPTX such additional information about its Commercialization activities as may be reasonably requested by TPTX from time to time. All updates and reports generated pursuant to this Section 8.8 shall be the Confidential Information of Zai.

ARTICLE 9

PAYMENTS AND MILESTONES

9.1. Upfront Payment. In partial consideration of the licenses and rights granted by TPTX to Zai hereunder, Zai shall pay to TPTX a one-time, irrevocable, non-refundable, non-creditable amount of twenty-five million U.S. Dollars ($25,000,000) (the "**Upfront Payment**") within [***] days of the Effective Date.

9.2. Development Milestones Payments to TPTX.

(a) In partial consideration of the rights granted herein, when the Product first achieves the Milestone Events set forth below (each such event, a "**Development Milestone Event**"), Zai shall pay to TPTX the following one-time, irrevocable, non-refundable, non-creditable Development milestone payments (each such payment, a "**Development Milestone Payment**") within [***] days of the achievement of the corresponding Milestone Events.

No.	Development Milestone Event	Development Milestone Payment
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]
5.	[***]	[***]
6.	[***]	[***]
7.	[***]	[***]
8.	[***]	[***]
9.	[***]	[***]
10.	[***]	[***]
11.	[***]	[***]
12.	[***]	[***]
13.	[***]	[***]
14.	[***]	[***]
15.	[***]	[***]

16.	[***]	[***]
17.	[***]	[***]
18.	[***]	[***]
19.	[***]	[***]
20.	[***]	[***]
21.	[***]	[***]
22.	[***]	[***]
23.	[***]	[***]
24.	[***]	[***]
25.	[***]	[***]
26.	[***]	[***]
27.	[***]	[***]
28.	[***]	[***]
29.	[***]	[***]
30.	[***]	[***]

(b) For the avoidance of doubt, (i) each Development Milestone Payment shall be payable on the first occurrence of the corresponding Development Milestone Event for a Product, whether such Development Milestone Event is achieved through the Development of a Product as a Monotherapy or a Combination Therapy involving the Product, and (ii) none of the Development Milestone Payments shall be payable more than once, other than [***]. For clarity, any achievement of any event above solely through the Development of the Other Component (and not the Licensed Component) of a Combination Product shall not be deemed an achievement of any Development Milestone Event and shall not trigger any Development Milestone Payment. In the event the Development Milestone Event [***] shall be payable. [***]. In the event the Development Milestone Event pairs of [***] shall be payable. [***]. Subject to the foregoing, [***] shall be payable, only once for a given Product [***].

9.3. Sales Milestones.

(a) In partial consideration of the rights granted herein, Zai shall pay to TPTX the following one-time, irrevocable, non-refundable, non-creditable milestone payments (each such payment, a "**Net Sales Milestone Payment**") for the achievement of the corresponding Net Sales milestone events set forth below (each such event, a "**Net Sales Milestone Event**") within [***] days after the end of the Calendar Quarter in which the Net Sales Milestone Event is achieved.

Net Sales Milestone Event	Net Sales Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(b) For the avoidance of doubt (i) each Net Sales Milestone Payment shall be payable on the first occurrence of the corresponding Net Sales Milestone Event, and (ii) none of the Net Sales Milestone Payments shall be payable more than once. If annual Net Sales in a given Calendar Year exceed more than one (1) applicable threshold, then all corresponding Net Sales Milestone Payments shall be payable.

9.4. Royalties.

(a) **Royalty Payment**. During the Royalty Term, Zai shall pay to TPTX tiered royalties as calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental, aggregated Net Sales of all Products in the Territory in a Calendar Year (a "**Royalty Payment**"). The tiered royalty rates on Net Sales shall be as set forth below:

For that portion of annual Net Sales in a Calendar Year	Royalty Rate
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%
[***]	[***]%

(b) **Royalty Term**. The Royalty Payments payable under this Section 9.4 shall be payable on a Product-by-Product and region-by-region basis from the first occurrence of Net Sales of the applicable Product in such region until the later of: (i) the date the last-to-expire Valid Claim in such region expires; (ii) the expiry of the regulatory exclusivity for such Product in such region; or (iii) the close of business of the day that is exactly ten (10) years after the date of the First Commercial Sale of such Product in such region (the "**Royalty Term**").

(c) **Royalty Reductions**.

(i) During the Royalty Term for a Product in a region in the Territory, subject to Section 9.4(c)(iv), the royalty rate applicable to Net Sales of such Product in such region shall be reduced by [***] after the expiration of the last-to-expire Valid Claim in such region.

(ii) During the Royalty Term for a Product in a region in the Territory, subject to Section 9.4(c)(iv), the royalty rate applicable to Net Sales of such Product in such region shall be reduced by [***] starting from the Calendar Quarter in which a Generic Competition with respect to such Product occurs in such region.

(iii) If Zai reasonably determines in good faith after advice of counsel that it is [***] and enters into such a license, subject to Section 9.4(c)(iv), Zai shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this Section 9.4, an amount equal to [***] of the royalties paid by Zai to such Third Party pursuant to such license on account of the sale of the Product in the Territory; provided that (1) prior to entering into such license, Zai shall [***]; and (2) in the event [***], (A) [***], (B) [***], and (C) [***], then the Parties shall [***] (and, for clarity, [***]). Within [***] days following the execution of any such Third Party license, Zai shall provide TPTX with a true and complete copy of such Third Party license. In addition, subject to Section 9.4(c)(iv), Zai shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this Section 9.4, an amount equal to [***].

(iv) Notwithstanding the foregoing, in no event shall the operation of Section 9.4(c)(i) through 9.4(c)(iii), individually or in combination, reduce the royalties payable by Zai to TPTX with respect to the Net Sales of any Product in any region in the Territory in any Calendar Quarter to an amount less than [***] of the amount that would otherwise have been due pursuant to Section 9.4(a) with respect to such Net Sales.

(d) **Royalty Estimate and Royalty Reports**. Following the First Commercial Sale of a Product for which royalties are due pursuant to this Section 9.4, and continuing for so long as royalties are due hereunder:

(i) Zai shall, within [***] Business Days after the end of each Calendar Quarter, provide TPTX with a good faith estimate of the royalties due for such Calendar Quarter.

(ii) Zai shall, within [***] days after the end of each Calendar Quarter, provide TPTX with a royalty report (in a template agreed to by the Parties) showing, on a region-by-region basis:

(1) the gross sales and Net Sales of each Product sold by Zai, its Affiliates and Sublicensees during such Calendar Quarter reporting period and supporting gross-to-net calculations;

(2) the Royalty Payments in United States dollars which shall have accrued hereunder with respect to such Net Sales, with supporting calculations showing the applicable royalty rate applied and any royalty reduction taken; and

(3) the rate of exchange with supporting calculations, determined in accordance with Section 9.5(b), used by Zai in determining the amount of United States dollars payable hereunder.

(e) **Royalty Payment**. After the receipt of each royalty report provided by Zai under Section 9.4(d) above, TPTX shall issue to Zai an invoice for the amount of Royalty Payment set forth therein. Zai shall pay to TPTX the royalties for each Calendar Quarter within [***] days after the receipt of the invoice from TPTX. If no royalty is due for any Calendar Quarter following commencement of the reporting obligation, Zai shall so report.

9.5. Payment.

(a) **Mode of Payment**. All payments to be made under this Agreement shall be made in U.S. Dollars and shall be paid by electronic transfer in immediately available funds to such bank account in the United States as is designated in writing by TPTX. All payments shall be free and clear of any transfer fees or charges.

