# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

FORM 10-Q

(Mark			
	,		
$\times$	QUARTERLY REPORT PURSUANT TO	SECTION 13 OR 15(d) OF THE SECURI	TIES EXCHANGE ACT OF 1934
	F	or the quarterly period ended June 30, 2021	
		OR	
	TRANSITION REPORT PURSUANT TO	SECTION 13 OR 15(d) OF THE SECURI	ITIES EXCHANGE ACT OF 1934
	For the	transition period from to	
		Commission File Number: 001-38205	
	Z	AI LAB LIMITED	
		t Name of Registrant as Specified in its Charter)	
	Constant		00.11.44505
	Cayman Islands (State or other jurisdiction of		98-1144595 (I.R.S. Employer
	incorporation or organization)		Identification No.)
	4560 Jinke Road Bldg. 1, Fourth Floor		
	Pudong		
	Shanghai, China (Address of principal executive offices)		201210 (Zip Code)
	(Address of principal executive offices)	+86 21 6163 2588	(Zip Couc)
	(Reg	gistrant's Telephone Number, Including Area Code)	
	Securiti	ies registered pursuant to Section 12(b) of the Act:	
		Trading	Name of each exchange
———An	Title of each class nerican Depositary Shares, each representing 1	Symbol(s)  ZLAB	on which registered The Nasdaq Global Market
	Ordinary Share, par value \$0.00006 per share		1
O	rdinary Shares, par value \$0.00006 per share*	9688	The Stock Exchange of Hong Kong Limited
*	Included in connection with the registration of the Amer	rican Depositary Shares with the Securities and Exchan	· ·
	registered of fisted for trading in the Officed States but a	re listed for trading on The Stock Exchange of Hong K	ong Limited.
preced	Indicate by check mark whether the registrant (1) has filling 12 months (or for such shorter period that the registrate Yes ⊠ No □	led all reports required to be filed by Section 13 or 15(a	d) of the Securities Exchange Act of 1934 during the
preced days.	Indicate by check mark whether the registrant (1) has filing 12 months (or for such shorter period that the registr	led all reports required to be filed by Section 13 or 15(or rant was required to file such reports), and (2) has been nitted electronically every Interactive Data File required	d) of the Securities Exchange Act of 1934 during the subject to such filing requirements for the past 90 d to be submitted pursuant to Rule 405 of Regulation
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# Zai Lab Limited Quarterly Report on Form 10-Q

		Page
PART I.	FINANCIAL INFORMATION	1
Item 1.	<u>Financial Statements (Unaudited)</u>	1
	Condensed Consolidated Balance Sheets as of June 30, 2021 and December 31, 2020	1
	Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2021 and 2020	2
	Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2021 and 2020	3
	Condensed Consolidated Statements of Shareholders' Equity for the Three and Six Months Ended June 30, 2021 and 2020	4
	Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2021 and 2020	5
	Notes to the Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	30
Item 4.	Controls and Procedures	31
PART II.	OTHER INFORMATION	31
Item 1.	<u>Legal Proceedings</u>	31
Item 1A.	Risk Factors	31
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
Item 3.	<u>Defaults Upon Senior Securities</u>	36
Item 4.	Mine Safety Disclosures	36
Item 5.	Other Information	36
Item 6.	<u>Exhibits</u>	37
<b>Signatures</b>		39

#### 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. These forward-looking statements include, without limitation, statements containing words such as "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potentially," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these terms or similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information, that are not statements of historical facts, nor are they guarantees or assurances of future performance. These forward-looking statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements because they relate to events and depend on circumstances that may or may not occur in the future. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to the risk factors 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. We anticipate that subsequent events and developments will cause our expectations and assumptions to change and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q. 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)

		As	of
	Notes	June 30, 2021 \$	December 31, 2020 \$
Assets			
Current assets:			
Cash and cash equivalents	3	1,766,573	442,116
Short-term investments	5	_	744,676
Accounts receivable (net of allowance of \$5 and \$1 as of June 30, 2021 and December 31, 2020, respectively)		18,029	5,165
Inventories	6	11,114	13,144
Prepayments and other current assets		12,887	10,935
Total current assets		1,808,603	1,216,036
Restricted cash, non-current	4	743	743
Investments in equity investees	7	1,070	1,279
Prepayments for equipment		1,846	274
Property and equipment, net	8	31,642	29,162
Operating lease right-of-use assets		17,015	17,701
Land use rights, net		7,849	7,908
Intangible assets, net		1,733	1,532
Long term deposits		891	862
Value added tax recoverable		23,823	22,141
Total assets		1,895,215	1,297,638
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		125,621	62,641
Current operating lease liabilities		6,371	5,206
Other current liabilities	11	61,925	30,196
Total current liabilities		193,917	98,043
Deferred income		17,632	16,858
Non-current operating lease liabilities		11,968	13,392
Total liabilities		223,517	128,293
Commitments and contingencies (Note 17)			
Shareholders' equity			
Ordinary shares (par value of \$0.00006 per share; 500,000,000 shares authorized, 94,758,189 and 87,811,026 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively)		6	5
Additional paid-in capital		2,799,318	1,897,467
Accumulated deficit		(1,109,837)	(713,603)
Accumulated other comprehensive loss		(16,865)	(14,524)
Treasury Stock (at cost, 6,086 and nil shares as of June 30, 2021 and December 31, 2020, respectively)		(924)	(14,524)
Total shareholders' equity		1,671,698	1,169,345
Total liabilities and shareholders' equity		1,895,215	1,297,638
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The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

# Zai Lab Limited

# Unaudited condensed consolidated statements of operations

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

		Three Months Ended June 30,		Six Months End	ded June 30,
	Notes	2021	2020	2021	2020
D	0	\$ 20025	10.005	\$	\$ 10.212
Revenue	9	36,935	10,995	57,038	19,213
Expenses:					
Cost of sales		(10,868)	(2,896)	(18,373)	(4,980)
Research and development		(142,224)	(68,307)	(346,076)	(102,049)
Selling, general and administrative		(54,414)	(23,758)	(90,252)	(42,472)
Loss from operations		(170,571)	(83,966)	(397,663)	(130,288)
Interest income		244	1,227	458	2,882
Interest expenses		_	(55)	_	(114)
Other income (expense), net		7,406	2,434	1,179	(691)
Loss before income tax and share of loss from equity method investment		(162,921)	(80,360)	(396,026)	(128,211)
Income tax expense	10	_	_	_	_
Share of loss from equity method investment		(403)	(269)	(208)	(406)
Net loss		(163,324)	(80,629)	(396,234)	(128,617)
Net loss attributable to ordinary shareholders		(163,324)	(80,629)	(396,234)	(128,617)
Loss per share - basic and diluted	12	(1.76)	(1.08)	(4.37)	(1.74)
Weighted-average shares used in calculating net loss per ordinary share - basic and diluted		93,045,531	74,738,563	90,723,132	73,847,551

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 End	led June 30,	Six Months Ende	d June 30,
	2021	2020	2021	2020
	\$	\$	\$	\$
Net loss	(163,324)	(80,629)	(396,234)	(128,617)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	(5,241)	(1,173)	(2,341)	2,366
Comprehensive loss	(168,565)	(81,802)	(398,575)	(126,251)

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

# Zai Lab Limited

# Unaudited condensed consolidated statements of shareholders' equity

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

	Ordinary S	hares	Additional		Accumulated other	Treasur	y Stock	
	Number of Shares	Amount \$	paid <u>in capital</u> \$	Accumulated <u>deficit</u> \$	comprehensive (loss) income \$	Shares	Amount \$	Total
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 15)	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
Issuance of ordinary shares upon vesting of								
restricted shares	32,100	0	0	_	_	_	_	0
Exercise of shares option	490,517	0	3,289	_	_	_	_	3,289
Issuance of ordinary shares upon follow-on public	,		,					Ź
offering, net of issuance cost of \$879	5,716,400	1	817,995	_	_	_	_	817,996
Receipt of employees' shares to satisfy tax	, ,		,					
withholding obligations related to share-based								
compensation	_	_	_	_	_	(6,086)	(924)	(924)
Share-based compensation	_	_	10,232	_	_			10,232
Net loss	_	_	_	(163,324)	_	_	_	(163,324)
Foreign currency translation	_	_	_	_	(5,241)	_	_	(5,241)
Balance at June 30, 2021	94,758,189	6	2,799,318	(1,109,837)	(16,865)	(6,086)	(924)	1,671,698
Balance at December 31, 2019	68,237,247	4	734,734	(444,698)	4,620			294,660
Issuance of ordinary shares upon vesting of	00,207,217	•	75.,75.	(11,000)	.,020			25 1,000
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
Issuance of ordinary shares upon vesting of	· 1,000,120		1,022,111	(102,000)	0,100			337,333
restricted shares	36,000	0	0		_	_		0
Exercise of shares option	179.613	0	2,729	_	_	_	_	2,729
Issuance cost for follow-on public offering		_	(13)	_		_		(13)
Share-based compensation	_	_	6,964	_	<u>_</u>	_		6,964
Net loss	_	_		(80,629)		_	_	(80,629)
Foreign currency translation			_	(50,023)	(1,173)	_	_	(1,173)
Balance at June 30, 2020	74,882,338	4	1,031,791	(573,315)	6,986			465,466
Datatice at Julie 30, 2020	74,002,330		1,031,791	(3/3,313)	0,300			403,400

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)

	Six Months End	ed June 30,
	2021	2020
Operating activities	<b>\$</b>	\$
Net loss	(396,234)	(128,617)
Adjustments to reconcile net loss to net cash used in operating activities:	(===,===)	(===,==:)
Allowance for doubtful accounts	4	2
Inventory write-down	290	7
Depreciation and amortization expenses	2,975	2,107
Amortization of deferred income	(156)	(156)
Share-based compensation	17,550	13,427
Noncash research and development expenses (Note 15)	62,250	_
Share of loss from equity method investment	208	406
Loss on disposal of property and equipment	4	1
Noncash lease expenses	2,779	2,114
Changes in operating assets and liabilities:		
Accounts receivable	(12,868)	(3,235)
Inventories	1,740	(571)
Prepayments and other current assets	(1,952)	(948)
Long term deposits	(29)	(335)
Value added tax recoverable	(1,682)	(2,422)
Accounts payable	62,980	9,732
Other current liabilities	28,077	4,697
Operating lease liabilities	(2,214)	(1,539)
Deferred income	930	13,011
Net cash used in operating activities	(235,348)	(92,319)
Cash flows from investing activities:		
Purchases of short-term investments	<u> </u>	(205,000)
Proceeds from maturity of short-term investments	743,902	200,000
Purchase of property and equipment	(5,647)	(1,303)
Purchase of intangible assets	(427)	(218)
Net cash provided by (used in) investing activities	737,828	(6,521)
Cash flows from financing activities:	737,623	(0,021)
Repayment of short-term borrowings		(2,130)
Proceeds from exercises of stock options	3,992	3,075
Proceeds from issuance of ordinary shares upon public offerings	818,874	281,295
Payment of public offering costs	(1,323)	(740)
Employee taxes paid related to net share settlement of equity awards	(594)	(740)
Net cash provided by financing activities	820,949	281,500
. ,		
Effect of foreign exchange rate changes on cash, cash equivalents and restricted cash	1,028	12
Net increase in cash, cash equivalents and restricted cash	1,324,457	182,672
Cash, cash equivalents and restricted cash - beginning of period	442,859	76,442
Cash, cash equivalents and restricted cash - end of period	1,767,316	259,114
Supplemental disclosure on non-cash investing and financing activities:		
Payables for purchase of property and equipment	1,720	984
Payables for intangible assets	58	_
Payables for public offering costs	555	_
Supplemental disclosure of cash flow information:		
Cash and cash equivalents	1,766,573	258,604
Cush that cush equivalents		510
	743	510
Restricted cash, non-current Total cash and cash equivalents and restricted cash	1,767,316	259,114

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

#### 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 Company and its subsidiaries are eliminated upon consolidation.

## (c) Use of estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and 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 15). 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 measure 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 June 30, 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 abslity 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		
	June 30, 2021	December 31, 2020	
	\$	\$	
Cash at bank and in hand	1,465,757	441,283	
Cash equivalents (note (i))	300,816	833	
	1,766,573	442,116	
Denominated in:			
US\$	907,662	297,813	
RMB (note (ii))	36,222	23,898	
Hong Kong dollar ("HK\$")	822,182	119,695	
Australian dollar ("A\$")	471	710	
Taiwan dollar ("TW\$")	36	_	
	1,766,573	442,116	

#### Note:

- (i) Cash equivalents represent short-term and highly liquid investments in a money market fund.
- (ii) Certain cash and bank balances denominated in RMB were deposited with banks in 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 June 30, 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 June 30, 2021, the Group held no short-term investments. 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 remote 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 \$11,114 and \$13,144 as of June 30, 2021 and December 31, 2020, respectively, mainly consisted of finished goods purchased from Tesaro, Inc., now GlaxoSmithKline (GSK), for distribution in Hong Kong, and from NovoCure Limited ("Novocure") and Deciphera Pharmaceuticals, LLC ("Deciphera") for distribution in Hong Kong and China, as well as finished goods, work in process and certain raw materials for ZEJULA commercialization in China.

		As of		
	June 30, 2021	December 31, 2020		
Finished goods	4,477	3,041		
Raw materials	6,269	10,103		
Work in process	368	_		
Inventories	11,114	13,144		

The Group writes down inventory for any excess or obsolete inventories or when the Group believes that the net realizable value of inventories is less than the carrying value. During the three and six months ended June 30, 2021, the Group recorded write-downs of \$277 and \$290, respectively, in cost of revenues. During the three months and six months ended June 30, 2020, the Group recorded write-downs of \$7 and \$7, 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 June 30, 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 nil and \$463 for the three months and six months ended June 30, 2021, and recorded loss of \$403 and \$671 for its portion of JING's net loss for the three months and six months ended June 30, 2021, respectively. The Group recorded share of loss in this investee of \$269 and \$406 for the three and six months ended June 30, 2020, 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)

#### 8. Property and equipment, net

Property and equipment consist of the following:

	As of		
	June 30, 2021	December 31, 2020	
	\$	\$	
Office equipment	444	430	
Electronic equipment	3,269	2,646	
Vehicle	218	143	
Laboratory equipment	13,384	11,933	
Manufacturing equipment	12,838	12,198	
Leasehold improvements	9,889	9,641	
Construction in progress	4,699	2,423	
	44,741	39,414	
Less: accumulated depreciation	(13,099)	(10,252)	
Property and equipment, net	31,642	29,162	

Depreciation expenses for the three and six months ended June 30, 2021 were \$1,407 and \$2,747, respectively. Depreciation expenses for the three and six months ended June 30, 2020 were \$968 and \$1,974, respectively.

#### 9. Revenue

The Group's revenue is derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The table below presents the Group's net product sales for the three and six months ended June 30, 2021 and 2020.

	Three Months E	Three Months Ended June 30,		ed June 30,
	2021	2021 2020		2020
	\$	\$	\$	\$
Product revenue - gross	41,380	11,478	87,935	20,415
Less: Rebate and sales return	(4,445)	(483)	(30,897)	(1,202)
Product revenue - net	36,935	10,995	57,038	19,213

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 and six months ended June 30, 2021 and 2020:

	Three Month	Three Months Ended June 30,		s Ended June 30,
	2021	2020	2021	2020
	\$	\$	\$	\$
ZEJULA	23,366	7,446	35,972	13,791
Optune	9,535	3,549	16,665	5,422
QINLOCK	4,034	_	4,401	_
Product revenue - net	36,935	10,995	57,038	19,213

## 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 June 30, 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:

	A	As of
	June 30, 2021	December 31, 2020
	\$	\$
Payroll	12,474	13,694
Professional service fee	9,610	3,128
Payables for purchase of property and equipment	1,720	788
Accrued rebate to distributors	22,416	7,067
Others (note (i))	15,705	5,519
Total	61,925	30,196

# Note:

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

# 12. Loss per share

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

	Three Months E	Three Months Ended June 30, Six Months		ıs Ended June 30,	
	2021	2020	2021	2020	
Numerator:	J	Φ	<b>J</b>	<b>.</b>	
Net loss attributable to ordinary shareholders	(163,324)	(80,629)	(396,234)	(128,617)	
Denominator:					
Weighted average number of ordinary shares- basic and diluted	93,045,531	74,738,563	90,723,132	73,847,551	
Product revenue - net	(1.76)	(1.08)	(4.37)	(1.74)	

As a result of the Group's net loss for the six months ended June 30, 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	s of
	June 30, 2021	June 30, 2020
Share options	8,629,440	9,808,561
Non-vested restricted shares	632,535	710,068

# 13. Related party transactions

The table below sets forth the major related party and the relationship with the Group as of June 30, 2021:

<u>Company Name</u> MEDx (Suzhou) Translational Medicine Co., Ltd. Relationship with the Group
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 and six months ended June 30, 2021, the Group incurred \$104 and \$207 research and development expense with MEDx (Suzhou) Translational Medicine Co., Ltd. for product research and development services, respectively. The Group incurred \$129 and \$184 research and development expense for the three and six months ended June 30, 2020, 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 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 six months ended June 30, 2020, the Group granted 960,878 share options to certain management, employees and individual advisors of the Group at the exercise price ranging from \$44.94 to \$82.13 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 six months ended June 30, 2021, the Group granted 512,088 share options to certain management and employees of the Group at the exercise price ranging from \$130.96 to \$180.00 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 six months ended June 30, 2021 and 2020 were \$81.37 and \$33.51 per share, respectively. The Group recorded compensation expense related to the options of \$12,776 and \$10,355 for the six months ended June 30, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months En	Three Months Ended June 30,		led June 30,
	2021	2020	2021	2020
	\$	\$	\$	\$
Selling, general and administrative	4,123	2,804	7,382	5,548
Research and development	3,104	2,630	5,394	4,807
Total	7,227	5,434	12,776	10,355
	<del></del>		=======================================	

#### 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)

As of June 30, 2021, there was \$97,837 of total unrecognized compensation expense related to unvested share options granted. That cost is expected to be recognized over a weighted-average period of 1.48 years which is determined based on the number of shares and unrecognized years.