(b) **Currency Exchange Rate**. All payments under this Agreement shall be payable in U.S. Dollars. The rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars for calculating Net Sales in a Calendar Quarter (for purposes of both the royalty calculation and whether a Net Sales milestone has been achieved) shall be made at the average exchange rate as published by the Wall Street Journal for such Calendar Quarter, or such other source as the Parties may agree in writing.

(c) **Payment Timeline**. Except as otherwise provided in this Agreement, all payments to be made by one Party to the other Party under this Agreement shall be due within [***] days following such Party's receipt of an invoice from the other Party.

9.6. Audits.

(a) Zai shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with the GAAP), for a period not less than [***] years from the end of the Calendar Year to which they pertain, complete and accurate records in sufficient detail to properly reflect Net Sales and to enable any Milestone Payment payable hereunder to be determined.

(b) Upon the written request of TPTX, Zai shall permit, and shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by TPTX and reasonably acceptable to Zai, at TPTX's expense, to have access during normal business hours to such records of Zai or its Affiliates as may be reasonably necessary to verify the accuracy of the payments hereunder for any Calendar Year ending not more than [***]. These rights with respect to any Calendar Year shall [***] end of any such Calendar Year and shall be limited to once each Calendar Year (provided that the foregoing frequency limit shall not apply if TPTX has cause). TPTX shall provide Zai with a copy of the accounting firm's written report [***]. If such accounting firm concludes that an underpayment was made, then Zai shall pay the amount due within [***] days of the date TPTX delivers to Zai such accounting firm's written report so concluding. If such accounting firm concludes that an overpayment was made, then such overpayment shall be credited against any future payment due to TPTX hereunder (if there is no future payment due, then TPTX shall promptly refund such overpayment to Zai). TPTX shall bear the full cost of such audit unless such audit discloses that the additional payment payable by Zai for the audited period is more than [***] of the amount otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

(c) TPTX shall treat all financial information subject to review under this Section 9.6 in accordance with the confidentiality provisions of ARTICLE 10, and, prior to commencing such audit, shall cause its accounting firm to enter into a confidentiality agreement with Zai obligating it to treat all such financial information in confidence pursuant to such confidentiality provisions. Such accounting firm shall not disclose Zai's Confidential Information to TPTX, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Zai or the amount of payments to or by Zai under this Agreement.

(d) Zai shall include in each relevant sublicense granted by it a provision requiring any Sublicensee to maintain records of sales of Products made pursuant to such sublicense, and to grant access to such records by an accounting firm to the same extent and under the same obligations as required of Zai under this Agreement. TPTX shall advise Zai in advance of each audit of any such Sublicensee with respect to the Net Sales of the Products either by TPTX or its designated auditor under the terms of such Sublicensee agreement. TPTX shall provide Zai with a summary of the results received from the audit and, if Zai so requests, a copy of the audit report. TPTX shall pay the full costs charged by the accounting firm, unless the audit discloses that the additional payments payable to TPTX for the audited period is more than [***] from the amounts otherwise paid for that audited period, in which case Zai shall pay the reasonable fees and expenses charged by the accounting firm.

9.7. Interest. Each Party shall pay interest on any amounts overdue under this Agreement [***] from the day payment was initially due; provided, however, that in no case shall such interest rate exceed the highest rate permitted by Applicable Laws. The payment of such interest shall not foreclose a Party from exercising any other rights it may have because any payment is overdue.

9.8. Taxes.

(a) **Withholding VAT Taxes**. [***] any deduction for any VAT that Zai may be required by Applicable Laws in the Territory to pay to any tax authorities in the Territory. TPTX will use Commercially Reasonable Efforts to assist Zai to minimize and obtain all available exemptions from such VAT, but if applicable, Zai will pay any such VAT to the proper taxing authorities upon receipt of a valid VAT invoice (where such invoice is required under local VAT laws). If Zai is required to deduct or withhold any VAT on any payments payable by Zai under this Agreement (the "**Withholding VAT Taxes**"), Zai will (i) pay such Withholding VAT Tax on behalf of TPTX to the appropriate Governmental Authority, (ii) furnish TPTX with proof of payment of such Withholding VAT Tax within [***] Business Days following such payment., and (iii) [***]. Zai will promptly provide to TPTX applicable receipts evidencing payment of such Withholding VAT Taxes and other documentation reasonably requested by TPTX. Upon Zai's request, TPTX shall provide reasonable assistance to Zai for Zai to recover any such Withholding VAT Taxes. For clarity, [***].

(b) **Withholding Incomes Taxes**. If other than the Withholding VAT Taxes, any deductions or withholdings are required by Applicable Laws in the Territory to be paid to any tax authorities in the Territory from any payment from Zai to TPTX hereunder (including those on any incomes of TPTX) (the "**Withholding Income Taxes**", together with the Withholding VAT Taxes, the "**Withholding Taxes**"):

(i) **Upfront Payment and Development Milestone Payments**. With respect to the Upfront Payment and Development Milestones Payments payable by Zai to TPTX, Zai shall (A) pay Withholding Income Taxes on such payments on behalf of TPTX to the appropriate Governmental Authority in the [***]; (B) furnish TPTX with proof of payment of such Withholding Income Taxes within [***] Business Days following such payment; and (C) [***]. Zai will promptly provide to TPTX applicable receipts evidencing payment of such Withholding Incomes Taxes and other documentation reasonably requested by TPTX. Upon TPTX's request, Zai shall provide reasonable assistance to TPTX for TPTX to recover any such Withholding Income Taxes. [***].

(ii) **Net Sales Milestone Payments and Royalty Payments**. With respect to the Net Sales Milestone Payments and Royalty Payments payable by Zai to TPTX, Zai shall (A) pay Withholding Income Taxes on such payments on behalf of TPTX to the appropriate Governmental Authority in the Territory; (B) furnish TPTX with proof of payment of such Withholding Income Taxes within [***] Business Days following such payment; and (C) deduct such Withholding Income Taxes from the payment payable to TPTX. Zai will promptly provide to TPTX applicable receipts evidencing payment of such Withholding Incomes Taxes and other documentation reasonably requested by TPTX. Upon TPTX's request, Zai shall provide reasonable assistance to TPTX for TPTX to recover any such Withholding Income Taxes. For clarity, in the event that TPTX actually recovers any such Withholding Income Taxes from the applicable Governmental Authority to which such Taxes were paid, such recovered Withholding Income Taxes shall be retained by TPTX with no obligation to Zai.

(c) **Cooperation**. Zai shall inform TPTX in writing of any prescribed forms that are necessary to claim a reduced rate or exemption from any Withholding Taxes and if TPTX is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, applicable Withholding Tax, TPTX shall use Commercially Reasonable Efforts to deliver to Zai or the appropriate Governmental Authority (with the assistance of Zai to the extent that this is reasonably required) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Zai of its obligation to withhold such Withholding Taxes, and Zai shall apply the reduced rate of withholding if so permitted by Applicable Laws.

(d) **Assignment**. If TPTX assigns, transfers or otherwise disposes of some or all of its rights and obligations under this Agreement to any Person and if, as a result of such action, the Withholding Taxes required by Applicable Laws with respect to payments under this Agreement is increased, then any amount payable to TPTX's assignee or transferee under this Agreement shall be limited to the amount that would have been payable to TPTX had no such assignment, transfer or disposal occurred. If Zai assigns, transfers or otherwise disposes of some or all of its rights and obligations under this Agreement to any Person and if, as a result of such action, the Withholding Income Taxes required by Applicable Laws with respect to payments under this Agreement is increased, then any amount payable by Zai's assignee or transferee under this Agreement shall be increased to ensure that TPTX receives the amount that would have been payable to TPTX had no such assignment, transfer or disposal occurred and it shall be a condition precedent to any such assignment, transfer or disposal that such assignee or transferee shall assume Zai's withholding and payment obligations as set forth in this Section 9.8.

9.9. Blocked Currency. If by Applicable Laws in a region in the Territory, conversion into U.S. Dollars or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Zai shall promptly notify TPTX and, thereafter, amounts accrued in such country or region under this ARTICLE 9 shall be paid to TPTX (or its designee) in such country or region in local currency by deposit to an escrow account in a local bank designated by TPTX and to the credit of TPTX, unless the Parties otherwise agree.

ARTICLE 10

CONFIDENTIALITY; PUBLICATION

10.1. Nondisclosure Obligation.

(a) For the Term and [***] years thereafter, the Party receiving (the "**Receiving Party**") the Confidential Information of the other Party (the "**Disclosing Party**") shall keep confidential and not publish, make available or otherwise disclose any Confidential Information to any Third Party, without the express prior written consent of the Disclosing Party; provided, however, the Receiving Party may disclose the Confidential Information to those of its Affiliates, officers, directors, employees, agents, consultants or independent contractors (including licensees and sublicensees) of such Receiving Party who need to know the Confidential Information in connection with exercising rights or performing obligations as contemplated by this Agreement or any other written agreement between the Parties and are bound by confidentiality and non-use obligations with respect to such Confidential Information consistent with those set forth herein; the Receiving Party shall remain responsible for the compliance by its Affiliates, officers, directors, employees, agents, consultants or independent contractors (including licensees and sublicensees) with such confidentiality and non-use obligations. The Receiving Party shall exercise at a minimum the same degree of care it would exercise to protect its own Confidential Information (and in no event less than a reasonable standard of care) to keep confidential the Confidential Information. The Receiving Party shall use the Confidential Information solely in connection with exercising rights or performing obligations as contemplated by this Agreement or any other written agreement between the Parties.

(b) It shall not be considered a breach of this Agreement if the Receiving Party discloses Confidential Information or either Party discloses the terms and conditions of this Agreement in order to comply with a lawfully issued court or governmental order or with a requirement of Applicable Laws or the rules of any internationally recognized stock exchange; provided that: (i) the Receiving Party gives prompt written notice of such disclosure requirement to the Disclosing Party and cooperates with the Disclosing Party's efforts to oppose such disclosure or obtain a protective order for such Confidential Information, and (ii) if such disclosure requirement is not quashed or a protective order is not obtained, the Receiving Party shall only disclose those portions of the Confidential Information that it is legally required to disclose and shall make a reasonable effort to obtain confidential treatment for the disclosed Confidential Information. To the extent there is any conflict between this ARTICLE 10 and any other agreement related to Confidential Information entered into between the Parties, the terms of this ARTICLE 10 shall control to the extent of such conflict.

(c) **Scientific Publication**. The JSC shall discuss the publication strategy for the publication of scientific papers, abstracts, meeting presentations and other disclosure of the results of the Clinical Trials carried out under this Agreement, taking into consideration the Parties' interest in publishing the results of the Product Development work in order to obtain recognition within the scientific community and to advance the state of scientific knowledge, and the need to protect Confidential Information, intellectual property rights and other business interests of the Parties. Subject to the immediately preceding sentence, Zai shall provide TPTX with the opportunity to review and comment on any proposed publication that pertains to the Products at least [***] days prior to its intended submission for publication which shall only be permitted in the Territory and as to data, results and the like with respect to patients or subjects located in the Territory. TPTX shall provide Zai with its comments, if any, within [***] days after the receipt of such proposed publication. Zai shall consider in good faith the comments provided by TPTX and shall comply with TPTX's request to: (a) remove any and all Confidential Information of TPTX from such proposed publication; and (b) delay the submission for a period up to [***] days as may be reasonably necessary to seek patent protection for the information disclosed in the proposed publication. Zai agrees to acknowledge the contribution of TPTX and TPTX's employees in all publication as scientifically appropriate. Zai shall have no right to publish outside the Territory (including in any form or media that may be distributed outside the Territory) without TPTX's prior written consent.

10.2. Publicity; Use of Names.

(a) Subject to permitted disclosures under Section 10.1(b) or under Section 10.2(c), each of the Parties agrees not to disclose to any Third Party the terms and conditions of this Agreement without the prior approval of the other Party, except to (i) advisors (including consultants, financial advisors, attorneys and accountants), (ii) bona fide potential and existing investors, acquirers, merger partners or other financial or commercial partners on a need to know basis for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship, in each case under circumstances that reasonably protect the confidentiality thereof, (iii) to the extent necessary to comply with the terms of agreements with Third Parties, or (iv) to the extent required by Applicable Laws, including securities laws and regulations. Notwithstanding the foregoing, the Parties agree upon the initial press release(s) to announce the execution of this Agreement as contained in Schedule 10.2(a); thereafter, TPTX and Zai may each disclose to Third Parties the information contained in such press release(s) or in any other press releases or disclosures made in accordance with this Section 10.2, without the need for further approval by the other.

(b) The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding a Product for use in the Field in the Territory and other activities in connection with this Agreement, beyond what may be strictly required by Applicable Laws and the rules of a recognized stock exchange, and each Party may make such disclosures from time to time with respect to a Product in the case of TPTX, with prior notice to Zai, and in the case of Zai, with the prior written approval of TPTX, which approval shall not be unreasonably withheld, conditioned or delayed. Such disclosures may include achievement of significant events in the Development (including regulatory process) or Commercialization of a Product for use in the Field in the Territory. Unless otherwise requested by the applicable Party, Zai shall indicate that TPTX is the licensor of a Product and Licensed Technology in each public disclosure issued by Zai regarding a Product. When Zai elects to make any public disclosure under this Section 10.2(b) or TPTX elects to make any public disclosure regarding results and significant developments regarding a Product for use in the Field in the Territory under this Section 10.2(b), the disclosing Party shall give the other Party reasonable notice to review and comment on such statement, and, in the case of proposed disclosures by Zai, (i) if TPTX does not notify Zai in writing within [***] days or such shorter period if required by Applicable Laws of any reasonable objections, as contemplated in this Section 10.2(b), such disclosure shall be deemed approved, and (ii) if TPTX does notify Zai in writing within the time period set forth in clause (i) above, and reasonably determines that such public disclosure would entail the public disclosure of TPTX's Confidential Information or of patentable Inventions upon which patent applications should be filed prior to such public disclosure, such public disclosure shall be delayed for such period as may be reasonably necessary for deleting any such Confidential Information of TPTX, or the drafting and filing of a patent application covering such Inventions; provided that such additional period shall not exceed [***] days from the proposed date of the public disclosure, and, in any event, TPTX shall work diligently and reasonably to agree on the text of any proposed disclosure in an expeditious manner. The principles to be observed in such disclosures shall be accuracy, compliance with Applicable Laws and regulatory guidance documents, and reasonable sensitivity to potential negative reactions of applicable Regulatory Authorities.