#### Non-vested restricted shares

For the six months ended June 30, 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 six months ended June 30, 2020, 45,000 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 six months ended June 30, 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 six months ended June 30, 2021, 203,575 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 June 30, 2021, there was \$40,562 of total unrecognized compensation expense related to non-vested restricted shares. The Group recorded compensation expense related to the restricted shares of \$4,774 and \$3,072 for the six months ended June 30, 2021 and 2020, respectively, which were classified in the accompanying unaudited condensed consolidated statements of operations as follows:

	Three Months E	Three Months Ended June 30,		ided June 30,
	2021	2020	2021	2020
	\$	\$	\$	\$
Selling, general and administrative	1,839	1,046	3,050	2,114
Research and development	1,166	484	1,724	958
Total	3,005	1,530	4,774	3,072

#### 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)

#### 15. Licenses and collaborative arrangement

The following is a description of the Group's significant ongoing collaboration agreements for the three and six months ended June 30, 2021.

#### License and collaboration agreement with GSK

In September 2016, the Group entered into a collaboration, development and license agreement with Tesaro, Inc., a company later acquired by GSK, pursuant to which it obtained an exclusive sublicense under certain patents and know-how of GSK (including such patents and know-how licensed from Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., and AstraZeneca UK Limited) to develop, manufacture and commercialize GSK's proprietary PARP inhibitor, niraparib, in China, Hong Kong and Macau for the diagnosis and prevention of any human diseases or conditions (other than prostate cancer). The Group also obtained the right of first negotiation to obtain a license to develop and commercialize certain follow-on compounds of niraparib being developed by GSK in the licensed territory. Under the agreement, the Group agreed not to research, develop or commercialize certain competing products, and the Group also granted GSK the right of first refusal to license certain immuno-oncology assets developed by the Group. In February 2018, the Group entered into an amendment with GSK that eliminated GSK's option to co-market niraparib in the licensed territory.

Under the terms of the agreement, the Group made an upfront payment of \$15,000 and one milestone payment of \$1,000, and accrued one development milestone payment of \$3,500 to GSK. On top of those, if the Group achieves other specified regulatory, development and commercialization milestones, the Group may be additionally required to pay further milestone payments up to \$36,000 to GSK. In addition, if the Group successfully develops and commercializes the licensed products, the Group will pay GSK tiered royalties on the net sales of the licensed products, until the later of the expiration of the last-to-expire licensed patent covering the licensed product, the expiration of regulatory exclusivity for the licensed product, or the tenth anniversary of the first commercial sale of the licensed product, in each case on a product-by-product and region-by-region basis.

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

License and collaboration agreements with MacroGenics Inc. ("MacroGenics")

In November 2018, the Group entered into a collaboration agreement with MacroGenics, pursuant to which it obtained an exclusive license under certain patents and know-how of MacroGenics to develop and commercialize margetuximab, tebotelimab (MGD-013) and an undisclosed multi-specific TRIDENT molecule in pre-clinical development, each as an active ingredient in all human fields of use, except to the extent limited by any applicable third party agreement of MacroGenics in Greater China.

Under the terms of the agreement, the Group paid an upfront license fee of \$25,000 and two milestone payments in total of \$4,000 to MacroGenics. The Group also agreed to pay certain development and regulatory-based milestone payments up to an aggregate of \$136,000, and tiered royalties at percentage rates for net sales of Margetuximab, tebotelimab and TRIDENT molecule in the territory.

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

In June 2021, the Group entered into a collaboration and license agreement with MacroGenics, pursuant to which the Group and MacroGenics made four collaboration programs involving up to four immuno-oncology molecules. The first collaboration program covers a lead research molecule that incorporates MacroGenics' DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors. The second collaboration program will cover a target to be designated by MacroGenics. For both molecules, the Group received commercial rights in Greater China, Japan, and Korea and MacroGenics received commercial rights in all other territories. For the lead molecule, the Group receives an option upon reaching a predefined clinical milestone to convert the regional arrangement into a global 50/50 profit share. The Group also obtained exclusive, global licenses from MacroGenics to develop, manufacture and commercialize two additional molecules. For these four programs, each company will contribute intellectual property to generate either CD3- or CD47-based bispecific antibodies.

Under the terms of the agreement, the Group accrued an upfront payment of \$25,000 to MacroGenics. In addition, MacroGenics is also eligible to receive up to \$1,386,000 in potential development, regulatory and commercial milestone payments for the four programs. If products from the collaboration are commercialized, MacroGenics would also receive royalties on annual net sales in the Group's territories.

Pursuant to the collaboration and license agreement, the Group also agreed to make an equity investment of \$30,000 in MacroGenics' common stock at \$31.30 per share (see Note 18).

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

#### 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 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 three milestone payments of \$12,000. 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.

License agreements 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 and one milestone payment of \$2,000, and accrued two milestone payments totaling \$3,000 to Turning Point. Turning Point is also eligible to receive up to \$146,000 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.

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.

#### 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)

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 efgartigimed, 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.

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.

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

In May 2021, the Group entered into a collaboration and license agreement with Mirati. The Group obtained the right to research, develop, manufacture and exclusively commercialize adagrasib in Greater China. The Group will support accelerated enrollment in key global, registration-enabling clinical trials of adagrasib in patients with cancer who have a KRASG12C mutation. Mirati has an option to co-commercialize in Greater China and retains full and exclusive rights to adagrasib in all countries outside of Greater China.

Under the terms of the agreement, the Group accrued an upfront payment of \$65,000 to Mirati. Mirati is also eligible to receive up to \$273,000 in development, regulatory and sales-based milestone payments. Mirati is also eligible to receive high-teen- to low-twenties-percent tiered royalties based on annual net sales of adagrasib in Greater China.

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

#### 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)

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 and this Quarterly Report on Form 10-Q. 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 \$4,541,502 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.

#### 16. 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 Chinese 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 and six months ended June 30, 2021 and 2020, no appropriation to statutory reserves was made because the Group's Chinese subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the restrictions 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 regulations 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 June 30, 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.

## 17. Commitments and Contingencies

## (a) Purchase commitments

As of June 30, 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 \$28,191 and \$49 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 15).

## 18. Subsequent Event

In July 2021, the Group made an equity investment in MacroGenics in a private placement with total contributions amounting to \$30,000 and obtained 958,467 newly issued common shares of MacroGenics at \$31.30 per share.

In July and August 2021, the Group granted 11,701 share options to certain management and employees of the Group at exercise prices ranging from \$144.61 to \$178.37 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 July and August 2021, 32,341 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.

In August 2021, the Group entered into a global discovery, development and commercialization collaboration with Schrödinger, Inc., or Schrödinger, pursuant to which the parties will jointly conduct a research program focused on a novel DNA damage repair program in the area of oncology. Following the selection of a development candidate, the Group will assume primary responsibility for global development, manufacturing and commercialization of the program.

## 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 August 9, 2021, we have three commercialized products that have received marketing approval in one or more territories in Greater China and twelve 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 unaudited condensed consolidated financial statements and totaled \$269.2 million for the six months ended June 30, 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

On April 12, 2021, we achieved first-patient-in for the Phase 3 pivotal LUNAR trial.

On April 13, 2021, we announced in a joint press release with our partner, Novocure, an update regarding Novocure's Phase 3 pivotal LUNAR trial of Tumor Treating Fields in stage 4 non-small cell lung cancer (NSCLC) following platinum failure. Following a routine review of the study by an independent data monitoring committee (DMC), Novocure was informed that the pre-specified interim analysis for the LUNAR trial would be accelerated given the length of accrual and the number of events observed to date. The interim analysis included data from 210 patients accrued to the LUNAR trial through February 2021. After review of the interim analysis report, the DMC concluded that the LUNAR trial should continue with no evidence of increased systemic toxicity. On May 18, 2021, Novocure announced the U.S. Food and Drug Administration (FDA) has approved its Investigational Device Exemption (IDE) supplement, reducing the enrollment requirement for its LUNAR trial to 276 patients with 12 months follow-up. In addition, in April 2021, we achieved first-patient-in for the LUNAR trial in Greater China.

On April 23, 2021, we announced the closing of a global offering of American depositary shares and ordinary shares, including the full exercise of the greenshoe option, for total gross proceeds to us of \$857.5 million. This offering was the first ever dual-tranche offering on both Nasdaq and the Stock Exchange of Hong Kong.

On May 24, 2021, we announced the first patient treated in the METIS Phase 3 pivotal trial of Tumor Treating Fields in brain metastases from NSCLC in Greater China.

On June 1, 2021, we announced that we entered into a collaboration and license agreement with Mirati for adagrasib, a small-molecule KRASG12C inhibitor, in Greater China (mainland China, Hong Kong, Macau and Taiwan). Under the terms of the agreement, we obtained the right to research, develop, manufacture and exclusively commercialize adagrasib in Greater China. We will support accelerated enrollment in key global, registration-enabling clinical trials of adagrasib in patients with cancer who have a KRAS G12C mutation.

On June 4, 2021, our partner, Cullinan, announced additional details pertaining to Cullinan's ongoing Phase 1/2a trial of CLN-081 in NSCLC patients whose tumors harbor epidermal growth factor receptor (EGFR) exon 20 insertion mutations, including that CLN-081 continues to demonstrate acceptable overall safety and tolerability with encouraging GI toxicity profile.

On June 15, 2021, we announced that we entered into an exclusive collaboration and license agreement with MacroGenics, pursuant to which we agreed to collaboratively develop and commercialize up to four bispecific antibody-based molecules with MacroGenics based on the MacroGenics' proprietary DART® and TRIDENT® multi-specific technology platforms. Under the agreement, each party agrees to contribute specified intellectual property to enable the research, development, manufacture and commercialization of up to four future CD3 or CD47-based bispecific molecules. We were granted exclusive rights in Greater China, Japan, and Korea for two programs and exclusive global rights for two other programs.

On August 4, 2021, we announced that we entered into a global discovery, development and commercialization collaboration with Schrödinger, pursuant to which we will jointly conduct a research program focused on a novel DNA damage repair program in the area of oncology. Schrödinger is a recognized leader in providing physics-based computational software platforms used in drug discovery. The research program will be conducted jointly by the scientific teams of our two companies. Following the selection of a development candidate, we will assume primary responsibility for global development, manufacturing and commercialization of the program.

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 China's National Medical Products Administration (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 published by the National Medical Products Administration (NMPA) and became 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 #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 may be subject to 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.
- *Encouraging innovations*. As a core theme of its drafting philosophy, Order #739 encourages innovations in medical device technologies and will continue to allow the "fast track approval process" to accelerate the product launch timeline for innovative devices. Under Order #739, imported medical devices that are "first-in-class" and have Chinese invention patent(s) covering their core technologies do not need to be approved outside of China before the NMPA's marketing authorization.
- *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.

To implement Order #739, from March to June of 2021, the NMPA also published draft administrative regulations on the registration, manufacturing, distribution, Good Clinical Practices and company-led type tests for medical devices for public comment.

## PRC Biosecurity Law

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

## PRC Patent Law

On June 1, 2021, the fourth amendment to the PRC Patent Law took effect.

On July 3, 2021, the Implementing Measure to Early-Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (the "Measures"), jointly issued by the NMPA and the China National Intellectual Property Administration jointly, took effect. The Measures give practical guidance on the patent linkage system in China, where the drug originators are permitted to list on a public registration system certain patents that are relevant to approved drugs. Generic and biosimilar drug applicants must then make certifications when applying for drug approval in respect of the listed patents. Where the certification is a type IV certification which alleges the invalidity of the listed patents or alleges that the scope of the listed patents does not cover the generic or biosimilar drug that is the subject of the drug approval application, drug originators have an opportunity to pursue administrative or judicial litigation to determine patent infringement prior to commercial sale, and in the case of chemical generics, obtain a 9-month approval stay on the chemical generic drug approval application. Upon successful litigation prior to the approval of the generic or biosimilar drug, the drug originators may delay the grant of the approval of a chemical generic drug until after patent expiry or have the approval of a biosimilar drug be conditioned upon patent expiry.

#### PRC Data Security and Cybersecurity

In June 2021, China's top legislative body, the National People's Congress, passed the Data Security Law (DSL). Being the first comprehensive data security legislation in China, the DSL will take effect on September 1, 2021, and it covers a wide range of issues relating to the collection, storage, processing, use, provision, transaction and publication of data. The DSL provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection. The DSL has extraterritorial effect and it applies to any data processing activities outside China if such activities would be detrimental to the national security or public interest of China or the interests of Chinese citizens or organizations.

In July 2021, the Cyberspace Administration of China published a revised draft of the Measures on Cybersecurity Review, expanding the cybersecurity review to data processing operators in possession of personal information of over 1 million users if the operators intend to list their securities in a foreign country.

Also, recently, the National People's Congress released the second consultation draft of the Personal Information Protection Law. The draft proposes a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The draft also proposes that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold to-be-set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the draft contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year.

# **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 twelve late-stage clinical product candidates being investigated as of June 30, 2021.

To date, we have financed our activities primarily through private placements, our initial public offering on Nasdaq in September 2017, a secondary listing on the Stock Exchange of Hong Kong and multiple follow-on offerings. Through June 30, 2021, we have raised approximately \$164.6 million in private equity financing and approximately \$2,462.7 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 \$235.3 million and \$92.3 million, for the six months ended June 30, 2021 and June 30, 2020, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our twelve 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 contract research organizations ("CROs"), contract manufacture organizations ("CMOs"), investigators and clinical strial sites that conduct our clinical studies;
- employee compensation related expenses, including salaries, benefits and equity compensation expenses;
- expenses for licensors;
- the cost of acquiring, developing and manufacturing clinical study materials;
- facilities, 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 June 30, 2021, twelve 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 our receipt of regulatory approvals 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 approvals in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts before we generate any revenue from product sales.

#### **Our License Arrangements**

Our results of operations have been, and we expect them to continue to be, affected by our licensing, collaboration and development agreements. We are required to make upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones for the relevant products under these agreements as well as tiered royalties based on 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 \$269.2 million for the six months ended June 30, 2021 and \$98.0 million for the three months ended June 30, 2021. The upfront payments and milestone payments are recorded in research and development expense and was \$51.7 million for the six months ended June 30, 2020 and \$42.5 million for the three months ended June 30, 2020.

# **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 six months ended June 30, 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 six months ended June 30, 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.

	Three months ended June 30,			Six months ende			ıne 30,	
		2021		2020		2021	_	2020
(in thousands, except share and per share data)								
Comprehensive Loss Data:	_						_	
Revenue	\$	36,935	\$	10,995	\$	57,038	\$	19,213
Expenses:								
Cost of sales		(10,868)		(2,896)		(18,373)		(4,980)
Research and development		(142,224)		(68,307)		(346,076)		(102,049)
Selling, general and administrative		(54,414)		(23,758)		(90,252)		(42,472)
Loss from operations	\$	(170,571)	\$	(83,966)	\$	(397,663)	\$	(130,288)
Interest income		244		1,227		458		2,882
Interest expenses		_		(55)		_		(114)
Other income (expense), net		7,406		2,434		1,179		(691)
Loss before income tax and share of loss from equity								
method investment	\$	(162,921)	\$	(80,360)	\$	(396,026)	\$	(128,211)
Income tax expense								
Share of loss from equity method investment		(403)		(269)		(208)		(406)
Net loss attributable to ordinary shareholders	\$	(163,324)	\$	(80,629)	\$	(396,234)	\$	(128,617)
Weighted-average shares used in calculating net loss per								
ordinary share, basic and diluted	93	,045,531	74	1,738,563	9	0,723,132	7	3,847,551
Net loss per share, basic and diluted	\$	(1.76)	\$	(1.08)	\$	(4.37)	\$	(1.74)

#### Three Months Ended June 30, 2021 Compared to Three Months Ended June 30, 2020

#### Revenue

Our revenue is derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The following table disaggregates net revenue by product for the three months ended June 30, 2021 and 2020:

	T	Three Months Ended June 30,		
(in thousands)	2021	%	2020	%
ZEJULA	\$23,366	63.3	\$ 7,446	67.7
Optune	9,535	25.8	3,549	32.3
QINLOCK	4,034	10.9		
Total product revenue—Net	\$36,935	100.0	\$10,995	100.0

# Research and Development Expenses

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

	Th	Three Months Ended June 30,			
(in thousands)	2021	%	2020	%	
Research and Development Expenses:			· <u> </u>		
Personnel compensation and related costs	\$ 17,282	12.1	\$11,596	17.0	
Licensing fees	97,966	68.9	42,480	62.2	
Payment to CROs/CMOs/Investigators	19,618	13.8	9,982	14.6	
Other costs	7,358	5.2	4,249	6.2	
Total	\$142,224	100.0	\$68,307	100.0	

Research and development expenses increased by \$73.9 million to \$142.2 million for the three months ended June 30, 2021 from \$68.3 million for the three months ended June 30, 2020. The increase in research and development expenses included the following:

- \$5.7 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 June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- \$55.5 million for increased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees; and
- \$9.6 million for increased payments to CROs, CMOs and investigators in the three months ended June 30, 2021 as we advanced our drug candidate pipeline.