(c) The Parties acknowledge the need to keep investors and others informed regarding such Party's business under this Agreement, including as required by Applicable Laws or the rules of a recognized stock exchange. To the extent a Party is publicly listed or becomes publicly listed, and subject to Section 10.2(b) as applicable, such Party may issue press releases or make disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, as reasonably necessary to comply with laws or regulations or for appropriate market disclosure; provided that each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties shall consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws.

10.3. Equitable Relief. Each Party acknowledges that its breach of this ARTICLE 10 would cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this ARTICLE 10 by the other Party.

ARTICLE 11

REPRESENTATIONS, WARRANTIES, AND COVENANTS

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

(a) it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder;

(b) (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement; and

(d) all consents, approvals and authorization from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with execution of this Agreement have been obtained.

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

(a) TPTX is the sole owner of the Licensed Patents and it has the right under the Licensed Technology to grant the licenses to Zai as purported to be granted pursuant to this Agreement;

(b) there is no agreement between TPTX or its Affiliates with any Third Party pursuant to which TPTX or its Affiliates has in-licensed any Licensed Technology;

(c) Schedule 1.70 sets forth a complete and accurate list all Licensed Patents as of the Effective Date;

(d) neither TPTX nor any of its Affiliates is a party to any license or similar agreement under which it has granted or agreed to grant a license to any Third Party to any Licensed Technology that would conflict with the rights or licenses granted to Zai under this Agreement;

(e) TPTX and its Affiliates and their employees, consultants and contractors involved in the Development of the Licensed Compound and Products are not, and have not been, debarred or disqualified by any Regulatory Authority as of the Effective Date, and have complied in all material respects with all Applicable Laws in connection with the Development of the Licensed Compound and Product;

(f) [***]; and

(g) no claim or action has been brought against TPTX or, to TPTX's knowledge, threatened in writing to TPTX, by any Third Party alleging that (i) the Licensed Patents are invalid or unenforceable, or (ii) the exploitation of the Licensed Compound or Product infringes the Patents or misappropriates the Know-How of any Third Party; and, to TPTX's knowledge, no interference, opposition, cancellation or other protest proceeding has been filed against a Licensed Patent owned by TPTX.

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

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

(b) Zai and its Affiliates are not, and have not been, debarred or disqualified by any Regulatory Authority.

11.4. Covenants of Each Party. Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, it shall, and shall cause its Affiliates, Sublicensees to, comply with the Clinical Development Plan, all agreements referenced herein, all Applicable Laws, including as applicable, cGMP, GCP, GLP, and GSP standards, and shall not employ or engage any party who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Without limiting the foregoing, (a) Zai will conduct its obligations with respect to Joint Global Studies in the Territory under the Global Development Plan in strict adherence with the study design set forth in the protocol for such Joint Global Studies 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 TPTX in connection therewith, and (b) Zai will only engage Clinical Trial sites under the Clinical Development Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the NMPA.

11.5. Compliance with Anti-Corruption Laws.

(a) Notwithstanding anything to the contrary in the Agreement, each Party hereby covenants to each other that:

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

(ii) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it shall, on request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or shall provide details of any exception to the foregoing; and

(iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 11.5, and upon request of the other Party, upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section 11.5. Acceptance of a proposed Third Party auditor may not be unreasonably withheld or delayed by either Party. It is expressly agreed that the costs related to the Third Party auditor shall be fully paid by the Party requesting the audit, and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

(b) To its knowledge as of the Effective Date and during the Term, neither Zai nor any of its subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of Zai or any of its subsidiaries or any of their Affiliates:

(i) has taken or shall take any action in violation of any applicable anticorruption law, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78 dd-1 et seq.); or

(ii) has corruptly, offered, paid, given, promised to pay or give, or authorized or shall corruptly, offer, pay give, promise to pay or give or authorize, the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 11.5(d) below), for the purposes of:

(iii) has influenced or shall influence any act or decision of any Public Official in his official capacity;

(iv) has induced or shall induce such Public Official to do or omit to do any act in violation of his lawful duty;

(v) has secured or shall secure any improper advantage; or

(vi) has induced or shall induce such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever.

(c) As of the Effective Date, none of the officers, directors, employees, of Zai or of any of its Affiliates or agents acting on behalf of Zai or any of its Affiliates, in each case that are employed or reside outside the United States, are themselves Public Officials.

(d) For purposes of this Section 11.5, "**Public Official**" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

11.6. NO OTHER REPRESENTATIONS OR WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL SUCH REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 12

INDEMNIFICATION

12.1. By Zai. Zai shall indemnify and hold harmless TPTX, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**TPTX Indemnitee**(**s**)") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) (individually and collectively, "**Losses**") incurred by them in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Claims**") arising after the Effective Date to the extent arising from (a) the Development, packaging or labeling, Manufacture (after the Manufacturing Technology Transfer), use and Commercialization of the Products in the Territory, (b) the packaging or labeling of the Products outside the Territory, (c) the gross negligence, illegal conduct or willful misconduct of Zai or any of its Affiliates or Sublicensees, (d) Zai's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, or (e) TPTX holding any Regulatory Approval for any Product for Zai's benefit in accordance with Section 6.1, in each case of clauses (a) through (e) above except to the extent such Losses arise from, are based on, or result from any activity or occurrence for which TPTX is obligated to indemnify the Zai Indemnitees under Section 12.2.

12.2. By TPTX. TPTX shall indemnify and hold harmless Zai, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Zai Indemnitee(s)**") from and against all Losses incurred by them in connection with any Claims to the extent arising from (a) Manufacture, Development, use and Commercialization of the Licensed Compounds and Products outside the Territory or in the Territory with respect to Global Studies or any Manufacturing activities in the Territory, in each such case by TPTX or any of its Affiliates or licensees (other than Zai or its Affiliates or Sublicensees); (b) the gross negligence, illegal conduct or willful misconduct of TPTX or any of its Affiliates or licensees (other than Zai), or (c) TPTX's breach of any of its representations, warranties or covenants made in or pursuant to this Agreement or any covenants or obligations set forth in or entered into pursuant to this Agreement, in each case of clauses (a) through (c) above, except to the extent Losses arise from, are based on, or result from any activity or occurrence for which TPTX is obligated to indemnify the Zai Indemnitees under Section 12.1.

12.3. Defined Indemnification Terms. Either of the Zai Indemnitee or the TPTX Indemnitee shall be an "**Indemnitee**" for the purpose of this ARTICLE 12, and the Party that is obligated to indemnify the Indemnitee under Section 12.1 or Section 12.2 shall be the "**Indemnifying Party**."

12.4. Defense. If any such Claims are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnitee; provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such Claim, subject to the terms of this ARTICLE 12.

12.5. Settlement. The Indemnifying Party may settle any such Claim or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld or delayed.

12.6. Notice. The Indemnitee shall notify the Indemnifying Party promptly of any Claim with respect to which it seeks indemnification under Sections 12.1 or 12.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

12.7. Permission by Indemnifying Party. The Indemnitee may not settle any such Claim or otherwise consent to an adverse judgment in any such Claim or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

12.8. Insurance. Each Party 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. Each Party shall provide the other Party with evidence of such insurance upon request and shall provide the other Party with written notice at least [***] days prior to such Party's decision or receipt of notice from the insurance company, as applicable, with respect to the cancellation, non-renewal or material decrease in the coverage level of such insurance. It is understood that such insurance shall not be construed to create a limit of either Party's liability. Zai shall impose substantially identical obligations on its Affiliates (to the extent not named insureds under Zai's coverages) and Sublicensees.

12.9. LIMITATION OF LIABILITY. SUBJECT TO AND WITHOUT LIMITING (A) THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTIONS 12.1 OR 12.2, (B) LIABILITY AS A RESULT OF A BREACH OF ARTICLE 10, (C) LIABILITY FOR MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY THE OTHER PARTY, OR (D) LIABILITY FOR BREACH OF COVENANTS UNDER SECTION 2.6, NEITHER PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

ARTICLE 13

INTELLECTUAL PROPERTY

13.1. Ownership.

(a) As between the Parties, (i) TPTX shall remain the sole and exclusive owner of all Licensed Technology and (ii) Zai shall remain the sole and exclusive owner of all Zai IP.

(b) Ownership of all Inventions (other than any Invention that is an Improvement) shall be allocated based on inventorship, as determined in accordance with the rules of inventorship under the United States patent laws. All Improvements, whether invented, discovered, generated or made solely by either Party, its Affiliates, or its or its Affiliates' employees, agents or independent contractors or jointly by both Parties, their Affiliates, or their or their Affiliates' employees, agents or independent contractors, shall be the sole property of TPTX and shall be included in the Licensed Technology (if within the scope of such definition) and included in the licenses and rights granted to Zai. A Party shall own all Inventions (in the case of Zai, other than Improvements) that are invented, discovered, generated or made solely by it, its Affiliates, or its or its Affiliates' employees, agents or independent contractors ("**Sole Inventions**"), and (i) TPTX's Sole Inventions shall be included in the Licensed Technology (if within the scope of such definition) and included in the licenses and rights granted to Zai by TPTX hereunder; and (ii) Zai's Sole Inventions (which are not Improvements) shall be included in the Zai IP (if within the scope of such definition) and included in the licenses and rights granted to TPTX by Zai hereunder. The Parties shall jointly own all Inventions (other than Improvements) that are made jointly by a Party, its Affiliate, or its or its Affiliate's employees, agents or independent contractors together with the other Party, its Affiliates, or its or its Affiliate's employees, agents or independent contractors ("**Joint Inventions**"). Patents claiming the Joint Inventions shall be referred to as "**Joint Patents**." Each Party shall own an undivided equal interest in the Joint Inventions and Joint Patents, without a duty of accounting or an obligation to seek consent from the other Party for the exploitation or license of the Joint Inventions or Joint Patents (subject to the licenses granted to the other Party under this Agreement).

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

13.2. Disclosure of Inventions. Each Party shall promptly disclose to the other Party all Inventions, including all invention disclosure or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating to such Inventions, and shall also promptly respond to reasonable requests from the other Party for additional information relating to such Inventions.

13.3. Patent Prosecution.

(a) **Licensed Patents and Joint Patents in the Territory**. TPTX shall have the first right, but not the obligation, to conduct Patent Prosecution and maintenance of (i) the Licensed Patents in the Territory and (ii) Joint Patents in the Territory, at its sole cost. TPTX shall consult with Zai and keep Zai reasonably informed of the Patent Prosecution or maintenance of the Licensed Patents and Joint Patents in the Territory and shall provide Zai with all material correspondence received from any patent authority in the Territory in connection therewith. In addition, TPTX shall provide Zai with drafts of all proposed material filings and correspondence to any patent authority in the Territory in connection with the Patent Prosecution or maintenance of the Licensed Patents or Joint Patents for Zai's review and comment prior to the submission of such proposed filings and correspondence. TPTX shall consider in good faith Zai's comments on such Patent Prosecution or maintenance but shall have final decision-making authority under this Section 13.3(a). Further, TPTX shall notify Zai of any decision to cease Patent Prosecution or maintenance of any Licensed Patent or Joint Patent in the Territory at least [***] days before any due date for filing, payment or other action to avoid loss of rights, in which case Zai shall have the right to continue the Patent Prosecution or maintenance of such Licensed Patent or Joint Patent in the Territory at Zai's discretion and expense. If Zai decides to take over Patent Prosecution or maintenance of a Licensed Patent or Joint Patent in such region(s) in the Territory, then TPTX shall promptly deliver to Zai copies of all necessary files related to such Licensed Patent or Joint Patent in such region(s) in the Territory and shall take all actions and execute all documents reasonably necessary for Zai to assume such responsibility. For the avoidance of doubt, Zai's assumption of responsibility for Patent Prosecution or maintenance of any Licensed Patent or Joint Patent in any region(s) in the Territory pursuant to this Section 13.3(a) shall not change the Parties' respective ownership rights with respect to such Licensed Patent or Joint Patent.

(b) **Zai Patents**. Zai shall, at its sole cost and expense, have the sole right, but not the obligation, in the Territory and the first right, but not the obligation, outside the Territory, to conduct the Patent Prosecution and maintenance of any Patents within the Zai IP (the "**Zai Patent**"). Zai shall keep TPTX reasonably informed of the status of all actions taken, and shall consider in good faith TPTX's recommendations with respect to the Zai Patents prosecuted by Zai worldwide. Further, Zai shall notify TPTX of any decision to cease Patent Prosecution or maintenance of any Zai Patent outside the Territory at least [***] days before any due date for filing, payment or other action to avoid loss of rights, in which case TPTX shall have the right to continue the Patent Prosecution or maintenance of such Zai Patent outside the Territory at TPTX's discretion and expense. If TPTX decides to take over Patent Prosecution or maintenance of a Zai Patent outside the Territory, then Zai shall promptly deliver to TPTX copies of all necessary files related to such Zai Patent outside the Territory and shall take all actions and execute all documents reasonably necessary for TPTX to assume such responsibility. For the avoidance of doubt, TPTX's assumption of responsibility for Patent Prosecution or maintenance of any Zai Patent outside the Territory pursuant to this Section 13.3(b) shall not change the Parties' respective ownership rights with respect to such Licensed Patent or Joint Patent.

(c) **Joint Patents Outside the Territory**. TPTX shall have the sole decision-making authority, at its sole cost and expense, over the Patent Prosecution and maintenance of Joint Patents outside the Territory.

13.4. Enforcement.

(a) Each Party shall notify the other within [***] Business Days of becoming aware of any alleged or threatened infringement by a Third Party of any of the Licensed Patents (including any Joint Patents in the Territory), which infringement adversely affects or is expected to adversely affect any Product in the Field in the Territory, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the Licensed Patents (including any Joint Patents in the Territory) in the Territory (collectively "**Product Infringement**").

(b) Zai shall have the first right to bring and control any legal action in connection with such Product Infringement in the Territory at its own expense as it reasonably determines appropriate. If Zai does not bring such legal action prior to the earlier of: (i) [***] days following Zai's receipt or delivery of the notice under Section 13.4(a), or (ii) [***] days before the deadline, if any, set forth in the Applicable Laws for the filing of such actions, or discontinues the prosecution of any such action after filing without abating such infringement, TPTX shall have the right to bring and control any legal action in connection with such Product Infringement at its own expense as it reasonably determines appropriate.

(c) TPTX shall have the exclusive right, but not the obligation, to bring and control any legal action in connection with any alleged or threatened infringement by a Third Party of any of the Licensed Patents (other than Joint Patents) that is not a Product Infringement, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the Licensed Patents (other than Joint Patents), at its own expense as it reasonably determines appropriate.