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The following table summarizes our research and development expenses by program for the three months ended June 30, 2021 and 2020, respectively:

	I n	I nree Months Ended June 30,			
(in thousands)	2021	%	2020	%	
Research and Development Expenses:					
Clinical programs	\$ 93,433	65.7	\$52,003	76.1	
Pre-clinical programs	28,545	20.1	2,227	3.3	
Unallocated research and development expenses	20,246	14.2	14,077	20.6	
Total	\$142,224	100.0	\$68,307	100.0	

During the three months ended June 30, 2021, 65.7% and 20.1% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the three months ended June 30, 2020, 76.1% and 3.3% 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.

	Th	Three Months Ended June 30,			
(in thousands)	2021	%	2020	%	
Selling, General and Administrative Expenses:	<u> </u>				
Personnel compensation and related costs	30,060	55.2	14,040	59.1	
Professional service fees	4,806	8.8	2,543	10.7	
Other costs	19,548	36.0	7,175	30.2	
Total	\$54,414	100.0	\$23,758	100.0	
Total	\$54,414	100.0	\$23,758	100.0	

Selling, general and administrative expenses increased by \$30.7 million to \$54.4 million for the three months ended June 30, 2021 from \$23.8 million for the three months ended June 30, 2020. The increase in general and administrative expenses included the following:

- \$16.0 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 June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- \$2.3 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
- \$12.4 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 \$1.0 million, to \$0.2 million for the three months ended June 30, 2021, from \$1.2 million for the three months ended June 30, 2020 primary due to the decrease of short-term investments balance.

#### Interest Expenses

Interest expenses is nil for the three months ended June 30, 2021, compared to \$0.1 million for the three months ended June 30, 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. ("JING"), an entity which provides services for product discovery and development, consultation and transfer of pharmaceutical technology. We recorded loss of \$0.4 million and \$0.3 million for its portion of JING's net loss for the three months June 30, 2021 and 2020, respectively.

# Other Income (Expense), net

Other income (expense), net increased by \$5.0 million for the three months ended June 30, 2021, as compared to the three months ended June 30, 2020, primarily as a result of an increase in foreign exchange gain and partially offset by a decrease in governmental subsidies.

#### Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of \$163.3 million for the three months ended June 30, 2021 compared to net loss attributable to ordinary shareholders of \$80.6 million for the three months ended June 30, 2020.

#### Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

#### Revenue

Our revenue is derived from the sale of ZEJULA, Optune and QINLOCK in China and Hong Kong. The amount of revenue of ZEJULA for the six months ended June 30, 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 six months ended June 30, 2021 and 2020:

		Six Months Ended June 30,		
(in thousands)	2021	%	2020	%
ZEJULA	\$35,972	63.1	\$13,791	71.8
Optune	16,665	29.2	5,422	28.2
QINLOCK	4,401	7.7		
Total product revenue—Net	\$57,038	100.0	\$19,213	100.0

## Research and Development Expenses

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

	Six Months Ended June 30,			
(in thousands)	2021	%	2020	%
Research and Development Expenses:				
Personnel compensation and related costs	\$ 29,979	8.7	\$ 21,600	21.2
Licensing fees	269,248	77.8	51,720	50.7
Payment to CROs/CMOs/Investigators	35,144	10.1	19,812	19.4
Other costs	11,705	3.4	8,917	8.7
Total	\$346,076	100.0	\$102,049	100.0

Research and development expenses increased by \$244.0 million to \$346.1 million for the six months ended June 30, 2021 from \$102.0 million for the six months ended June 30, 2020. The increase in research and development expenses included the following:

- \$8.4 million for increased personnel compensation and related costs which was primarily attributable to increased employee compensation costs, due to hiring of more personnel during the six months ended June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- \$217.5 million for increased licensing fees in connection with the upfront payments for new licensing agreements as well as certain milestone fees; and
- \$15.3 million for increased payment to CROs, CMOs and investigators in the six months ended June 30, 2021 as we advanced our drug candidate pipeline.

The following table summarizes our research and development expenses by program for the six months ended June 30, 2021 and 2020, respectively:

	Six	Six Months Ended June 30,		
(in thousands)	2021	%	2020	%
Research and Development Expenses:				
Clinical programs	\$279,689	80.8	\$ 72,335	70.9
Pre-clinical programs	31,045	9.0	2,915	2.9
Unallocated research and development expenses	35,342	10.2	26,799	26.2
Total	\$346,076	100.0	\$102,049	100.0

During the six months ended June 30, 2021, 80.8% and 9.0% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. During the six months ended June 30, 2020, 70.9% and 2.9% 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.

	S	Six Months Ended June 30,		
(in thousands)	2021	%	2020	%
Selling, General and Administrative Expenses:				
Personnel compensation and related costs	\$53,472	59.2	\$27,082	63.8
Professional service fees	8,389	9.3	4,570	10.7
Other costs	28,391	31.5	10,820	25.5
Total	\$90,252	100.0	\$42,472	100.0

Selling, general and administrative expenses increased by \$47.8 million to \$90.3 million for the six months ended June 30, 2021 from \$42.5 million for the six months ended June 30, 2020. The increase in general and administrative expenses included the following:

- \$26.4 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 six months ended June 30, 2021 and the grants of new share options and vesting of restricted shares to certain employees;
- \$3.8 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
- \$17.6 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 \$2.4 million, to \$0.5 million for the six months ended June 30, 2021, from \$2.9 million for the six months ended June 30, 2020 primary due to the decrease of short-term investments balance.

## Interest Expenses

Interest expenses is nil for the six months ended June 30, 2021, compared to \$0.1 million for the six months ended June 30, 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 product discovery and development, consultation and transfer of pharmaceutical technology. We recorded the gain on deemed disposal in this investee of \$0.5 million and share of loss of \$0.7 million for the six months ended June 30, 2021, and recorded share of loss in this investee of \$0.4 million for the six months ended June 30, 2020.

## Other Income (Expense), net

Other income (expense), net increased by \$1.9 million for the six months ended June 30, 2021, as compared to the six months ended June 30, 2020, primarily as a result of an increase in foreign exchange gain and partially offset by a decrease in governmental subsidies.

## Net Loss Attributable to Ordinary Shareholders

As a result of the foregoing, we had net loss attributable to ordinary shareholders of \$396.2 million for the six months ended June 30, 2021 compared to net loss attributable to ordinary shareholders of \$128.6 million for the six months ended June 30, 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 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 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. Our product revenues were primarily generated from the sale of ZEJULA (niraparib), Optune (Tumor Treating Fields) and QINLOCK (ripretinib) 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 June 30, 2021 and December 31, 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 measure 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 June 30, 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 June 30, 2021, we have raised approximately \$164.6 million in private equity financing and approximately \$2,462.7 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 \$235.3 million and \$92.3 million, for the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, we had cash, cash equivalents and restricted cash of \$1,767.3 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 August 9, 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 six months ended June 30, 2021 and 2020:

	Six months ended June 30,		
(in thousands)	2021	2020	
Net cash used in operating activities	\$ (235,348)	\$ (92,319)	
Net cash provided by (used in) investing activities	737,828	(6,521)	
Net cash provided by financing activities	820,949	281,500	
Effect of foreign exchange rate changes	1,028	12	
Net increases in cash, cash equivalents and restricted cash	\$1,324,457	\$182,672	

#### Net cash used in operating activities

During the six months ended June 30, 2021, our operating activities used \$235.3 million of cash, which resulted principally from our net loss of \$396.2 million, adjusted for non-cash charges of \$85.9 million, and cash provided in our operating assets and liabilities of \$75.0 million. Our net non-cash charges during the six months ended June 30, 2021 primarily consisted of \$62.3 million non-cash research and development expenses, a \$3.0 million depreciation expense, a \$17.6 million share-based compensation expense and a \$2.8 million non-cash lease expense.

## Net cash provided by (used in) investing activities

Net cash provided by investing activities was \$737.8 million for the six months ended June 30, 2021 compared to net cash used in investing activities of \$6.5 million for the six months ended June 30, 2020. The increase in cash provided by investing activities was primarily due to the proceeds from maturity of short-term investments.

# Net cash provided by financing activities

Net cash provided by financing activities was \$820.9 million for the six months ended June 30, 2021 compared to \$281.5 million for the six months ended June 30, 2020. The increase in cash provided by financing activities was primarily due to the issuance of ADSs in our follow-on offering during the six months ended June 30, 2021.

## C. Research and Development, Patents and Licenses, etc.

Full details of our research and development activities and expenditures are provided 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 June 30, 2021. Amounts we pay in future periods may vary from those reflected in the table.

		Less than		3 to 5	More than
(in thousands)	Total	1 year	1 to 3 years	years	5 years
Purchase Obligations	\$28,240	\$28,191	\$ 49		_
Operating Lease Obligations	\$18,847	\$ 6,557	\$ 6,180	\$4,373	\$ 1,737

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 RMB 234.0 million and RMB 155.9 million, which were denominated in RMB, as of June 30, 2021 and December 31, 2020, respectively, representing 2% and 5% of the cash and cash equivalents as of June 30, 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 RMBs, while ADSs will be traded in U.S. dollars.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in 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.

A significant portion of our cash is kept in Hong Kong dollars (HK dollars) as well as U.S. dollars. The value of our ADSs will, therefore, be affected by the foreign exchange rates between U.S. dollars, HK dollars and the RMB. For example, to the extent that we need to convert U.S. dollars or HK dollars into RMB for our operations or if any of our arrangements with other parties are denominated in U.S. dollars or HK dollars and need to be converted into RMB, appreciation of the RMB against the U.S. dollar or the HK dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars or HK dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar or the HK dollar against the RMB would have a negative effect on the conversion amounts available to us.

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

#### 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 June 30, 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 June 30, 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 June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

## Changes in Internal Control over Financial Reporting

During the six months ended June 30, 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, except as follows:

Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. We conduct preclinical and clinical activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of raw materials in relation to drug development, our ability to raise capital, the market price of our ordinary shares and/or our ADSs or prevent us from selling our drug products in certain countries.

Furthermore, the SEC has issued statements primarily focused on companies with significant China-based operations, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which Chairman Gensler stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with significant China-based operations. The statement also addressed risks inherent in companies with a Variable Interest Entity, or a VIE structure. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations by China. Further, we believe that we have robust disclosures relating to our operations in China, including the relevant risks noted in Chairman Gensler's statement. However, it is possible that the Company's periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States.

In response to the SEC's July 30 statement, the China Securities Regulatory Commission (CSRC) announced on August 1, 2021, that "[i]t is our belief that Chinese and U.S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of China-based companies listed in the U.S. so as to form stable policy expectations and create benign rules framework for the market." While the CSRC will continue to collaborate "closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures," it emphasized that it "has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations."

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ordinary shares and/or our ADSs.

Compliance with China's new Data Security Law, Measures on Cybersecurity Review (revised draft for public consultation), Personal Information Protection Law (second draft for consultation), regulations and guidelines relating to the multi-level protection scheme and any other future laws and regulations may entail significant expenses and could materially affect our business.

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China's new Data Security Law promulgated by the Standing Committee of the National People's Congress of China in June 2021, or the Data Security Law, will take effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. As the Data Security Law has not yet come into effect, we may need to make adjustments to our data processing practices to comply with this law.

Additionally, China's Cyber Security Law, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopt a multi-level protection scheme (MLPS), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network systems belong—from the lowest Level 1 to the highest Level 5 pursuant to the Measures for the Graded Protection and the Guidelines for Grading of Classified Protection of Cyber Security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

Recently, the Cyberspace Administration of China has taken action against several Chinese internet companies in connection with their initial public offerings on U.S. securities exchanges, for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law, the Cyber Security Law and the Measures on Cybersecurity Review, which are aimed at "preventing national data security risks, maintaining national security and safeguarding public interests." On July 10, 2021, the Cyberspace Administration of China published a revised draft of the Measures on Cybersecurity Review, expanding the cybersecurity review to data processing operators in possession of personal information of over 1 million users if the operators intend to list their securities in a foreign country.

It is unclear at the present time how widespread the cybersecurity review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. China's regulators may impose penalties for non-compliance ranging from fines or suspension of operations, and this could lead to us delisting from the U.S. stock market.

Also, recently, the National People's Congress released the second consultation draft of the Personal Information Protection Law. The draft proposes a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The draft also proposes that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold to-be-set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the draft contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement. Compliance with the Cyber Security Law and the Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law and the recent Chinese government actions could materially adversely affect our ability, on fa

The audit report included in our periodic reports are prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, you are deprived of the benefits of such inspection, we may be subject to additional Nasdaq listing criteria or other penalties and our ADSs may be delisted from the U.S. stock market.

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

Inspections of auditors conducted by the PCAOB outside China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in China prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors are deprived of the benefits of PCAOB inspections and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of lawmakers introduced bills in both houses of the U.S. Congress, which if passed, would require the SEC to maintain a list of issuers for which PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on Our Exchanges Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges, such as the Nasdaq, of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted.

Furthermore, there have been recent deliberations within the U.S. government regarding potentially limiting or restricting China-based companies from accessing U.S. capital markets. On May 20, 2020, the U.S. Senate passed the Holding Foreign Companies Accountable Act (HFCA Act), which includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction and to prohibit the securities of such issuers that have has three consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq. The U.S. House of Representatives passed the HFCA Act on December 2, 2020, and the HFCA Act was signed into law on December 18, 2020. On May 13, 2021, the PCAOB issued proposed PCAOB Rule 6100 Board Determinations under the HFCA Act for public comment. The proposed rule provides a framework for making determinations as to whether PCAOB is unable to inspect an audit firm in a foreign jurisdiction, including the timing, factors, bases, publication and revocation or modification of such determinations, and provides that such determinations may be made on a jurisdiction-wide basis in a consistent manner applicable to all firms headquartered in the jurisdiction.

Additionally, in July 2020, the U.S. President's Working Group on Financial Markets issued recommendations for actions that can be taken by the executive branch, the SEC, the PCAOB or other federal agencies and departments with respect to Chinese companies listed on U.S. stock exchanges and their audit firms, in an effort to protect investors in the United States. In response, on November 23, 2020, the SEC issued guidance highlighting certain risks (and their implications to U.S. investors) associated with investments in China-based issuers and summarizing enhanced disclosures the SEC recommends China-based issuers make regarding such risks.

On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act (AHFCA Act), which amends the requirements of the HFCA Act to require that the SEC identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by any non-U.S. authority and to prohibit the securities of such issuers that have had two consecutive non-inspection years from being traded on U.S. national securities exchanges such as the Nasdaq.

Under the HFCA Act (and, if passed, the AHFCA Act), our securities may be prohibited from trading on the Nasdaq or other U.S. stock exchanges if our auditor is not inspected by the PCAOB for three consecutive years (or, if the AHFCA Act is passed, two consecutive years), and this ultimately could result in our ADSs being delisted which would materially adversely affect the Company.

Additionally, the Nasdaq has proposed adopting additional listing criteria applicable to companies that primarily operate in jurisdictions where local regulators impose secrecy laws, national security laws or other laws that restrict U.S. regulators from accessing information relating to the issuer, or a Restrictive Market. Under the proposed rule, whether a jurisdiction permits PCAOB inspection would be a factor in determining whether a jurisdiction is deemed by the Nasdaq to be a Restrictive Market. If the Nasdaq adopts this rule, China will likely be determined to be a Restrictive Market and, as a result, the Nasdaq may impose on us additional listing criteria or deny continued listing of our securities on the Nasdaq.

There can be no assurance that we or our auditor will be able to comply with requirements imposed by Nasdaq or the U.S. regulators. We are evaluating additional business processes and control changes with the goal of meeting the requirements of the HFCA Act. However, any business processes and control changes that we may implement may not be sufficient or may take time for us to implement and they ultimately may not be successful. We may also be subject to enforcement under the HFCA Act, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act (or, if passed, the AHFCA Act). Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong or may incur increased costs or suffer losses in order to do so. The market price of our ADSs could be materially adversely affected as a result of anticipated negative impacts of these rules and executive, regulatory or legislative actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these rules and executive, regulatory or legislative actions are implemented and regardless of our actual operating performance. Failure to adopt effective contingency plans may also have a material adverse impact on our business and the price of our ADSs and ordinary shares.