(d) Zai shall have the first right, but not the obligation, to enforce the Joint Patents in the Territory for any infringement that is not a Product Infringement at its own expense as it reasonably determines appropriate. TPTX shall have the first right, but not the obligation, to enforce the Joint Patents outside the Territory for any infringement at its own expense as it reasonably determines appropriate. If the Party with the first right of enforcement in respect of Joint Patents under this Section 13.4(d) decides not to bring such legal action in any jurisdiction(s) subject to its first right, it shall so inform the other Party promptly and the other Party shall have the right, but not the obligation, to bring and control any legal action in connection with such infringement in such jurisdiction(s) at its own expense as it reasonably determines appropriate.

(e) TPTX shall have the first right to bring and control any legal action in connection with any alleged or threatened infringement by a Third Party of any of the Zai Patents (other than Joint Patents), which infringement adversely affects or is expected to adversely affect any Product in the Field outside the Territory, and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the Zai Patents (other than Joint Patents) outside the Territory, at its own expense as it reasonably determines appropriate. If TPTX does not bring such legal action prior to the earlier of: (i) [***] days following receipt or delivery of notice between the Parties regarding such alleged infringement, or (ii) [***] days before the deadline, if any, set forth in the Applicable Laws for the filing of such actions, or discontinues the prosecution of any such action after filing without abating such infringement, Zai shall have the right to bring and control any legal action in connection with infringement at its own expense as it reasonably determines appropriate. Except as otherwise provided in this Section 13.4(e), Zai shall have the exclusive right, but not the obligation, to bring and control any legal action in connection with any alleged or threatened infringement by a Third Party of any of the Zai Patents (other than Joint Patents), and any related declaratory judgment, opposition, or similar action by a Third Party alleging the invalidity, unenforceability or non-infringement of any of the Zai Patents (other than Joint Patents), at its own expense as it reasonably determines appropriate.

(f) At the request of the Party bringing an action related to Product Infringement or otherwise as described in this Section 13.4, 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 Laws to pursue such action, at each such Party's sole cost and expense. In connection with an action related to Product Infringement or otherwise as described in this Section 13.4, the Party bringing the action shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in the Licensed Patents, Zai Patents or Joint Patents, as applicable, without the prior written consent of the other Party. The enforcing Party shall keep the non-enforcing Party reasonably informed of the status of any action it brought in connection with such Product Infringement or otherwise as described in this Section 13.4. The non-enforcing Party shall be entitled to attend any substantive meetings, hearings, or other proceedings related to any such action pursued by the enforcing Party. The enforcing Party shall provide the non-enforcing Party with copies of all pleadings and other documents to be filed with the court reasonably in advance and shall consider in good faith reasonable and timely input from the non-enforcing Party during the course of the action.

(g) Any recoveries resulting from enforcement action relating to a claim of Product Infringement or otherwise as described in this Section 13.4 shall be first applied against payment of the enforcing Party's costs and expenses in connection therewith and then the non-enforcing Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall [***].

13.5. Defense.

(a) Each Party shall notify the other in writing of any allegations it receives from a Third Party that the Development, Manufacture, use, Commercialization or other exploitation of any Licensed Compound or Product or any embodiment of any technology or intellectual property licensed by a Party under this Agreement infringes the intellectual property rights of such Third Party. Such notice shall be provided promptly, but in no event after more than [***] days following receipt of such allegations. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties.

(b) As between the Parties, Zai shall have the first right, but not the obligation to control and be solely responsible for the defense of any such suit against Zai, at Zai's sole cost and expense; provided, however, Zai shall not enter into any compromise or settlement relating to such suit that (i) admits the invalidity or unenforceability of any Licensed Patents or Joint Patents; or (ii) requires abandonment of any Licensed Patents or Joint Patents; or (iii) contemplates payment or other action by TPTX or has a material adverse effect on TPTX's business, in all cases ((i) through (iii)), without obtaining the prior written consent of TPTX.

(c) If Zai decides not to bring such legal action subject to its first right, it shall so inform TPTX promptly and TPTX shall have the right to bring and control any such legal action in connection with such infringement in the Territory at its own expense as it reasonably determines appropriate; provided, however, TPTX shall not enter into any compromise or settlement relating to such suit that (i) admits the invalidity or unenforceability of any Licensed Patents or Joint Patents; or (ii) requires abandonment of any Licensed Patents or Joint Patents; or (iii) contemplates payment or other action by Zai or has a material adverse effect on Zai's business, in all cases ((i) through (iii)), without obtaining the prior written consent of Zai.

(d) Upon the defending Party's request and at the defending Party's expense, the non-defending Party shall provide reasonable assistance to the defending Party for such defense and shall join such suit if deemed a necessary party. If the non-defending Party does not join such suit, the defending Party shall keep the non-defending Party reasonably informed of the status of such suit. The non-defending Party shall be entitled to attend any substantive meetings, hearings, or other proceedings related to such suit. The defending Party shall provide the non-defending Party with copies of all pleadings and other documents to be filed with the court reasonably in advance and shall consider in good faith reasonable and timely input from the non-defending Party during the course of the suit.

ARTICLE 14

TERMS AND TERMINATION

14.1. Term and Expiration.

(a) **Term**. The term of this Agreement shall be effective as of the Effective Date, and shall continue in effect until the expiration of the last Royalty Term with respect to any Product in any region in the Territory (the "**Term**", and the date of such expiration with respect to such region, the "**Expiration Date**").

(b) **Expiration of Royalty Term**. On a region-by-region basis, upon the expiration of the Royalty Term for a given Product in a given region, the licenses granted by TPTX to Zai under Section 2.1 of this Agreement in such region with respect to such Product in the Field shall become fully paid-up, perpetual, irrevocable and sublicenseable in multiple tiers.

(c) **Supply after Expiration**. In the event that no Manufacturing Technology Transfer has occurred before [***] in which the expiration is to occur, the Parties shall discuss in good faith the terms and conditions on which TPTX would supply Products to Zai after the Expiration Date; provided, however, that if the Parties fail to reach such an agreement before [***].

14.2. Termination for Mutual Agreement. This Agreement may be terminated by the Parties' mutual written agreement.

14.3. Termination for Convenience. Zai shall have the right to terminate this Agreement in its entirety for any or no reason upon [***] days' written notice to TPTX. Zai shall terminate this Agreement upon [***] days' written notice to TPTX if it determines that it shall permanently discontinue all Development and Commercialization activities with respect to the Product under this Agreement.

14.4. Termination for Material Breach.

(a) This Agreement may be terminated in its entirety at any time during the Term upon [***] days' (or [***] days' with respect to any payment breach) written notice by either Party if the other Party is in material breach of this Agreement and, if such breach is curable, such breach has not been cured within [***] days (or [***] days with respect to any payment breach) of such written notice.

(b) Notwithstanding the foregoing, if the alleged breaching Party disputes the existence or materiality of the alleged breach, the other Party shall not have the right to terminate this Agreement unless and until it is determined in accordance with ARTICLE 15 that the alleged breaching Party has materially breached this Agreement and fails to cure such breach within [***] days after such determination.

14.5. Termination for Insolvency. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization under the Chapter 7 of the United States of Bankruptcy Code or other similar Applicable Law or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within ninety (90) days of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

14.6. Termination for Patent Challenge. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, TPTX may terminate this Agreement in its entirety (a) immediately upon written notice to Zai if Zai or any of its Affiliates or Sublicensees commences a legal, administrative or other action challenging the validity, enforceability or scope of any Licensed Patent or (b) within [***] day written notice to Zai if Zai or its Affiliates or Sublicensees commences a legal, administrative or other action challenging the validity, enforceability or scope of any Patent (other than any Licensed Patent) owned or Controlled by TPTX or its Affiliates anywhere in the world, unless such action is withdrawn during such [***]-day period. Notwithstanding the foregoing, if Zai promptly terminates the sublicense agreement of any Sublicensee that commences a legal action challenging the validity, enforceability or scope of any Licensed Patents anywhere in the world, TPTX shall not have the right to terminate this Agreement under this Section 14.6.