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

Substantially all of our operations (and all of our commercial operations) are conducted in China. Accordingly, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China as well as China's economic, political, legal and social conditions in relation to the rest of the world. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, and control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. China's government has implemented various measures to encourage economic development, data protection and allocation of resources. Some of these measures may benefit the overall economy in China but may have a negative effect on us. Our financial condition and results of operations may be adversely affected by government control, perceived government interference and/or changes in tax, cyber and data security, capital investments, cross-border transaction and other regulations that are currently or may in the future be applicable to us. Recently, Chinese regulators have announced regulatory actions aimed at providing China's government with greater oversight over certain sectors of China's economy, including the for-profit education sector and technology platforms that have a quantitatively significant number of users located in China. Although the biotech industry is already highly regulated in China and while there has been no indication to date that such actions or oversight would apply to companies that are similarly situated as us and that are pursuing similar portfolios of drug products and therapies as us, China's government may in the future take regulatory actions that materially adversely affect the busine

# The uncertainties in the China legal system could materially and adversely affect us.

On July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued a document to enhance its enforcement against illegal activities in the securities markets and promote the high-quality development of the capital markets, which, among other things, requires the relevant governmental authorities to strengthen cross-border oversight of law-enforcement and judicial cooperation, to enhance supervision over China-based companies listed overseas, and to establish and improve the system of extraterritorial application of the Chinese securities laws. Since this document is relatively new, uncertainties exist in relation to how soon legislative or administrative regulation-making bodies will respond and what existing or new laws or regulations or detailed implementations and interpretations will be modified or promulgated, if any, and the potential impact such modified or new laws and regulations will have on companies like us.

It is especially difficult for us to accurately predict the potential impact to the Company of new legal requirements in China because the China legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. In 1979, the Chinese government began to promulgate a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. In particular, the China legal system is based on written statutes and prior court decisions have limited value as precedents. Since these laws and regulations are relatively new and the China legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the China legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

#### Other Risk Factors

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.

None.

## Item 6. Exhibits.

# **Exhibit Index**

Exhibit Number	Exhibit Title	
3.1	Fifth Amended and Restated Memorandum of 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	Fifth Amended and Restated Articles of Association of Zai Lab Limited (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-38205) filed with the SEC on June 24, 2021)	
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	
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 September 1, 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*	Amendment to the Amended and Restated Employment Agreement, dated as of May 7, 2021, by and between Zai Lab (US) LLC and Tao Fu	
10.2*^	Collaboration and License Agreement, dated as of May 28, 2021, by and between Zai Lab (Hong Kong) Limited and Mirati Therapeutics, Inc.	
10.3*∧	License and Collaboration Agreement, dated as of June 15, 2021, by and between Zai Lab (US) LLC and MacroGenics, Inc.	
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(a) 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(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code	
101.INS*	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	

Exhibit Number	Exhibit Title
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definitions Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

- \* Filed herewith
- \*\* Furnished herewith
- ^ 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.

Dated: August 9, 2021

# **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

By: /s/ Samantha Du

Name: Samantha Du

Title: Chief Executive Officer

39

## ZAI LAB LIMITED

Number	Ordinary Shares			
[ ]	-[ ]-			
Incorporated under the laws of the Cayman Islands Share capital is <b>US\$30,000</b> divided into <b>500,000,000</b> Shares of <b>US\$0.0006</b> par value each				
THIS IS TO CERTIFY THAT [ ] is the registered holder of [ Amended and Restated Memorandum and Articles of Association thereof.	] Ordinary Shares in the above-named Company subject to the Fifth			
EXECUTED on behalf of the said Company on the [ ] day of [	] 2021 by:			
DIRECTOR				

### ZAI LAB (US) LLC

May 7, 2021

RE: Amendment to the Amended and Restated Employment Agreement

Dear Tao,

This letter agreement (the "<u>Letter Amendment</u>") confirms the terms of your continued employment with Zai Lab (US) LLC, a Delaware limited liability company (the "<u>Company</u>") and amends the Amended and Restated Employment Agreement between you and the Company, dated as of January 25, 2019 (the "<u>Amended Employment Agreement</u>"). This Letter Amendment shall be effective as of May 7, 2021 (the "<u>Effective Date</u>"). All capitalized terms used in this Letter Amendment shall have the meaning ascribed to them by the Amended Employment Agreement unless otherwise expressly provided herein.

You and the Company hereby agree as follows:

- 1. As of the Effective Date, Section 1.1 of the Amended Employment Agreement will be amended as follows: "President and Chief Operating Officer of the Company and President and Chief Operating Officer of the Parent Company" shall be deleted in its entirety and replaced with "Chief Strategy Officer".
- 2. As of the Effective Date and without any further action required therefor, you will be deemed to have resigned from any and all positions and offices (including any position on the Board) that you hold with the Company or any of its Affiliates, except with respect to your position of Chief Strategy Officer (collectively, the "Resignations"). The Company, on its own behalf and on behalf of its Affiliates, hereby accepts the Resignations as of the Effective Date, and you agree to sign and return any documents relating to the Resignations as the Company or any of its Affiliates may reasonably require.
- 3. You acknowledge and agree that the changes contemplated by this Letter Amendment shall not constitute "Good Reason" as defined in Section 4.7 of the Amended Employment Agreement and will not entitle you to any severance benefits or other rights under the Amended Employment Agreement or any other agreement between you and the Company or any of its Affiliates, to which you might otherwise be entitled in connection with this Letter Amendment. You expressly waive any entitlement to severance benefits or other rights under the Amended Employment Agreement and any other such agreement which may arise as a result of actions contemplated or undertaken in connection with this Letter Amendment. For the avoidance of doubt, your severance benefits and other rights under the Amended Employment Agreement and any other such agreement will remain in effect in all respects other than as expressly addressed herein.

- 4. With respect to the Existing Option to purchase 500,000 American Depository Shares representing ordinary shares of the Parent Company (the "<u>Shares</u>"), 200,000 Shares representing 40% of Shares subject to the Existing Option are currently vested. The unvested portion of the Existing Option shall be scheduled to vest as follows:
  - 100,000 Shares, representing 20% of Shares subject to the Existing Option, that are scheduled to vest on September 24, 2021 (the "September 2021 Option Tranche") will instead be scheduled to vest in accordance with the following schedule:
    - 25,000 Shares, representing 25% of Shares subject to the September 2021 Option Tranche, will be scheduled to vest on September 24, 2021, and
    - the remaining 75,000 Shares, representing 75% of the Shares subject to the September 2021 Option Tranche, will be scheduled to vest on March 24, 2022;
  - 100,000 Shares, representing 20% of Shares subject to the Existing Option, that are scheduled to vest on September 24, 2022 will
    instead be scheduled to vest on March 24, 2023; and
  - 100,000 Shares, representing 20% of Shares subject to the Existing Option, that are scheduled to vest on September 24, 2023 will instead be scheduled to vest on March 24, 2024.

Except as modified by this paragraph 4, the Existing Option will continue to be subject to the terms and conditions of the Option Agreement and the Plan, and any other restrictions and limitations generally applicable to the equity of the Parent Company, equity awards held by Company executives or otherwise imposed by law.

- 5. With respect to the Existing Restricted Stock Award, 80,000 Shares representing 40% of the Shares subject to the Existing Restricted Stock Award are currently vested. The unvested portion of the Existing Restricted Stock Award shall be scheduled to vest as follows:
  - 40,000 Shares, representing 20% of Shares subject to the Existing Restricted Stock Award, that are scheduled to vest on September 24, 2021 (the "September 2021 RS Tranche") will instead be scheduled to vest in accordance with the following schedule:
    - 20,000 Shares, representing 50% of the Shares subject to the September 2021 RS Tranche, will be scheduled to vest on September 24, 2021, and
    - the remaining 20,000 Shares, representing 50% of the Shares subject to the September 2021 RS Tranche, will be scheduled to vest on March 24, 2022;
  - 40,000 Shares, representing 20% of Shares subject to the Existing Restricted Stock Award, that are scheduled to vest on September 24, 2022 will instead be scheduled to vest on March 24, 2023; and
  - 40,000 Shares, representing 20% of Shares subject to the Existing Restricted Stock Award, that are scheduled to vest on September 24, 2023 will instead be scheduled to vest on March 24, 2024.

Except as modified by this paragraph 5, the Existing Restricted Stock Award will continue to be subject to the terms and conditions of the Restricted Stock Agreement and the Plan, and any other restrictions and limitations generally applicable to the equity of the Parent Company, equity awards held by Company executives or otherwise imposed by law.

- 6. You agree that you have no rights or claims to any additional stock options, restricted stock or other equity incentive awards other than the Existing Option and the Existing Restricted Stock Award. Notwithstanding the foregoing, you will be eligible to receive new equity incentive awards in the future if and when approved by the Board of Directors of the Parent Company and subject to your continued employment with the Company at the time such awards are granted.
- 7. Except as expressly modified herein, the Amended Employment Agreement, and all of its terms and provisions, shall remain in full force and effect.
- 8. This Letter Amendment embodies the entire agreement between the parties with respect to amending the Amended Employment Agreement and supersedes all prior communications, agreements and understandings, whether written or oral, with respect to the same.
- 9. This Letter Amendment may be executed in one or more counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same instrument.
- 10. This Letter Amendment may be amended or modified only by a written instrument signed by you and by an expressly authorized representative of the Company.
- 11. This Letter Amendment shall be governed by, and construed and enforced in accordance with, the laws of the State of California, without giving effect to its principles or rules of conflict of laws to the extent such principles or rules would require or permit the application of the laws of another jurisdiction.

Please acknowledge your agreement with the terms and conditions of this Letter Amendment by signing and returning the enclosed copy of this Letter Amendment to the undersigned, whereupon this Letter Amendment will become a binding agreement between us.

Sincerely,

Zai Lab (US) LLC

By: /s/ Samantha Du

Name: Samantha Du

Title: CEO and Chairperson

Accepted and agreed:

Signature: /s/ Tao Fu

Tao Fu

Date: May 7, 2021

Exhibit 10.2

## COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (this "Agreement") is entered into as of May 28, 2021 (the "Effective Date") by and among Mirati Therapeutics, Inc., a Delaware corporation, having a place of business at 3545 Cray Court, San Diego, CA 92121 USA ("Mirati") and Zai Lab (Hong Kong) Limited, incorporated and registered in Hong Kong with the company number 1899671 whose registered office is at Room 2301, 23/F, Island Place Tower, 510 King's Road, North Point, Hong Kong ("Licensee"). Mirati and Licensee may be referred to herein individually as a "Party" and collectively as the "Parties."

#### RECITALS

**WHEREAS,** Mirati controls certain intellectual property rights, data and know-how with respect to the clinical stage oncology product referred to as "adagrasib" or "MRTX849";

WHEREAS, Licensee wishes to obtain from Mirati the right to develop and commercialize the adagrasib product in the Licensed Territory (as defined below), including the People's Republic of China, both alone and in combination with other drugs and drug candidates, and is willing to commit to conduct development and regulatory activities to obtain approval of the adagrasib product in such Licensed Territory, all as provided in and subject to the following terms; and

**WHEREAS**, Mirati is willing to grant such rights to Licensee, subject to Licensee's commitment to the collaborative development of the adagrasib product, including Licensee's collaboration in Global Studies (as defined below), and to the other terms set forth below.

### AGREEMENT

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Licensee and Mirati hereby agree as follows:

## 1. DEFINITIONS

- **1.1** "Acquiror" has the meaning set forth in Section 17.5(c).
- **1.2** "Active Development Activities" has the meaning set forth in Section 5.1(d).
- **1.3 "Additional Global Study"** as the meaning set forth in Section 5.4(e).
- **1.4** "Affiliate" means, with respect to a given Party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party, as the case may be, but for only so long as such control exists. As used in this Section 1.4, the term "control" (with correlative meanings for the terms "controlled by" and "under common control with") means that the applicable entity has direct or indirect beneficial ownership of more than 50% of the voting share capital or other equity interest in the controlled Party, or the actual ability (directly or indirectly) to control the management and business policies of such Party. Notwithstanding the foregoing, for the purposes of this definition, in no event shall Licensee be deemed an Affiliate of Mirati, and in no event shall Mirati be deemed an Affiliate of Licensee.

- **1.5** "Alliance Manager" has the meaning set forth in Section 3.8.
- **1.6** "Applicable Laws" means all laws, statutes, rules, regulations, ordinances, and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city, or other political subdivision, agency, or other body, domestic or foreign, that are applicable to the particular situation, circumstances, rights or obligations.
  - **1.7** "Arbitrator" has the meaning set forth in Section 16.2(a).
  - 1.8 [\*\*\*]
  - **1.9** "Breach Notice" has the meaning set forth in Section 15.2(b)(i).
  - 1.10 "Breakthrough Designation" means designation of a drug as a breakthrough therapy by the NMPA.
- **1.11** "Business Day" means a day other than Saturday, Sunday or any day on which banks located in the state of California, USA 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 each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.
  - 1.13 "Calendar Year" means each respective period of twelve (12) consecutive months ending on December 31.
- **1.14** "cGCP" means the current good clinical practice as set out in ICH Harmonized Guidance on current Good Clinical Practice (CPMP/ICH/135/95) or U.S. 21 C.F.R. Chapters 50, 54, 56, 58, 210, 211 and 312, as may be amended from time to time.
- **1.15** "cGLP" means the current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58, as may be amended from time to time.
- 1.16 "cGMP" means the then-current good manufacturing practices required by the FDA and other Applicable Laws in the United States relating to the manufacture and testing of pharmaceutical materials, and comparable Applicable Laws and requirements of the NMPA relating to the manufacture and testing of pharmaceutical materials in the Licensed Territory, as may be amended from time to time, including applicable rules and guidelines promulgated under the ICH.

- **1.17** "Change of Control" shall mean, with respect to a Party, (a) a merger, consolidation, reorganization, amalgamation, arrangement, share exchange, tender or exchange offer, private purchase, business combination or other transaction of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's assets.
  - **1.18** "Checkpoint" has the meaning set forth in Section 5.4(c).
  - **1.19 "Checkpoint Enrollment Allocation"** has the meaning set forth in Section 5.4(c).
  - **1.20** "Claim" has the meaning set forth in Section 14.1.
- **1.21** "Clinical Data" means any and all data (together with all clinical trial reports and the results of analyses thereof, including case report forms) derived or generated in any Clinical Trial involving the Compound or any Licensed Product conducted by or on behalf of either Party.
  - **1.22** "Clinical Development Milestone Event" has the meaning set forth in Section 9.2(a).
  - **1.23** "Clinical Development Plan" has the meaning set forth in Section 5.2.
  - **1.24** "Clinical Supply Agreement" has the meaning set forth in Section 8.1.
- **1.25** "Clinical Trial" means any human clinical trial of the Compound or a Licensed Product, including any phase 1 clinical trial, phase 2 clinical trial, phase 3 clinical trial and/or Pivotal Clinical Trial.
  - **1.26** "CMC" has the meaning set forth in Section 1.98.
  - 1.27 "CMOs" means Third Party contractor manufacture organizations.
- **1.28** "Co-Commercialization" or "Co-Commercialize" or "Co-Commercializing" means, with respect to a Party, (a) each of the following Commercialization activities, to the extent assigned to such Party in the applicable Co-Commercialization Plan, undertaken by personnel of such Party with respect to Commercialization of the applicable Licensed Product in the applicable Region in the Licensed Territory. For clarity, Co-Commercialization does not include activities related to [\*\*\*].

- **1.29** "Co-Commercialization Exercise Notice" has the meaning set forth in Section 7.4(a).
- **1.30** "Co-Commercialization Option" has the meaning set forth in Section 7.4(a).
- **1.31 "Co-Commercialization Plan**" has the meaning set forth in Section 7.4(b)(i)
- **1.32** "Co-Commercialization Term" means, on a Licensed Product by Licensed Product basis and Region by Region basis, the period commencing on the date of delivery of the Co-Commercialization Exercise Notice until the earlier of (i) the date such date Parties mutually agree to terminate the Co-Commercialization with respect to such Licensed Product, and (ii) the expiration date of the applicable Royalty Term for such Licensed Product in such Region.
  - 1.33 "Code" means Title 11 of the U.S. Code.
  - **1.34** "Combination Regimen" has the meaning set forth in Section 1.106.
  - **1.35** "Combined Therapy" has the meaning set forth in Section 1.106.
- 1.36 "Commercialization" or "Commercialize" means the conduct of all activities undertaken after Regulatory Approval relating to the promotion, sales, booking of sales, marketing, detailing, appropriate medical support, and distribution of Licensed Products, including Detailing, advertising, promotional materials, market research, market access (including list price and reimbursement activities), and appropriate medical education and information services, publication, and scientific and medical affairs.
  - **1.37** "Commercialization Plan" has the meaning set forth in Section 7.3.
- 1.38 "Commercially Reasonable Efforts" means, with respect to an objective of a Party, the reasonable, diligent, good faith efforts of such Party (including the efforts of its Affiliates, and permitted sublicensees), of the type to accomplish such objective as similarly situated (with respect to size, stage of development, and assets) companies in the pharmaceutical industry would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that, with respect to efforts to be expended in relation to the Compound or any Licensed Product, efforts that are consistent with the efforts applied and commonly used by similarly situated (with respect to size, stage of development, and assets) companies in the pharmaceutical industry to conduct such tasks for a compound or product of similar strategic importance and market potential, and at a similar stage of development taking into account efficacy, safety, Regulatory Authority-approved labeling, the competitiveness of alternative products in the marketplace sold by Third Parties, the patent and other proprietary position of the product, the cost and likelihood of regulatory approval given the regulatory structure involved, the expected and actual profitability of the product, and other relevant factors based on conditions then prevailing, provided, however, Licensee may not take into account [\*\*\*]. Commercially Reasonable Efforts requires that Licensee, at a minimum, (a) assign responsibility for such obligations to qualified employees, (b) set annual goals and objectives for carrying out such obligations, and (c) allocate resources designed to meet such goals and objectives, in each case, in order to Exploit the Licensed Product as an active and ongoing program, and obtain Regulatory Approval for the Exploitation of the Licensed Product in the Licensed Territory in an expeditious manner. Commercially Reasonable Efforts shall be determined [\*\*\*].

- **1.39** "Committee" means the JSC, JDC, JCC, or any subcommittee established by the JSC, JDC or JCC, as applicable.
- **1.40** "Competitive Product" means any small molecule compound or product that binds specifically to the Target only and inhibits the signaling of the Target with [\*\*\*].
- **1.41 "Compound"** means the small molecule KRAS G12C inhibitor compound known as adagrasib, having the chemical structure set forth in **Exhibit 1.41**.
- 1.42 "Confidential Information" means all information of a confidential or proprietary nature disclosed by or on behalf of a Party to the other Party under this Agreement, which may include any such information related to any scientific, clinical, engineering, manufacturing, marketing, financial, or personnel matters relating to a Party, or related to a Party's present or future products, sales, suppliers, customers, employees, investors, business plans, Know-How, regulatory filings, data, compounds, research projects, work in progress, future developments or business, in all such cases whether disclosed in oral, written, graphic or electronic form, and whether or not specifically marked as confidential or proprietary, where under the circumstances in which such disclosure was made or given the nature of information disclosed, a reasonable person would consider such information confidential; provided, however, that in any event, the term "Confidential Information" of a Party (as disclosing Party) excludes any particular information that (a) is known by receiving Party (or its Affiliate) at the time of disclosure, and not through a prior disclosure by or on behalf of the disclosing Party, as documented by written records; (b) is or becomes properly in the public domain through no fault of the receiving Party; (c) is subsequently rightfully disclosed to the receiving Party by a Third Party who is not directly or indirectly under an obligation of confidentiality to the disclosing Party, as documented by written records; or (d) is developed by the receiving Party independently of, and without reference to or use of, Confidential Information received from or on behalf of the disclosing Party as documented by written records. The term "Confidential Information" of a party includes information disclosed as Confidential Information by or on behalf of either Party pursuant to the Confidentiality Agreement.
- **1.43** "Confidentiality Agreement" means the Mutual Non-Disclosure Agreement between the Mirati and Zai Lab (US) LLC, an Affiliate of Licensee, dated as of [\*\*\*].
- **1.44 "Control"** or "**Controlled"** means, with respect to any Know-How, Patent, or other intellectual property right, that the applicable Party (or its Affiliate) owns or has a license (or sublicense) (but without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to or under such Know-How, Patent, or other intellectual property right and has the legal authority and right to grant access, a license, or a sublicense of or otherwise transfer or grant the right to the other Party as set forth under this Agreement under such Know-How, Patent, or other intellectual property rights, or to otherwise disclose proprietary or trade secret information to such other Party, in each case without (a) breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party or (b) incurring payments to a Third Party, except for (i) [\*\*\*], and (ii) any Know-How, Patents or other intellectual property right which a Party in-licenses and under which the other Party elects to take a sublicense and agrees to make the associated payments, which will be considered under the Control of such first Party.

- **1.45** "Cover," "Covering" or "Covered" means, with respect to a particular subject matter at issue and the relevant Patent, that, but for a license granted to a Party or a Third Party under a claim included in such Patent, the manufacture, use, sale, offer or sale or importation by such Party of the subject matter at issue would infringe such claim or, in the case of a Patent that is a patent application, would infringe a claim in such patent application if it were to issue as a patent in a particular Region or country.
- **1.46** "CTA" means: (a) a clinical trial application or any successor application or procedure required to initiate clinical testing of any Licensed Product in humans and (b) all supplements and amendments to any of the foregoing.
- **1.47** "**Detailing**" means a face-to-face meeting in an individual or group practice setting (or other method of individual contact if mutually agreed by the Parties), including a hospital setting, between a professional sales representative of the applicable Party, and a health care professional licensed or authorized to prescribe drugs, during which a presentation of a Licensed Product's attributes is presented in a manner consistent with Applicable Laws and industry standards and with the quality of similar presentations made by a Party's sales representatives for such Party's other products, if applicable. A Detail does not include a reminder or sample drop made by a sales representative or contacts made at conventions, exhibit booths or speaker meetings.
- **1.48** "Development" or "Develop" means the conduct of all activities that are directed to obtaining or maintaining Regulatory Approval of a Licensed Product, obtaining Regulatory Approval for an additional Indication for a Licensed Product that has previously obtained Regulatory Approval for an Indication, or other lifecycle management of a Licensed Product in the applicable territory, including (a) the conduct of non-clinical studies and clinical trials, and (b) all regulatory activities relating to conducting such clinical trials, all activities relating to preparing and filing applications for such Regulatory Approvals, and to prosecuting such applications through obtaining the Regulatory Approvals.
  - **1.49** "Development Report" has the meaning set forth in Section 5.6(a).
  - **1.50** "Enrollment Completion Date" has the meaning set forth in Section 5.4(b).
  - **1.51** "Enrollment Completion Date Shortfall" has the meaning set forth in Section 5.4(b).

-6-

- **1.52** "Enrollment Period" has the meaning set forth in Section 5.4(b).
- **1.53** "Excess Enrollment Budget" has the meaning set forth in Section 5.4(b).
- **1.54** "Existing Global Studies" has the meaning set forth in Section 5.4(a).
- **1.55** "Exploit" or "Exploitation" means to make, have made, import, export, use, have used, sell, have sold, offer for sale or otherwise exploit, including to Develop, Commercialize, register, modify, enhance, improve, manufacture, have manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of.
- **1.56** "Field" means all human uses, including the diagnosis, treatment, palliation or prevention of any Indications, diseases or disorders in humans.
- **1.57** "First Commercial Sale" means the first sale or other commercial transfer by Licensee or any of its Affiliates or Sublicensees to a Third Party of a Licensed Product in the Licensed Territory for end use after Regulatory Approval has been granted with respect to such Licensed Product in the Licensed Territory; provided, that, the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or Sublicensee (unless the Affiliate or Sublicensee is the last entity in the distribution chain of any Licensed Product), (b) any use of a Licensed Product in Clinical Trials, pre-clinical studies or other research or Development activities, or (c) the disposal or transfer of any Licensed Product for a bona fide charitable purpose, without consideration, including for any compassionate use or as "named patient sales".
  - 1.58 "FTE" means the equivalent of the work of one (1) person full time for one (1) Calendar Year [\*\*\*]. [\*\*\*]
  - **1.59** "Generic Competition" has the meaning set forth in Section 9.3(c).
- **1.60 "Generic Product**" means, with respect to a Licensed Product in a particular Region in the Licensed Territory, any pharmaceutical product that (a) is marketed for sale by a Third Party not authorized by Licensee (or its Affiliate or Sublicensee), (b) contains the same active pharmaceutical ingredient(s) as such Licensed Product, and (c) is deemed consistent with such Licensed Product in quality and efficacy by the applicable Regulatory Authorities in such Region in the Licensed Territory and that has received all necessary Regulatory Approvals from such Regulatory Authorities in such Region to market and sell such product as a pharmaceutical product for any of the indications included in the approved labeling for such Licensed Product in such Region.
  - **1.61** "Global Commercialization Strategy" has the meaning set forth in Section 7.2(a).
- **1.62** "Global Study" means a clinical study designed to obtain Regulatory Approvals for the Licensed 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.

- **1.63** "[\*\*\*]" has the meaning set forth in Section 5.4(c).
- **1.64** "ICC" has the meaning set forth in Section 16.2.
- **1.65** "ICH" means the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).
  - **1.66** "Incremental Withholding" has the meaning set forth in Section 10.3(b).
- **1.67** "IND" means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority in the Licensed Territory, which application is required to commence or conduct particular human clinical trial(s) in the Licensed Territory.
- **1.68** "**Indemnified Party**" means a Mirati Indemnitee or Licensee Indemnitee (as applicable) that seeks indemnification from the applicable Party pursuant to the terms of Section 14.3.
  - **1.69** "Indemnifying Party" has the meaning set forth in Section 14.3.
- **1.70 "Indication"** means a separate and distinct disease or condition, sign or symptom of a disease or medical condition, or distinct tissue of origin. For clarity, different lines of treatment or the treatment of separate stages or forms of the same disease or medical condition shall not constitute separate Indications.
- **1.71 "Initiation"** or "**Initiate"** means, with respect to a clinical trial, the enrollment of the first human subject satisfying the enrollment criteria in such clinical trial.
- **1.72** "**Invention**" means all inventions, improvements, and Know-How conceived, discovered, developed or otherwise made, as necessary to establish authorship (in case of publication and other copyrightable work), inventorship (in case of inventions, whether patentable or not) or ownership under Applicable Law, whether or not patentable, and any and all Patent and other intellectual property rights thereto.
  - **1.73** "**IRB**" has the meaning set forth in Section 5.1(d).
  - **1.74** "JCC" has the meaning set forth in Section 3.3.
  - **1.75** "JDC" has the meaning set forth in Section 3.2.
  - **1.76** "Joint Global Study" has the meaning set forth in Section 5.4(b).
  - **1.77** "**Joint Inventions**" has the meaning set forth in Section 11.1(b)(iii).
  - **1.78** "Joint Patents" has the meaning set forth in Section 11.1(b)(iii).
  - **1.79** "JSC" has the meaning set forth in Section 3.1.

-8-

- **1.80** "Know-How" means all proprietary business, scientific or technical results, data and other information, in any tangible or intangible form whatsoever, including techniques, technology, trade secrets, inventions (whether patentable or not), know-how, processes, methods, data, research data, clinical pharmacology data, chemistry-manufacture-controls data (including analytical and quality control data and stability data), Clinical Data and Manufacturing Data, pre-clinical data, regulatory documents, Regulatory Filings, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical material, and all other scientific, clinical, regulatory, marketing, financial, and commercial information.
- **1.81** "Knowledge" or "Known to" means, with respect to a particular representation or other statement of Party set forth in this Agreement, the actual knowledge of the chief executive officer or any executive officer (as defined for purposes of Section 14 of the Securities Exchange Act of 1934, as amended) of such Party after reasonable inquiry of the relevant persons who have responsibilities related to the subject matter of the applicable representation or other statement.
  - **1.82** "KRAS Variant" means [\*\*\*].
- **1.83** "Licensed Know-How" means all Know-How that (a) Mirati or its Affiliates Controls as of the Effective Date or during the Term, and (b) directly relates to the Compound or any Licensed Product (including any Combined Therapy), or any uses thereof, and is necessary or reasonably useful to Exploit any Compound or Licensed Product in the Field in the Licensed Territory. For clarity, Licensed Know-How includes all Product Inventions, Licensed Territory Data and Results, and subject to the initiation of the Manufacturing Technology Transfer pursuant to Section 8.5, Manufacturing Data, but excludes all Know-How that does not relate to the Compound and relates to another proprietary compound of Mirati or its Affiliates.
- **1.84** "Licensed Patents" means all Patents in the Licensed Territory that (a) Mirati or its Affiliates Controls as of the Effective Date or during the Term, and (b) that are necessary or reasonably useful to Exploit the Compound or any Licensed Products in the Field in the Licensed Territory, but excluding Mirati's interest in any Joint Patents, and excluding all Patents to the extent of claims in such Patents that Cover another proprietary compound of Mirati or its Affiliates and do not Cover the Compound. For purposes of clarity, the Licensed Patents shall include as of the Effective Date the Patents set forth on **Exhibit 1.84** attached hereto. **Exhibit 1.84** shall be periodically updated during the Term to add any Licensed Patents described in this definition of which either Party becomes aware. For clarity, any Patent that is a Licensed Patent (that is, it meets the definition in this Section 1.84) shall be considered a Licensed Patent for purposes of this Agreement even if such Patent is not listed on **Exhibit 1.84**. For clarity, Licensed Patents includes all Product Patents.
- **1.85** "Licensed Product" means any product that constitutes, contains, incorporates or comprises the Compound (whether alone or as a combination with other active ingredient(s)), in any form, presentation, or formulation (including manner of delivery and dosage).
  - **1.86** "Licensed Technology" means the Licensed Patents and Licensed Know-How.
  - 1.87 "Licensed Territory" means PRC, Hong Kong, Macau and Taiwan, each shall be deemed a "Region" under this Agreement.

- **1.88** "Licensed Territory Data and Results" means all results, data, and analyses thereof, including non-clinical data and Clinical Data, generated by or on behalf of Licensee or any of its Affiliates or Sublicensees during the Term with respect to the Development of the Compound or any Licensed Product (and is not related to another active pharmaceutical ingredient) pursuant to this Agreement, including Joint Global Studies and Local Studies, but for clarity excluding [\*\*\*].
  - **1.89** "Licensee Commercial Supply Agreement" has the meaning set forth in Section 8.6.
  - **1.90** "Licensee Commercialization FTEs" has the meaning set forth in Section 7.4(b)(i).
  - **1.91** "Licensee Indemnitee" has the meaning set forth in Section 14.2.
- **1.92** "Licensee Know-How" means all Know-How, other than Product Inventions, Licensed Territory Data and Results and Manufacturing Data, that (a) Licensee or any of its Affiliates Controls as of the Effective Date and during the Term, (b) directly relates to the Compound or any Licensed Product (including any Combined Therapy), or the manufacture or any uses thereof, and (c) is necessary or reasonably useful to Exploit the Compound or any Licensed Product in the Field. For clarity, Licensee Know-How shall exclude all Know-How that does not relate to the Compound and relates to another proprietary compound of Licensee or its Affiliates.
- 1.93 "Licensee Patents" means all Patents, other than Licensed Patents, Joint Patents and Product Patents, that (a) Licensee or any of its Affiliates Controls as of the Effective Date and during the Term, (b) relates to the Compound or Licensed Product, or the manufacture or any uses thereof, or claims or is based on any Licensee Technology, and (c) are necessary or reasonably useful for to Exploit the Compound or any Licensed Product in the Field in any country, Region or jurisdiction. For clarity, Licensee Patents shall exclude Licensee's interest in any Joint Patents, and exclude all Patents to the extent of claims in such Patents that Cover another proprietary compound of Licensee or its Affiliates and do not Cover the Compound.
  - 1.94 "Licensee Technology" means Licensee Know-How, Licensee Patents, and Licensee's rights under any Joint Inventions and Joint Patents.
- **1.95** "Local Study" means any Clinical Trial for any Licensed Product in the Field and which (a) Licensee determines to conduct and is conducted by or on behalf of Licensee in the Licensed Territory, and (b) does not include clinical sites in any country or jurisdiction outside the Licensed Territory.
  - **1.96** "Losses" has the meaning set forth in Section 14.1.
- **1.97** "Manufacturing Cost" means the actual, fully-burdened cost to manufacture Compound or Licensed Product, which means: (a) in the case of Compound or Licensed Product (and related services) acquired from Third Parties, payments made to such Third Parties plus any internal and out-of-pocket costs, if any, incurred by the supplying Party in connection with providing the Compound or Licensed Product to the purchasing Party, including any [\*\*\*]; [\*\*\*] and (b) in the case of manufacturing activities performed by the supplying Party or its Affiliates to manufacture Compound or Licensed Product, the actual unit costs of manufacture, which shall consist of [\*\*\*].

- **1.98** "Manufacturing Data" means all chemistry-manufacture-controls ("CMC") data (including analytical data, test data, quality control data and stability data) and any other data relating directly to manufacture of the Compound or any Licensed Product that are generated by or on behalf of either Party, or jointly by the Parties, in connection with the performance of this Agreement, including the Development or Commercialization of the Compound and any Licensed Products.
  - **1.99** "Manufacturing Technology Transfer" has the meaning set forth in Section 8.5.
  - **1.100 "Minimum Enrollment Threshold"** has the meaning set forth in Section 5.4(b).
  - **1.101** "Mirati Commercial Supply Agreement" has the meaning set forth in Section 8.2.
  - **1.102** "Mirati Indemnitee" has the meaning set forth in Section 14.1.
  - 1.103 "Mirati Invention Patents" means any Patents that contain one or more claims that Cover Mirati Inventions.
- **1.104** "Mirati Inventions" means any Inventions that are conceived, discovered, developed or otherwise made by or on behalf of Mirati or its Affiliates during the Term, and all Product Inventions.
  - **1.105** "[\*\*\*] **Enrollment Allocation**" has the meaning set forth in Section 3.2(d).
- 1.106 "Net Sales" means the gross amounts invoiced, billed or otherwise charged by Licensee and its Affiliates or Sublicensees in the Licensed Territory (each, a "Selling Party"), for sales or other dispositions for value of Licensed Products (for clarity, including Combined Therapy) to Third Parties that are not Sublicensees of the Selling Party, less the following deductions to the extent actually incurred, or accrued, or otherwise specifically allocated with respect to such sale of the Licensed Product by the Selling Party, using U.S. GAAP:

-11-

[\*\*\*]

In no event shall any particular amount of deduction identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of deductions). Sales of Licensed Product among Licensee and its Affiliates and Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Licensed Product to a Third Party that is not a Sublicensee shall be included within the computation of Net Sales. Notwithstanding anything to the contrary herein, sale, disposal, or use of Licensed Product without consideration for: [\*\*\*] shall not be deemed a sale hereunder.