14.7. Termination for Acquisition of Third Party by a Party. Each Party shall have the right to terminate this Agreement to the extent permitted under and in accordance with Section 2.6(b)(ii).

14.8. Election to Terminate. If either Party has the right to terminate under Sections 14.3 through 14.6, it may at its sole option, elect either to (a) terminate this Agreement and pursue any legal or equitable remedy available to it or (b) maintain this Agreement in effect and pursue any legal or equitable remedy available to it.

14.9. Effects of Termination.

(a) Upon the termination of this Agreement for any reason, all rights and licenses granted to Zai herein shall immediately terminate, and all sublicenses of such rights and licenses shall also terminate. Upon termination of this Agreement, if a Sublicensee is then in good standing under its sublicense agreement with Zai, then at TPTX's sole discretion, TPTX may grant to such Sublicensee a direct license under the Licensed Technology that is the same scope as the sublicense granted by Zai on substantially the same terms and conditions set forth in this Agreement, and Section 14.9(b) below shall not apply to such Sublicensee. Termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.

(b) Upon termination of this Agreement for any reason, the following additional provisions shall apply:

(i) **Reversion of Rights to TPTX; Extension of License to TPTX**. Any rights and licenses with respect to the Product granted to Zai under this Agreement shall immediately terminate, and all such rights shall revert back to TPTX. In addition, in the event that this Agreement is terminated by the Parties pursuant to Section 14.2, by Zai pursuant to Section 14.3 or by TPTX pursuant to Section 14.4, 14.5, 14.6, or 14.7, the licenses granted by Zai to TPTX pursuant to Section 2.4 shall automatically be extended to include the Territory.

(ii) **Regulatory Materials; Data**. Zai shall, and shall cause its Affiliates and Sublicensees to, [***], to the maximum extent permitted by Applicable Laws at the time of any such termination to promptly (1) assign all Regulatory Submissions and Regulatory Approvals and pricing and reimbursement approvals of Products to TPTX, and (2) assign all data generated by or on behalf of Zai or its designee while conducting Development or Commercialization activities under this Agreement to TPTX or its designee, including non-clinical and clinical studies conducted by or on behalf of Zai on Products and all pharmacovigilance data (including all Adverse Event database information) on Products.

(iii) **Trademarks**. Zai shall, and shall cause its Affiliates and Sublicensees, to promptly transfer and assign to TPTX, [***], all Product Marks.

(iv) **Transition Assistance**. Zai shall, and shall cause its Affiliates and Sublicensees, to provide assistance, [***], as may be reasonably necessary or useful for TPTX or its designee to commence or continue Developing or Commercializing Products in the Territory for a period of at least [***] days after the effective date of such termination (the "**Transition Period**") to the extent Zai is then performing or having performed such activities, including transferring or amending as appropriate, upon request of TPTX, any agreements or arrangements with Third Party to Develop and Commercialize the Products in the Territory. To the extent that any such contract between Zai and a Third Party is not assignable to TPTX or its designee, then Zai shall reasonably cooperate with TPTX to arrange to continue to and provide such services from such entity.

(v) **Ongoing Clinical Trial**. If at the time of such termination, any Clinical Trials for the Products are being conducted by or on behalf of Zai, then, at TPTX's election on a Clinical Trial-by-Clinical Trial basis: (1) Zai shall, and shall cause its Affiliates and Sublicensees to, (A) continue to conduct such Clinical Trial during the Transition Period or another period of time as determined by TPTX after the effective date of such termination at TPTX's cost, and (B) after such period, to (y) fully cooperate with TPTX to transfer the conduct of all such Clinical Trial to TPTX or its designee or (z) continue to conduct such Clinical Trials, at TPTX's cost, for so long as necessary to enable such transfer to be completed without interruption of any such Clinical Trials and (C) TPTX shall assume any and all liability and costs for such Clinical Trial after the effective date of such termination, and (2) Zai shall, and shall cause its Affiliates and Sublicensees to, [***], orderly wind down the conduct of any such Clinical Trial which is not assumed by TPTX under clause (1).

(vi) **Inventory**. At TPTX's election and request, Zai shall (1) transfer to TPTX or its designee all inventory of the Product [***] then in possession or control of Zai, its Affiliates or Sublicensees; provided that TPTX shall pay Zai a price equal to Zai's costs for such Products or (2) (A) continue to use Commercially Reasonable Efforts to Commercialize all inventory of the Products then in possession or control of Zai during the Transition Period and make the corresponding payments, including any milestone payments or royalties to TPTX under this Agreement as though this Agreement had not been terminated and (B) after the Transition Period, transfer to TPTX or its designee any remaining inventory of the Product to TPTX or its designee at a price equal to Zai's costs for such Products.

(vii) **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party shall return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Product that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); provided that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic.

(c) **Other Remedies**. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

(d) **Termination by Zai Due to Material Breach**. Upon the termination of this Agreement by Zai pursuant to Section 14.4, 14.5 or 14.7 all of the provisions of Section 14.9(b) shall apply, except that [***].

14.10. Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. The following provisions shall survive the termination or expiration of this Agreement for any reason: [***].

ARTICLE 15

DISPUTE RESOLUTION

15.1. General. The Parties recognize that a claim, dispute or controversy may arise relating to this Agreement or to the breach, enforcement, interpretation or validity of 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. Continuance of Rights and Obligations during Pendency of Dispute Resolution. If there are any Disputes in connection with this Agreement, including Disputes related to termination of this Agreement under ARTICLE 14, all rights and obligations of the Parties shall continue until such time as any Dispute has been resolved in accordance with the provisions of this ARTICLE 15.

15.3. Escalation. Any Dispute shall be referred to the Executive Officers for attempted resolution. In the event the Executive Officers are unable to resolve such Dispute within [***] days of such Dispute being referred to them, then, upon the written request of either Party to the other Party, the Dispute shall be subject to arbitration in accordance with Section 15.4.

15.4. Arbitration.

(a) If the Parties fail to resolve the Dispute through escalation to the Executive Officers under Section 15.3, and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for final resolution by arbitration under the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**"), excepted as modified herein. Any disputes concerning the propriety of the commencement of the arbitration or the scope or applicability of this agreement to arbitrate shall be finally settled by the arbitral tribunal. The arbitration shall be conducted by a tribunal of three (3) arbitrators, each with at least fifteen (15) years of pharmaceutical industry experience. An arbitrator shall be deemed to meet this qualification unless a Party objects within [***] days after the arbitrator is nominated. Within [***] days after initiation of arbitration, each Party shall nominate one (1) arbitrator and the two (2) Party-nominated arbitrators shall nominate a third arbitrator, who shall serve as the chairperson of the tribunal, within [***] days of the second arbitrator's appointment. The seat of arbitration shall be [***] and the language of the proceedings, including all communications, shall be English.

(b) The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction, and the Parties undertake to carry out any award without delay. The arbitral tribunal shall render its final award or decision within nine (9) months from the date on which the request for arbitration by one of the Parties wishing to have recourse to arbitration is received by the ICC Secretariat. The arbitral tribunal shall resolve the Dispute by applying the provisions of this Agreement and the governing law set forth in Section 16.5.