[\*\*\*]

If any Licensed Product is sold together with one or more other pharmaceutical products (each containing an active ingredient other than the Compound) that are either (x) packaged together for sale or shipment as a single unit or sold at a single price, or (y) marketed or sold collectively as a single product, or (z) marketed or sold where the Licensed Product is intended to be used in a Combination Regimen (as defined below and (x) through (z) collectively, "Combined Therapy"), then, the Net Sales from the Combined Therapy, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as determined above) of the Combined Therapy, during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the average sale price of the Licensed Product when sold separately in finished form and B is the average sale price of the other pharmaceutical products included in the Combined Therapy when sold separately in finished form, in each case during the applicable royalty reporting period or, if sales of both the Licensed Product and the other pharmaceutical products do not occur in such period, then in the most recent royalty reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both the Licensed Product and all other pharmaceutical products included in such Combined Therapy, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combined Therapy by the fraction of C/(C+D) where C is the fair market value of the Licensed Product and D is the fair market value of all other pharmaceutical products included in the Combined Therapy. In such event, the Parties shall negotiate in good faith to determine the respective fair market values of the Licensed Product and all other pharmaceutical products included in the Combined Therapy based on the relative value contributed by each component. If the Parties are unable to agree on the respective fair market values, the dispute will be resolved in accordance with Article 16. As used herein, "Combination Regimen" means, with respect to a given Licensed Product, the intended use of such Licensed Product for an Indication together with one or more other pharmaceutical products as two or more entities of active ingredients in a combination therapy, including concomitant or sequential therapy for commercial sale for such Indication as set forth in the approved label for such Licensed Product.

- **1.107** "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.
  - **1.108** "Non-Prosecuting Party" has the meaning set forth in Section 11.2(c).
  - **1.109 "Patent Challenge"** has the meaning set forth in Section 15.2(d).
- 1.110 "Patents" means (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings, and patent applications, and (b) any renewal, division, continuation (in whole or in part), or request for continued examination of any of such patents, certificates of invention, applications for certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
  - 1.111 "PD-1 Inhibitor" means any compound or product that directly inhibits the receptor known as Programmed Cell Death protein 1 ("PD-1").
  - 1.112 "PD-L1 Inhibitor" means any compound or product that directly inhibits the ligand known as Programmed Cell Death ligand 1 ("PD-L1").

-13-

- **1.113** "**Person**" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a governmental authority.
  - **1.114** "Pharmacovigilance Agreement" has the meaning set forth in Section 6.5(d).
- **1.115** "Pivotal Clinical Trial" means, with respect to a Licensed Product, (a) a phase 3 Clinical Trial or (b) any other clinical trial that is intended (as of the time the study is initiated) to obtain the results and data to support (without the need to conduct any additional clinical trial) the filing of an application for Regulatory Approval for such product.
  - 1.116 "PRC" means People's Republic of China, which for purposes of this Agreement, excludes Hong Kong, Macau, and Taiwan.
  - **1.117** "**Product Infringement**" has the meaning set forth in Section 11.3(a).
- **1.118 "Product Inventions**" means any Invention that (a) relates to [\*\*\*] or their manufacture or use, or claim or is based on [\*\*\*] and is not related to [\*\*\*]; and (b) is conceived, discovered, developed, invented, or generated as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, sublicensees, agents or contractors.
  - 1.119 "Product Patent" means any Patent that contains one or more claims that Cover solely Product Inventions.
  - **1.120 "Prosecuting Party"** has the meaning set forth in Section 11.2(c).
- **1.121** "Public Official" means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality, or subdivision of any government, military, or international organization, including, but not limited to, any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party, or any official of a political party.
  - **1.122** "Quality Agreement" has the meaning set forth in Section 8.7.
- 1.123 "Reference Data" means all data generated relating to the Compound or Licensed Products in the Field, including preclinical data, Clinical Data, safety data and CMC data contained in or referenced in any Regulatory Filings pertaining to the Licensed Product in the Field submitted by or on behalf of a Party, its Affiliates, or licensees, and all corresponding documentation Controlled by such party as of the Effective Date or at any time during the Term.
  - **1.124 "Region"** has the meaning set forth in Section 1.87.
  - **1.125** "Regional Mark" has the meaning set forth in Section 11.6.

- **1.126** "Regulatory Approval" means all approvals, licenses, registrations, or authorizations of each applicable country, Region, federal, supranational, state, or local Regulatory Authority (including agency, department, bureau, or other government entity) that are necessary for the manufacture, use, storage, import, transport, and sale of Compound or Licensed Product (as applicable) in a given jurisdiction, but excluding any pricing approvals and reimbursement approvals.
- **1.127** "**Regulatory Authority**" means any national, provincial, or local regulatory agency, department, bureau, or other government entity, that has responsibility in its applicable jurisdiction over the research, Development, manufacture, or Commercialization of the Compound or any Licensed Product in a given jurisdiction, including the NMPA, and any corresponding national or regional regulatory authorities.
- 1.128 "Regulatory Exclusivity" means any exclusivity (including for clarity new chemical entity exclusivity, new use or Indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity) conferred by the Regulatory Authority in a particular country, Region, or jurisdiction in the Licensed Territory which confers an exclusive commercialization period during which Licensee, its Affiliates or Sublicensees have the exclusive right to market and sell a Licensed Product in such country, Region or jurisdiction, other than issued patent exclusivity.
- **1.129 "Regulatory Filing"** means, all applications, filings, submissions, approvals, licenses, registrations, permits, notifications, and authorizations (or waivers) with respect to the testing, Development, manufacture, or Commercialization of the Compound or any Licensed Product (as applicable) made to or received from any Regulatory Authority in a given country or Region, including any INDs or CTAs.
  - **1.130** "Regulatory Meeting" has the meaning set forth in Section 6.4.
  - **1.131** "Regulatory Milestone Event" has the meaning set forth in Section 9.2(b).
- 1.132 "Royalty Term" means, with respect to a Licensed Product sold in a Region in the Licensed Territory, the period commencing with the First Commercial Sale of such Licensed Product in such Region and ending upon the latest to occur of: (i) the date of expiration of the last Valid Claim Covering such Licensed Product or the Compound in such Region; (ii) the date that is ten (10) years after the date of such First Commercial Sale in such Region; and (iii) the expiration date of any Regulatory Exclusivity for such Licensed Product in such Region.
  - **1.133** "Sales Milestone Event" has the meaning set forth in Section 9.2(c).
  - **1.134** "Securities Regulators" has the meaning set forth in Section 12.5.
  - **1.135** "Securitization Transaction" has the meaning set forth in Section 17.5(b).

-15-

- 1.136 "Segregate" shall mean, with respect to a particular Competitive Product, to use Commercially Reasonable Efforts to segregate the research, development and commercialization activities relating to such Competitive Product from the Development and Commercialization activities relating to the Compound or any Licensed Product under this Agreement, including putting in place appropriate firewalls that are reasonably designed to ensure that: (a) no personnel involved in performing the research, development or commercialization of such Competitive Product have access to non-public plans, non-public information or any other relevant Confidential Information of the applicable Party relating to the Development or Commercialization of the Compound or any Licensed Product under this Agreement; and (b) no personnel involved in performing the Development or Commercialization of the Compound or any Licensed Product under this Agreement have access to non-public plans or non-public information relating to the research, development or commercialization of such Competitive Product; provided, that, in either case of (a) or (b), senior management personnel may review and evaluate plans and information regarding the research, development and commercialization of such Competitive Product solely in connection with monitoring the progress of products including portfolio decision-making among product opportunities.
  - **1.137** "Selling Party" has the meaning set forth in Section 1.106.
  - **1.138** "Sell-Off Period" has the meaning set forth in Section 15.3(i).
  - **1.139** "Sublicense Agreement" has the meaning set forth in Section 2.2.
- **1.140** "Sublicensee" means a Third Party to whom Licensee (or any Affiliate of Licensee) has granted a sublicense in accordance with Section 2.2.
  - 1.141 "Target" means the protein target listed on Exhibit 1.141 attached hereto.
  - **1.142** "Term" has the meaning set forth in Section 15.1.
  - 1.143 "Third Party" means any entity other than Mirati, Licensee, or an Affiliate of Mirati or Licensee.
- **1.144** "[\*\*\*] **Decision Matter**" means any disputed matter that involves any activities of Licensee or any of its Affiliates or Sublicensees with respect to [\*\*\*] that would reasonably be expected [\*\*\*].
- **1.145** "Upstream Agreement" means any and all agreements between Mirati or any of its Affiliates, on the one hand, and any Third Party, on the other hand, pursuant to which Mirati has (a) in-licensed any material Patent or Know-How Controlled by such Third Party that are included as part of the Licensed Patents or Licensed Know-How or (b) agreed to provisions that would require Licensee to make any payments (including royalties) to any Third Party or to undertake or observe any restrictions or obligations with respect to the Exploitation of the Compound or any Licensed Products in the Field [\*\*\*]. Exhibit 1.145 sets forth a list of all Upstream Agreements as of the Effective Date.
- **1.146** "U.S. GAAP" means United States generally accepted accounting principles, which principles are currently used at the relevant time and consistently applied by the applicable Party.

1.147 "Valid Claim" means, with respect to a particular Region, a claim within (a) an unexpired and issued patent (or any patent term extensions or supplementary protection certificates thereof) included within the Licensed Patents that has not been irretrievably lapsed or been abandoned, disclaimed, permanently revoked, dedicated to the public or held invalid, unenforceable or not patentable by a final non-appealable decision of a court of competent jurisdiction or government agency, or (b) a pending patent application included within the Licensed Patents being prosecuted in good faith and has been pending for no more than seven (7) years from the earliest priority date; provided that, if a claim ceases to be a Valid Claim by reason of foregoing subclause (b), then such claim will again be deemed a Valid Claim in the event such claim subsequently issues prior to the end of the Royalty Term in such Region.

**1.148** "Withholding Action" has the meaning set forth in Section 10.3(b).

### 2. GRANT OF LICENSES

- **2.1 License Grants to Licensee**. Subject to the terms and conditions of this Agreement, Mirati hereby grants to Licensee during the Term the following licenses:
- (a) an exclusive (even as to Mirati, but subject to Mirati's retained rights as described in Section 2.3 below), royalty-bearing license, with the right to grant sublicenses as provided in Section 2.2, under the Licensed Technology and Mirati's rights under any Joint Inventions and Joint Patents, to sell, offer for sale and otherwise Commercialize any Licensed Products in the Field in the Licensed Territory; provided that such license to Commercialize the Licensed Products in the Field in the Licensed Territory shall be subject to Mirati's rights to Co-Commercialize pursuant to Section 7.4 during any applicable Co-Commercialization Term; and
- (b) a non-exclusive, royalty-bearing license, with the right to grant sublicenses as provided in Section 2.2, under the Licensed Technology and Mirati's rights under any Joint Inventions and Joint Patents, to research, Develop, use, import, and subject to the initiation of the Manufacturing Technology Transfer pursuant to Section 8.5, make and have made the Compound and any Licensed Products in the Field in the Licensed Territory.

-17-

- 2.2 Sublicenses. Licensee shall have the right to grant sublicenses under the rights and licenses granted under Section 2.1 through multiple tiers to (a) any Affiliates (for as long as such Person remains an Affiliate) without Mirati's prior written consent but upon prompt written notice to Mirati, and (b) any Third Party with respect to the Development, manufacture or Commercialization of the Compound or any Licensed Products in the Field and in the Licensed Territory, in each case with prior written consent of Mirati (which shall not be unreasonably withheld, delayed or conditioned). Any and all such sublicenses shall be granted and governed by written agreements (each, a "Sublicense Agreement") and shall be subject to, and consistent with, the terms and conditions of this Agreement and shall include a provision that permits Licensee to terminate the Sublicense Agreement if such Sublicensee (or an Affiliate of such Sublicensee) undertakes a Patent Challenge with respect to any Licensed Patents under which the Sublicensee is sublicensed or breaches the relevant terms of this Agreement. Licensee shall be and remain responsible for ensuring its Sublicensees' compliance with this Agreement and shall be and remain liable for any breaches hereof by any such Sublicensee as though the same were a breach by Licensee, [\*\*\*]. [\*\*\*] Licensee shall provide Mirati with a copy of each such Sublicense Agreement granted by Licensee to an Affiliate or Sublicensee (redacted with respect to financial terms and sensitive commercial or technical information to the extent not necessary for Mirati to confirm Licensee's compliance with the terms of this Agreement) within [\*\*\*] of executing such Sublicense Agreement, including an English translation, if applicable. Licensee shall, in each Sublicense Agreement, require its Sublicensee to provide the following to Mirati (or directly to Licensee): (i) the assignment and transfer of ownership and possession of, or a right of reference to, all Regulatory Filings and Regulatory Approvals Controlled by such Sublicensee, and (ii) the assignment of, or a freely sublicensable (through multiple tiers) exclusive license to, all intellectual property (including Know-How and Patents) Controlled by such Sublicensee that Covers the Compound and any Licensed Product or its respective use, manufacture, sale, or importation and was conceived, discovered, developed or otherwise made by or on behalf of such Sublicensee during the exercise of its rights or fulfillment of its obligations pursuant to such Sublicense Agreement. For clarity, in the case of any subcontractor, this Section 2.2 shall not apply but Section 2.8 shall apply.
- **2.3 Retained Rights**. Notwithstanding anything herein to the contrary, any rights not expressly granted to Licensee by Mirati under this Agreement are hereby retained by Mirati, including the right (on behalf of itself and its licensees and sublicensees other than Licensee (subject to Section 2.3(d))) under the Licensed Technology and Mirati's rights under any Joint Inventions and Joint Patents:
- (a) to exercise its rights, and perform its obligations, under this Agreement, whether directly or through one or more Affiliates, licensees or subcontractors;
- (b) to make and have made (itself or through its Affiliates and licensees) the Compound and any Licensed Product anywhere in the world including in the Licensed Territory solely for (i) use, Development or Commercialization of the Compound and any Licensed Product outside the Licensed Territory, or (ii) use, Development or Commercialization of the Compound and any Licensed Product by or on behalf of Licensee or its Affiliates or Sublicensees in the Licensed Territory;
  - (c) to conduct Development of the Compound and any Licensed Product [\*\*\*];
- (d) following Mirati's exercise of the Co-Commercialization Option for a Licensed Product in a Region and during the applicable Co-Commercialization Term, to Co-Commercialize any Licensed Product in such Region with the right to grant sublicenses through multiple tiers to (i) Mirati's Affiliates (for as long as such Person remains an Affiliate) without Licensee's prior written consent but upon prompt written notice to Licensee, (ii)[\*\*\*] [\*\*\*]; and

(e) to practice and grant licenses under the Licensed Know-How and Licensed Patents outside of the scope of the licenses granted to Licensee in Section 2.1.

## **2.4 License Grant to Mirati**. Licensee hereby grants to Mirati:

- (a) an exclusive, perpetual, royalty-free and fully-paid license, with the right to grant sublicenses through multiple tiers, under Licensee Technology, to Exploit the Compound and any Licensed Product in the Field outside the Licensed Territory; and
- (b) a non-exclusive, perpetual, royalty-free and fully-paid license, with the right to sublicense through multiple tiers, under the Licensee Technology, to Develop, make and have made, and use the Compound and the Licensed Products in the Licensed Territory (i) solely for use, Development or Commercialization outside of the Licensed Territory, (ii) solely to supply Licensee in the conduct of Development or Commercialization activities in the Licensed Territory, and (iii) to otherwise exercise its rights retained under Section 2.3; and
- (c) following Mirati's exercise of the Co-Commercialization Option for a Licensed Product in a Region and during the applicable Co-Commercialization Term, a co-exclusive (with Licensee) license, with the right to grant sublicenses through multiple tiers to Mirati's Affiliates (for as long as such Person remains an Affiliate) which shall be subject to Licensee's prior written consent, not to be unreasonably withheld, under the Licensee Technology, to Co-Commercialize such Licensed Product in the Field in the Licensed Territory.
- **2.5 Upstream Agreements.** All licenses and other rights granted to Licensee under this Agreement (including any sublicense rights) are subject to the rights and obligations of Mirati under the Upstream Agreements including the rights reserved to Third Parties, and grant back licenses set forth therein. Licensee is subject to and will comply with, and shall require its Affiliates and Sublicensees to comply with, all applicable provisions of the Upstream Agreements, [\*\*\*] Licensee will perform and take such actions as may be reasonably required to allow Mirati to comply with its obligations under the Upstream Agreements, including obligations relating to sublicensing, patent matters, additional licensed patents and know-how, confidentiality, reporting, audit rights, indemnification and diligence, in each case, to the extent that Licensee is provided a copy of the Upstream Agreements. [\*\*\*] [\*\*\*] The Parties will amend **Exhibit 1.145** from time to time as necessary to include all Upstream Agreements.