(c) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order to avoid irreparable harm, maintain the status quo, preserve the subject matter of the Dispute, or aid the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

(d) EACH PARTY HERETO WAIVES: (I) ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY, AND (II) ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST.

(e) The arbitrators will be authorized to award compensatory damages, but will not be authorized to (i) award non-economic damages, (ii) award punitive damages or any other damages expressly excluded under this Agreement, or (iii) reform, modify or materially change this Agreement or any other agreements contemplated hereunder; provided, however, that the damage limitations described in clauses (i) and (ii) will not apply if such damages are statutorily imposed. Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the administrator and the arbitrators; provided, however, that the arbitrators shall be authorized to determine whether a Party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the administrator and the arbitrators.

(f) Notwithstanding anything in this Section 15.4, in the event of a Dispute with respect to (i) the validity, scope, enforceability or ownership of any Patent or other intellectual property rights, (ii) a matter for which this Agreement assigns decision-making to the Parties or to the JSC or requires the consent of one or both of the Parties, (iii) the necessity of obtaining a Third Party license by Zai in the Territory in accordance with Section 9.4(c)(iii), or (iv) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, and such Dispute is not resolved in accordance with Section 15.3, such Dispute shall not be submitted to an arbitration proceeding in accordance with this Section 15.4, unless otherwise agreed by the Parties in writing, and instead, either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

ARTICLE 16

MISCELLANEOUS

16.1. Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, pandemics, epidemics or other acts of God or any other deity (or orders of any Governmental Authority related to any of the foregoing), or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, the JDC shall review and discuss any such matter to the extent related to any Clinical Trials in the Territory, and the affected Party shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

16.2. Assignment. Neither Party may assign this Agreement to a Third Party without the other Party's prior written consent (such consent not to be unreasonably withheld); except that (a) subject to Section 2.6, either Party may make such an assignment without the other Party's prior written consent to a successor to substantially all of the business of such Party to which this Agreement relates (whether by merger, sale of stock, sale of assets, exclusive license or other transaction), and (b) either Party may assign this Agreement to an Affiliate without the other Party's prior written consent for so long as such Affiliate remains an Affiliate of the Party making the assignment. For clarity, each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates and each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. This Agreement shall inure to the benefit of and be binding on the Parties' successors and permitted assignees. Any assignment or transfer in violation of this Section 16.2 shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

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

16.4. Notices. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to TPTX:

Turning Point Therapeutics, Inc.
Address: 10628 Science Center Drive, Suite 200, San Diego, CA 92121, USA
Attn: [***]
Email: [***]

with a copy to:

Cooley LLP
Address: 4401 Eastgate Mall, San Diego, CA 92121, USA
Attn: Kay Chandler
Email: kchandler@cooley.com

If to Zai:

Zai Lab (Shanghai) Co., Ltd.
Address: 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210
Attn: [***]
Email: [***]

with a copy to:

Ropes & Gray, LLP
Address: 36/F, Park Place, Nanjing Road West, Shanghai 200040, China
Attn: Arthur Mok; Geoffrey Lin
Email: Arthur.Mok@ropesgray.com; Geoffrey.Lin@ropesgray.com

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; (b) if sent by email, upon electronic confirmation of receipt; (c) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (d) on the fifth Business Day following the date of mailing if sent by mail.

16.5. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S. without reference to any rules of conflict of laws. The United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement and is expressly and entirely excluded.

16.6. Entire Agreement; Amendments. The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

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

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

16.9. Waiver. The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

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. 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 as described in this Agreement, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or” where applicable.

16.12. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall be entitled to rely on the delivery of executed facsimile copies of counterpart execution pages of this Agreement and such facsimile copies shall be legally effective to create a valid and binding agreement among the Parties.

16.13. Language. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall be for accommodation only and shall not be binding upon the Parties. All communications and notices to be made or given pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, shall be in the English language. If there is a discrepancy between any translation of this Agreement and this Agreement, this Agreement shall prevail.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Turning Point Therapeutics, **Inc**.

By: /s/ Athena Countouriotis
Name: Athena Countouriotis
Title: Chief Executive Officer

Date: January 10, 2021

Zai Lab (**Shanghai**) **Co**., **Ltd**.

By: /s/ Samantha Du
Name: Samantha Du
Title: CEO and Chairperson

Date: January 10, 2021

Schedule 1.70

Licensed Patents

[***]

Schedule 5.2

Initial Clinical Development Plan

[***]

Schedule 5.4(a)

Global Development Plan

[***]

Schedule 5.4(b)

Existing Global Studies

[***]

Schedule 10.2(a)

Press Release

[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Exhibit 10.3
Execution Version

AMENDMENT NO. 1
TO LICENSE AGREEMENT

This Amendment No. 1 to License Agreement **(**this **"Amendment No. 1")** is made effective as of March 31 , 2021 (the "**Amendment Effective Date**"), by and between **TURNING POINT THERAPEUTICS, INC.**, a corporation organized and existing under the laws of Delaware ("**TPTX**") located at 10628 Science Center Drive, Suite 200, San Diego, California 92121, United States of America, and **ZAI LAB (SHANGHAI) CO., LTD.,** an exempted company organized and existing under the laws of P.R. of China, located at 4F, Bldg 1, Jinchuang Plaza, 4560 Jinke Rd, Shanghai, China, 201210 ("**Zai**").

WHEREAS, TPTX and Zai are parties to a License Agreement, dated January 10, 2021 (the "**Agreement**"); and

WHEREAS, TPTX and Zai wish to amend the Agreement as described in this Amendment No. 1. Capitalized terms not defined in this Amendment No. 1 shall have the meaning ascribed such terms in the Agreement.

NOW, THEREFORE, TPTX and Zai agree to amend the Agreement as follows:

1. The first two sentences of Section 2.7 (TPTX's Right of First Negotiation) of the Agreement are hereby deleted and replaced in their entirety with the following:

   "During the [***] month period following the Effective Date, Zai will provide [***]. TPTX will [***], with such notice to be given [***] the "**Zai Pipeline Product**")."

2. As amended hereby, the terms and conditions of the Agreement remain in full force and effect.

3. This Amendment No. 1 may be executed in two or more counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Electronic signatures or signatures on pdf versions of this Amendment No. 1 exchanged via email, shall be deemed original signatures for all purposes.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Amendment No. 1 to be executed by their duly authorized representatives effective as of the Amendment Effective Date.

By: /s/ Athena Countouriotis	By: /s/ Samantha Du
Name: Athena Countouriotis	Name: Samantha Du
Title: Chief Executive Officer	Title: CEO and Chairperson
Date: April 01, 2021	Date: April 01, 2021

Exhibit 31.1

CERTIFICATIONS

I, Samantha (Ying) Du, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Zai Lab Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2021

/s/ Samantha (Ying) Du

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

Exhibit 31.2

CERTIFICATIONS

I, Billy Cho, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Zai Lab Limited;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2021

/s/ Billy Cho
Billy Cho
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report on Form 10-Q of Zai Lab Limited (the "Company"), for the three months ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Samantha (Ying) Du, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2021

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

This certification accompanies the quarterly report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Zai Lab Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this quarterly report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Zai Lab Limited (the "Company"), for the three months ended March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Billy Cho, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2021

/s/ Billy Cho
Billy Cho
Chief Financial Officer
(Principal Executive Officer)

This certification accompanies the quarterly report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Zai Lab Limited under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this quarterly report on Form 10-Q), irrespective of any general incorporation language contained in such filing.