-19-

### 2.6 No Implied Licenses; Negative Covenants.

- (a) No right or license under any Patents or other intellectual property rights of a Party is granted or shall be granted by implication to the other Party, and each Party agrees not to practice any Patents or other intellectual property rights of the other Party except pursuant to the licenses and other rights expressly granted in this Agreement or any other written agreement between the Parties. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Without limiting the foregoing, Mirati hereby acknowledges and agrees that no right or license is granted to Mirati by Licensee under this Agreement under any Patents or Know-How Controlled by Licensee that Covers or relates to any proprietary compound of Licensee. Without limiting the foregoing, and notwithstanding any other provision of this Agreement, Licensee hereby acknowledges and agrees that no right or license is granted to Licensee by Mirati under this Agreement under any Patents or Know-How owned or controlled by Mirati that Covers or relates to any proprietary compound of Mirati other than the Compound.
- (b) Licensee covenants that it, and its Affiliates and Sublicensees, will Develop, manufacture, and Commercialize the Licensed Products solely within the Licensed Territory for use in the Field, pursuant to and in accordance with the rights and licenses granted to it under and the terms and conditions of this Agreement, and will not use or practice Licensed Patents or Licensed Know-How licensed to it by Mirati except as expressly permitted in scope of the license granted to Licensee in Section 2.1. Licensee agrees and acknowledges that it has not been granted any rights (express or implied) to any Licensed Patents, Licensed Know-How, or Licensed Products under this Agreement outside of the Field or outside of the Licensed Territory, and accordingly agrees that during the Term it will not (i) Commercialize any Licensed Product outside of the Field or outside of the Licensed Territory or within the Licensed Territory for sale by or for Licensee outside of the Field or outside of the Licensed Territory, or (ii) provide any Licensed Product to any Third Party, Sublicensee or Affiliate if Licensee has actual knowledge or reasonably believes that such Third Party, Sublicensee or Affiliate, either directly or indirectly, is selling, or intends to sell such Licensed Product outside of the Field or outside of the Licensed Territory.
- (c) Mirati covenants that, except as otherwise expressly set forth or permitted in this Agreement (including under the retained rights in Section 2.3), Mirati, and its Affiliates and sublicensees, will Commercialize the Licensed Products solely outside the Licensed Territory. Mirati and its Affiliates and sublicensees will not use or practice any Licensee Technology licensed to it by Licensee except as expressly permitted in this Agreement. Mirati agrees and acknowledges that except as otherwise expressly set forth or permitted in this Agreement, it has not been granted any rights (express or implied) to any Licensee Technology, and accordingly agrees that during the Term it will not (i) Commercialize any Licensed Product in the Licensed Territory or outside the Licensed Territory intended for sale by or for Mirati inside of the Licensed Territory, or (ii) provide any Licensed Product to any Third Party, sublicensee or Affiliate if Mirati has actual knowledge or reasonably believes that such Third Party, sublicensee or Affiliate, either directly or indirectly, is selling, or intends to sell, such Licensed Product in the Licensed Territory.

-20-

### 2.7 Exclusivity.

- (a) During the Term, except as provided in Section 17.5(c), Licensee shall not, and shall cause its Affiliates and Sublicensees to not, directly or indirectly for or through any Third Party, including by grant of any rights to any Third Party [\*\*\*].
- (b) During the Term, except as provided in Section 17.5(c), Mirati shall not, and shall cause its Affiliates and licensees to not, directly or indirectly for or through any Third Party, including any grant of any rights to any Third Party, to [\*\*\*].
- 2.8 Subcontracting. Subject to the terms of this Section 2.8, each Party may engage Third Party subcontractors to perform its obligations under this Agreement; [\*\*\*]. In all cases, each Party will ensure that (a) such Party remains responsible for the work allocated to such subcontractors to the same extent it would if it had done such work itself, (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are at least as protective as those undertaken by the Parties with respect to Confidential Information pursuant to Article 12 hereof, and (c) the subcontractor undertakes in writing to assign all intellectual property with respect to the Compound or any Licensed Product, all results and all other intellectual property, in each case arising from the course of performing such subcontracted activities, so that the Party engaging such Third Party subcontractor will Control such intellectual property.

## 3. GOVERNANCE

- **3.1 Joint Steering Committee**. Within [\*\*\*] of the Effective Date or a period otherwise mutually agreed to by the Parties, the Parties will form a joint steering committee (the "JSC") to coordinate, oversee and provide strategic oversight of the activities under this Agreement and to facilitate communication between the Parties and provide a forum for the Parties to review matters pertaining to the Development, manufacture, and Commercialization of Licensed Product in the Licensed Territory. Except as otherwise provided herein, the role and responsibilities of the JSC are:
- (a) to review and discuss the Development, manufacture and Commercialization activities of the Compound and any Licensed Products in the Licensed Territory and any other ongoing activities under this Agreement;
- (b) to facilitate the flow of information between the Parties with respect to the Development, manufacture and Commercialization of the Compound and any Licensed Products;

- (c) to establish such additional committees as it deems necessary to achieve the objectives and intent of this Agreement;
- (d) to oversee the activities of the JDC, JCC and any other Committee and provide guidance thereto;
- (e) to attempt to resolve issues presented to it by, and disputes within, the JDC, JCC and any other Committee; and
- (f) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.
- **3.2 Joint Development Committee.** Within [\*\*\*] of the Effective Date or a period otherwise mutually agreed to by the Parties, the Parties will form a joint development and regulatory committee (the "**JDC**") to coordinate the overall strategy, plans, and responsibilities of the Parties for Development of the Compound and any Licensed Products in the Licensed Territory and outside the Licensed Territory, to facilitate communication between the Parties and provide a forum for the Parties to review Development and regulatory matters pertaining to the Licensed Products in the Licensed Territory and outside the Licensed Territory, and to coordinate such Development activities in the Licensed Territory with Licensed Product development work outside the Licensed Territory. Except as otherwise provided herein, the role and responsibilities of the JDC are:
- (a) to oversee strategy, progress, and results with respect to the Development of the Licensed Product in the Field in the Licensed Territory;
- (b) to review and discuss any material Development activities, including any Clinical Trials, with respect to any Licensed Product in the Field both in the Licensed Territory and outside the Licensed Territory;
- (c) to review and approve the initial Clinical Development Plan and any material amendments or revisions to the Clinical Development Plan;
- (d) to develop (but not approve): (i) for each Existing Global Study, the [\*\*\*] enrollment allocation (the [\*\*\*] Enrollment Allocation") for each [\*\*\*] in the Enrollment Period, and (ii) for each additional Global Study deemed a Joint Global Study (1) the Minimum Enrollment Threshold, and (2) if the Parties agree to include an obligation for Licensee to meet [\*\*\*] Enrollment Allocations, the [\*\*\*] Enrollment Allocation. Each [\*\*\*] Enrollment Allocation shall be mutually agreed upon or amended in writing by the Parties, and for each additional Global Study deemed a Joint Global Study, the applicable Minimum Enrollment Threshold shall be mutually agreed upon in writing by the Parties;
  - (e) to review and coordinate forecasting and supply of Licensee's expected requirements of Licensed Product for Development purposes;
  - (f) to review all material Clinical Data obtained from Clinical Trials of the Compound and any Licensed Product in the Licensed Territory;

- (g) to review all material Clinical Data for any Joint Global Studies within the Clinical Development Plan;
- (h) to review all material Reference Data Controlled by a Party and generated or produced in connection with any Development activities conducted for any Licensed Product in the Licensed Territory and outside the Licensed Territory;
- (i) to provide a forum for discussion of and coordinate interactions with Regulatory Authorities in the Licensed Territory and outside the Licensed Territory;
- (j) to review any material Regulatory Filings with respect to the Licensed Products to be submitted to any Regulatory Authority in the Licensed Territory;
  - (k) to review and discuss any proposals from Mirati regarding any Additional Global Studies;
- (l) to discuss and provide a forum for the exchange of pharmacovigilance and safety matters prior to commercial launch of the Licensed Product;
- (m) to provide a forum for discussion of and coordinate decisions related to research and Development of new Indications, new Licensed Product formulations, and Combined Therapy Development; and
- (n) to perform such other functions as the Parties may allocate to JDC in writing, where such functions are appropriate to further the purposes of this Agreement with respect to the Development of Licensed Products in the Licensed Territory.
- **3.3 Joint Commercialization Committee.** At least [\*\*\*] prior to the first anticipated Regulatory Approval of any Licensed Product in the Licensed Territory, the Parties will form a joint commercialization committee (the "JCC") to coordinate the overall strategy, plans, and responsibilities of the Parties, facilitate communication between the Parties and provide a forum for the Parties to review matters pertaining to Commercialization of Licensed Products in the Field in the Licensed Territory. Except as otherwise provided herein, the role and responsibilities of the JCC will be to:
  - (a) discuss strategy, progress, and results with respect to Licensed Product Commercialization in the Field in the Licensed Territory;
  - (b) review the Commercialization Plan and oversee implementation thereof;
  - (c) review the date of anticipated First Commercial Sale of such Licensed Product in the PRC provided by Licensee to the JCC;
- (d) if Mirati exercises the Co-Commercialization Option, (i) review, comment and approve [\*\*\*], (ii) review and approve the amount [\*\*\*] shall pay to [\*\*\*] for Co-Commercialization activities performed by [\*\*\*] in addition to [\*\*\*], and (iii) review and oversee the coordination of Co-Commercializing activities to be conducted by the Parties;

- (e) solely to the extent that Mirati is supplying Licensee with Compound or Licensed Product for Commercialization purposes, review and coordinate forecasting and supply of Licensee's expected requirements of Compound and Licensed Product for such Commercialization purposes;
- (f) discuss and provide a forum for the exchange of pharmacovigilance and safety matters following commercial launch of Licensed Product;
- (g) perform such other functions as the Parties may deem appropriate to further the purposes of this Agreement with respect to the Commercialization of Licensed Product in the Licensed Territory.
- **3.4 Committee Composition**. Each Committee will be composed of [\*\*\*] members appointed by Mirati and [\*\*\*] members appointed by Licensee, each of which members shall be senior level employees with decision-making authority and significant experience in the relevant business responsibilities of the Committee. Each Party will notify the other Party of its initial JSC and JDC member nominations within [\*\*\*] after the Effective Date. The Parties, through the applicable Committee, may mutually agree to change the number of Committee members. Each Party may change its Committee members at any time by written notice to the other Party. Any member of a Committee may designate a substitute to attend and perform the functions of that member at any particular Committee meeting. Each Party may invite a reasonable number of non-member, non-voting representatives of such Party to attend any Committee meeting; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Third Party shall be bound by confidentiality and non-use obligations consistent with the terms of this Agreement.
- **3.5 Meetings**. Each Committee will hold meetings at such frequency as determined by the Committee members, but no less than [\*\*\*], unless otherwise reasonably agreed to by the Parties. The first JSC and JDC meeting shall each be held within [\*\*\*] after the Effective Date. The first JCC meeting shall be held within [\*\*\*] after the JCC's formation pursuant to Section 3.3. Such meetings may be conducted by videoconference, teleconference, or in person, as agreed to by the Parties, provided that at least one such meeting shall be in person [\*\*\*], unless otherwise agreed to by the Parties. Minutes will be kept of all Committee meetings. Meeting minutes will be prepared by Licensee within [\*\*\*] after the applicable meeting and sent to each member of the Committee for review and preliminary approval, which minutes shall be formally approved by the Committee at its next scheduled meeting. Any costs and expenses incurred related to a Committee meeting, including, if applicable, travel or telecommunication expenses, shall be borne separately by each Party.
- **3.6 Decision-Making.** Decisions of a Committee with respect to matters within the responsibility of such Committee shall be made [\*\*\*], with Mirati's Committee members [\*\*\*] and Licensee's Committee members [\*\*\*]. If a Committee cannot reach unanimous agreement on such a matter before it for [\*\*\*], the matter shall be referred to [\*\*\*]. If such disagreement has not been resolved within [\*\*\*] after being referred to [\*\*\*], then [\*\*\*] shall have the casting vote for all matters, except any matters where the resulting decision would relate primarily to [\*\*\*], in which case, [\*\*\*] shall have the casting vote. [\*\*\*] shall only exercise such right to the casting vote [\*\*\*]. Notwithstanding the foregoing, if any such disputed or unresolved matter involves [\*\*\*], such disputed or unresolved matter shall be resolved by [\*\*\*]. [\*\*\*] shall only exercise its right to the casting vote, in all cases (including when using it in its sole discretion), in good faith and provided such Party shall not use its casting vote to materially increase the other Party's obligations or expenses under this Agreement. For clarity, [\*\*\*] shall have the casting vote for [\*\*\*]), provided in exercising such right to the casting vote, [\*\*\*] shall reasonably take into account [\*\*\*] may, thereafter, exercise its casting vote [\*\*\*]. If after [\*\*\*] exercises its casting vote [\*\*\*].

- **3.7 Scope of Governance**. Each Committee shall only have such powers, authority and responsibilities as are specifically assigned to it in this Agreement, and such powers shall be subject to the terms and conditions set forth herein. Without limiting the generality of the foregoing, no Committee will have any power to amend this Agreement, and no Committee decision shall be in contravention of or conflict with any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by a Committee are only those specific issues that are expressly provided in this Agreement to be decided by such Committee.
- 3.8 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual who shall be an employee of such Party having appropriate qualification and experience to act as the alliance manager for such Party with respect to the matters covered by this Agreement (the "Alliance Manager"). Each Alliance Manager shall be responsible for coordinating and managing processes and interfacing between the Parties on a day-to-day basis throughout the Term. The Alliance Manager will ensure communication to the applicable Committees of all relevant matters raised at any joint subcommittees or working groups. Each Alliance Manager shall be permitted to attend meetings of the applicable Committees as non-voting participants. The Alliance Managers shall be the primary contact for the Parties regarding the day-to-day activities contemplated by this Agreement and shall facilitate information exchange and discussion of all such activities hereunder, and the results thereof. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within each Committee and its subcommittees, if any. Costs with respect to Alliance Managers shall be borne separately by each Party.
- **3.9 Discontinuation of Participation on a Committee.** For clarity, [\*\*\*] membership in any particular Committee shall be at its sole discretion, as a matter of right and not obligation, for the sole purpose of participation in governance, decision-making, and information exchange with respect to activities within the jurisdiction of the Committee. [\*\*\*] shall have the right to withdraw, at any time, from membership on a Committee upon [\*\*\*] prior written notice to [\*\*\*], which notice shall be effective upon the expiration of such [\*\*\*] period. Following the issuance of such notice: (a) [\*\*\*] membership in such Committee shall be terminated, (b) [\*\*\*] Committee members shall no longer have any decision-making rights as provided in Section 3.6 and (c) each Party shall have the obligation to provide and the right to continue to receive the information it would otherwise be required to provide and entitled to receive under the Agreement and to participate directly with the other Party in discussions, reviews and approvals currently allocated to such Committee pursuant to this Article 3.

-25-

### 4. TECHNOLOGY TRANSFER

- **4.1 Technology Transfer**. Promptly after the Effective Date and in any event within [\*\*\*] following the Effective Date, Mirati will, [\*\*\*] in accordance with a reasonable schedule established by the JSC, disclose and make available to Licensee in reasonable form all Licensed Know-How (other than any Reference Data) in Mirati's Control as of the Effective Date (the "**Initial Technology Transfer**"). Throughout the Term, each Party will make available to other Party in reasonable form additional Licensed Know-How (with respect to Mirati) and Licensee Know-How (with respect to Licensee), in each case, other than any Reference Data, that such Party or its Affiliates comes to Control after the Effective Date, to the extent that such Licensed Know-How or Licensee Know-How, as applicable, comes to such Party's attention (or is reasonably requested by the other Party) and has not previously been provided or made available to the other Party.
- **4.2 Assistance by Mirati**. After the Initial Technology Transfer and subject to the terms of this Agreement, upon Licensee's reasonable request for any reasonable technical assistance as may be necessary in connection with the transfer of Licensed Know-How to Licensee, Mirati shall provide Licensee with such reasonable technical assistance.

## 5. DEVELOPMENT

## 5.1 Responsibilities and Diligence.

(a) **Development Responsibilities**. Subject to the terms and conditions of this Agreement, Licensee shall be primarily responsible for conducting all Development activities of the Compound and any Licensed Product required to obtain Regulatory Approval in the Licensed Territory, at its sole expense and in accordance with the Clinical Development Plan. Licensee will be solely responsible for obtaining all Regulatory Approvals in each Region in the Licensed Territory at its sole expense. Licensee will have the right to engage capable, reputable and experienced contract research organizations to conduct particular Development activities as are appropriate to be conducted by subcontractors. Licensee shall keep the JDC informed of the progress and results of such Development activities as provided below. Licensee acknowledges and agrees that the [\*\*\*] shall be coordinated and consistent with the worldwide (outside of the Licensed Territory) [\*\*\*].

- (b) **Diligence**. Licensee shall use Commercially Reasonable Efforts to Develop at least one Licensed Product and seek and maintain Regulatory Approvals for such Licensed Product in the Field in the Licensed Territory; provided that, for clarity, in no event shall the foregoing limit Licensee's obligations under Section 5.4.
- (c) **Compliance**. In conducting Development of the Compound and Licensed Products, Licensee shall comply, and will ensure that its Affiliates comply, and will include in each of its sublicense agreements an obligation of its Sublicensees to comply, with all Applicable Laws, including the regulations promulgated by the relevant Regulatory Authorities for the Development, manufacture, testing, and Commercialization of pharmaceutical products in the Licensed Territory, in good scientific manner, and in compliance in all material respects with all applicable national and international guidelines (e.g., ICH, cGCP, cGMP).
- (d) [\*\*\*]. If, prior to the earlier to occur of (i) [\*\*\*] or (ii) [\*\*\*], Licensee has not conducted [\*\*\*] whether by itself, its Affiliates or permitted Sublicensees for any [\*\*\*] period during the Term, and such [\*\*\*] was not caused by reasons outside of Licensee's, its Affiliates' and Sublicensees' reasonable control, then Licensee shall be deemed to have abandoned the [\*\*\*] for the Licensed Product in the Field in the Licensed Territory and Mirati shall have the right to terminate this Agreement in accordance with Section 15.2(b)(i). [\*\*\*] exist if Licensee has performed or is performing any of the following [\*\*\*] activities: (i) Licensee has [\*\*\*] in the applicable [\*\*\*] period for [\*\*\*] for the Licensed Product in the Licensed Territory if there is [\*\*\*], (ii) Licensee is waiting [\*\*\*] in the Licensed Territory as evident by written correspondences [\*\*\*] (or in the event that [\*\*\*], by written support provided by Licensee), (iii) Licensee is waiting for [\*\*\*].
- **5.2 Clinical Development Plan.** Licensee shall undertake the Development of Licensed Products in a collaborative and efficient manner in accordance with this Article 5. The Development of any Licensed Product relating to the Licensed Territory under this Agreement shall be governed by a written development plan (the "Clinical Development Plan"), as revised from time to time in accordance with this Section 5.2. The Clinical Development Plan shall include [\*\*\*]. 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 any Licensed Product in the Licensed Territory. Licensee has prepared an initial draft of the Clinical Development Plan, which is attached hereto as **Exhibit 5.2**. Promptly following the [\*\*\*] Licensee will prepare the final draft of the initial Clinical Development Plan, and the JDC shall review and approve such Clinical Development Plan. From time to time, but at least [\*\*\*], Licensee shall propose updates or amendments, if any, to the Clinical Development Plan in consultation with Mirati and submit such proposed updated or amended plan to the JDC for review, discussion and approval.

**5.3 Local Study**. Licensee shall be solely responsible for performing any Local Study at its sole cost (including handling relevant Regulatory Filings for any Local Studies in the Licensed Territory at its own cost, as applicable, in accordance with Article 6). Licensee shall use Commercially Reasonable Efforts to conduct all Local Studies set forth in the Clinical Development Plan; <u>provided</u> that [\*\*\*]. Each Local Study conducted in the Licensed 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 Licensed Territory. Notwithstanding the foregoing, Licensee shall not [\*\*\*] that includes a [\*\*\*], without the prior written consent of Mirati.

#### 5.4 Global Study.

(a) **General**. Mirati may initiate, suspend, or cease a Global Study anywhere in the world for any Licensed Product for any Indication, in its sole discretion. **Exhibit 5.4** attached hereto will identify all Global Studies existing or planned by Mirati as of the Effective Date that include clinical sites for Clinical Trials in the Licensed Territory (such Global Studies, the "**Existing Global Studies**"), as each may be updated or amended from time to time.

-28-

(b) Licensee Participation. Licensee (i) shall, at its sole cost and expense, participate in specific Existing Global Studies in accordance with the Clinical Development Plan by coordinating clinical trial sites in the Licensed Territory for such Existing Global Studies to enroll a certain percentage of the total subjects for each such Existing Global Studies, and (ii) may agree to participate in such other Global Studies presented by Mirati pursuant to Section 5.4(e) (each of the Existing Global Studies that Licensee participates in and any such future Global Studies that Licensee participates in, a "Joint Global Study"), provided that (A) upon any suspension initiated by Mirati with respect to any Joint Global Study, Licensee shall be relieved of obligations to meet the Enrollment Period (if applicable) or [\*\*\*] Enrollment Allocation with respect to such Joint Global Study that would have applied during such period of suspension, and upon [\*\*\*] of such suspended Joint Global Study, the Parties shall agree to either (1) extend the Enrollment Period by a period of [\*\*\*] and agree to new [\*\*\*] Enrollment Allocation for any additional [\*\*\*] of the extended Enrollment Period with respect to such Joint Global Study; or (2) reduce the Minimum Enrollment Threshold for such Joint Global Study by [\*\*\*] and, if adopting (1) or (2) would be insufficient to eliminate the negative effect of Mirati's suspension on Licensee's ability to meet the Enrollment Period, [\*\*\*] Enrollment Allocation, or Minimum Enrollment Threshold, the Parties will in good faith agree to further adjustment to the Enrollment Period, [\*\*\*] Enrollment Allocation, or Minimum Enrollment Threshold, with respect to such Joint Global Study; and (B) after any cessation initiated by Mirati with respect to any Joint Global Study in its entirety, Licensee shall be relieved of the obligations with respect to such Joint Global Study set forth in Section 5.4, Section 5.6, Section 5.8, and Section 6.3(b)(i) (for clarity, Licensee's obligation to provide Mirati with access or copies to Reference Data, Regulatory Filing, and correspondence generated prior to such cessation shall be unaffected). Licensee shall be responsible for all activities (if any) associated with conducting each Joint Global Study in the Licensed Territory set forth in the Clinical 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 Clinical Development Plan. With respect to each Existing Global Study, Licensee shall recruit and enroll in a timely manner [\*\*\*] (or such other percentage as agreed to by Mirati) of the total number of patients to be treated under the applicable protocol for such Joint Global Study (each applicable percentage, a "Minimum Enrollment Threshold") with respect to the applicable enrollment period for such Joint Global Study (the "Enrollment Period") in accordance with the Clinical Development Plan. With respect to each Existing Global Study, [\*\*\*] shall timely meet the [\*\*\*] Enrollment Allocation, and provide the JDC [\*\*\*] updates as to whether it expects to meet each [\*\*\*] Enrollment Allocation, and the Parties (through the JDC) shall cooperate in good faith to assist Licensee in meeting each [\*\*\*] Enrollment Allocation. The [\*\*\*] Enrollment Allocation for certain Existing Global Studies are set forth in Exhibit 5.4 attached hereto. Licensee shall be solely responsible for any and all costs (including costs of supply for any combination agents under the applicable Joint Global Study protocol) incurred by or on behalf of Licensee to meet the applicable Minimum Enrollment Threshold. Mirati may, in its sole discretion, request Licensee to enroll a number of patients for any Joint Global Study in excess of the applicable Minimum Enrollment Threshold. If Licensee agrees to enroll such number of excess patients, within [\*\*\*] of Licensee's receipt of Mirati's request, Licensee shall submit to Mirati for Mirati's review and written approval a detailed budget of all estimated costs (including Manufacturing Costs) to be incurred by or on behalf of Licensee for such excess enrollment (such approved budget, the "Excess Enrollment Budget"). Mirati shall reimburse Licensee for documented costs actually incurred by or on behalf of Licensee up to [\*\*\*] of the Excess Enrollment Budget on a [\*\*\*] basis. For avoidance of doubt, if with respect to a given Joint Global Study, the total patients to be enrolled based on the applicable Clinical Development Plan for such Joint Global Study are enrolled prior to the end of the Enrollment Period for such Joint Global Study (such date the total patient enrollment is achieved, the "Enrollment Completion Date"), then starting from the Enrollment Completion Date, Licensee would not be obligated to enroll any more patients as part of such Joint Global Study, and Licensee shall be relieved of all its obligations under Section 5.4(b) or Section 5.4(c) with respect to such Joint Global Study, subject to the following: [\*\*\*].

- (c) **Existing Global Study Shortfall**. With respect to each Existing Global Study, within [\*\*\*] of the applicable Enrollment Period [\*\*\*] and the subsequent [\*\*\*] of the applicable Enrollment Period [\*\*\*] (each such period, a "**Checkpoint**"), Licensee shall[\*\*\*] for the applicable Checkpoint (the "**Checkpoint Enrollment Allocation**"). If Licensee fails to fulfill the Checkpoint Enrollment Allocation, or notifies Mirati through the JDC prior to the end of the applicable Checkpoint that Licensee does not expect to fulfill the Checkpoint Enrollment Allocation, the Parties will [\*\*\*] Mirati shall, [\*\*\*] determine in good faith whether to [\*\*\*] or (ii) [\*\*\*] Mirati may, [\*\*\*] elect to help Licensee meet the enrollment requirements related to such Existing Global Study. If Mirati (A) in good faith [\*\*\*] or (B) grants Licensee [\*\*\*]; provided that, Licensee's failure to fulfill [\*\*\*] is not to the extent [\*\*\*].
- (d) **Joint Global Study Sponsor**. Subject to Section 6.3(c), Licensee, itself or with or through any other of its Affiliates or Sublicensees, shall be the sponsor of each Joint Global Study in the Licensed Territory, unless otherwise agreed by the Parties as set forth in the Clinical Development Plan. For any Joint Global Study, subject to the other provisions hereunder (including Section 5.4(b) which stipulates Mirati shall reimburse Licensee for certain costs pursuant to the Excess Enrollment Budget), Licensee shall be responsible for all costs incurred by or on behalf of Licensee in the performance of such Joint Global Study in the Licensed Territory, and Mirati shall be responsible for all other costs incurred for or in connection with such Joint Global Study.
- (e) Additional Global Studies. From time to time during the Term, Mirati may propose to Licensee, through the JSC, additional Global Studies for any Licensed Product that includes clinical sites for Clinical Trials in the Licensed Territory. The Parties will discuss in good faith and mutually agree on Licensee's participation in such additional Global Study in the Licensed Territory, and Licensee will elect to participate or not participate in such additional Global Study by notifying Mirati in writing within [\*\*\*] after the date of Mirati's presentation of such Global Study to the JSC. If Licensee elects to participate in an additional Global Study by notifying Mirati in writing, such additional Global Study shall be deemed a "Joint Global Study". If Licensee elects not to participate in any additional Global Study presented by Mirati by timely notifying Mirati of such election (or by failing to timely notify Mirati in writing), Mirati may conduct such Global Study in the Licensed Territory (each, an "Additional Global Study") at its sole cost. Any Know-How (except for safety data) or Patents resulting from any Additional Global Study that Licensee has not elected to participate in shall be excluded from Licensed Technology unless Licensee notifies Mirati in writing of Licensee's intent to include any such Know-How or Patents in Licensed Technology and pays to Mirati an amount that is equal to [\*\*\*] of the [\*\*\*] Additional Global Study. Mirati shall share with Licensee and hereby grants to Licensee a right of reference to, any safety data generated from any Additional Global Studies.

-30-

- (f) Notwithstanding anything herein to the contrary, Licensee shall have no obligations under this Section 5.4 with respect to any Joint Global Study (including any Existing Global Study or other Joint Global Study) unless the Reference Data, Regulatory Filings, and any other Know-How or Patents resulting from the conduct of such Joint Global Study outside the Licensed Territory, in each case, that is necessary or reasonably useful to Exploit the Compound or Licensed Product in the Field is Controlled by Mirati, included in the Licensed Technology, and granted and provided to Licensee in accordance with the terms of this Agreement (including Sections 2.1, 4.1, 4.2, 5.8, 6.3(b) and 6.3(d)). At least [\*\*\*] (i) prior to the projected Initiation of each Joint Global Study (with respect to a future Joint Global Study) or (ii) after the Effective Date (with respect to any Existing Global Study), each Party will provide to the other Party a written notice regarding whether it Controls and may grant and provide to the other Party the Reference Data, Regulatory Filings, and any other Know-How or Patents resulting from the conduct of such Joint Global Study in such Party's territory and which otherwise meets the definition of "Licensed Technology" or "Licensee Technology", as applicable, in accordance with the terms of this Agreement (including Sections 2.1, 2.4, 4.1, 4.2, 5.8, 6.3(b), and 6.3(d)).
- **5.5 Records**. Each Party shall maintain, in compliance with the highest industry standard, full, complete, and accurate records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully, accurately and properly reflect all work done and all data and other results achieved or obtained by or on behalf of such Party in the performance of Development activities with respect to the Compound or any Licensed Product under the Clinical Development Plan (with respect to Licensee) and Joint Global Studies and all other Development activities conducted outside the Licensed Territory (with respect to Mirati), and as contemplated by this Agreement.
- **5.6 Disclosures Regarding Development Efforts.** The Parties will share information about their respective Development activities in the Field through the JDC as follows:
- (a) **Licensee**. Licensee shall (i) provide to the JDC, not less than [\*\*\*] during the Term, a report (each, a "**Development Report**") that summarizes in reasonable detail (A) the Development activities conducted by or on behalf of Licensee with respect to the Compound and any Licensed Products in the Field and in the Licensed Territory and (B) any Product Inventions that are first conceived or reduced to practice by Licensee by over such [\*\*\*] period. Each Development Report shall contain sufficient information to allow Mirati to monitor Licensee's compliance with this Agreement, including Licensee's diligence obligation set forth in Section 5.1. [\*\*\*].

-31-

(b) **Mirati**. Mirati shall provide to the JDC, not less than [\*\*\*] during the Term, a report that summarizes any Product Inventions that are first conceived or reduced to practice by Mirati over such [\*\*\*] period.

5.7 Clinical Trial Audits. Upon [\*\*\*] prior written notification by Mirati but no more frequent than [\*\*\*] (except in the event that Mirati has reasonable cause), and based on an audit scope agreed upon by the Parties, Mirati or its representatives may conduct an audit of Licensee [\*\*\*], and all [\*\*\*], in each case, to ensure that the applicable Clinical Trials are conducted in compliance with the Clinical Development Plan, cGCP, and Applicable Laws; provided that (a) such audit will take place during regular business hours of the audited party in a manner that does not interfere with the audited party's normal business operations and shall be conducted under obligations of confidentiality, and (b) in the event any such audit [\*\*\*] requires Licensee's assistance, Licensee shall provide Mirati or its representatives with such assistance at [\*\*\*], to the extent reasonable, including providing personnel of Licensee to be present for such audit and producing any documents or authorizations allowing Mirati or its representatives to conduct such audit, to the extent reasonable. No later than [\*\*\*] after the completion of such audit, Mirati shall provide Licensee with a written summary of Mirati's findings of any deficiencies or other areas of remediation that Mirati identifies during any such audit. Licensee shall use Commercially Reasonable Efforts to respond or remediate any such deficiencies within [\*\*\*] following Licensee's receipt of such report. Without limiting the foregoing, Licensee shall have the right to be present at any such audit conducted by Mirati pursuant to this Section 5.7 [\*\*\*].

**5.8** Access to Data. Each Party shall promptly provide the other Party with access to all Reference Data Controlled by such Party or its Affiliates and generated or produced in connection with any Clinical Trial conducted involving the Compound or any Licensed Product in accordance with the Clinical Development Plan (in case of Licensee) and any Joint Global Studies (in case of Mirati). Upon the request of Licensee, Mirati shall, to the extent not previously provided to Licensee and necessary or reasonably useful to Exploit the Compound or any License Product in the Field and in the Licensed Territory, promptly provide Licensee with access to any Reference Data Controlled by Mirati or its Affiliates and generated or produced in connection with any Clinical Trial conducted involving the Compound or any Licensed Product as part of any Development activities conducted outside the Licensed Territory.

-32-

#### 6. REGULATORY ACTIVITIES

- **6.1 General**. Subject to, and in accordance with, the terms and conditions of this Agreement, the requirements of all Applicable Laws and the Clinical Development Plan, Licensee, at its own expense, shall prepare and file all Regulatory Filings required to Develop the Compound and any Licensed Product and, if successful, to obtain and maintain Regulatory Approvals of any Licensed Product in the Field in the Licensed Territory. Mirati will provide reasonable regulatory and administrative support and assistance to Licensee, to be coordinated by the JDC, in connection with the conduct by Licensee of its activities under this Section 6.1 including the submission by Licensee of any Regulatory Filings in the Licensed Territory. Without limiting the remainder of this Article 6, Licensee, through the JDC, shall keep Mirati fully informed in a timely manner of all material events and developments occurring in the course of seeking and obtaining Regulatory Approvals for the Licensed Products in the Licensed Territory, including material meetings with Regulatory Authorities in the Licensed Territory such that Mirati shall have the option to participate in such activities as provided below.
- **6.2 Regulatory Expenses.** Licensee shall be responsible for all costs and expenses of preparing, coordinating, maintaining, formatting, and filing Regulatory Filings for Licensed Products in the Licensed Territory and for maintaining Regulatory Approval for Licensed Products in the Licensed Territory. Licensee shall be responsible for all costs and expenses of providing English summaries of all information and documents (which are not in English) that Licensee is obligated to provide to Mirati under this Article 6.

# 6.3 Regulatory Filings.

(a) **Review**. The Alliance Managers shall coordinate communication and the exchange of information between the Parties with respect to Regulatory Filings to be prepared and submitted by or for Licensee in the Licensed Territory.

# (b) Copies.

(i) Subject to Applicable Laws, Licensee promptly shall provide to Mirati: (A) electronic copies (as filed with an English summary thereof) of each material Regulatory Filing Controlled by Licensee or its Affiliates or Sublicensees as submitted to Regulatory Authorities in the Licensed Territory, and (B) copies (both as filed or received, and an English summary thereof) of all material correspondence Controlled by Licensee or its Affiliates or Sublicensees with respect to Regulatory Filings to and from any Regulatory Authority in the Licensed Territory. Without limiting the generality of the foregoing, Licensee shall provide Mirati with copies of all material correspondence Controlled by Licensee or its Affiliates or Sublicensees with respect to the Licensed Products to and from any Regulatory Authority in the Licensed Territory (both as filed or received, and an English summary thereof) promptly so as to permit Mirati to comply with its obligations under Applicable Laws in and outside of the Licensed Territory or in accordance with such other timeline set forth in the Pharmacovigilance Agreement entered into by the Parties pursuant to Section 6.5(d). Upon Mirati's reasonable request, Licensee shall provide Mirati with an English translation of a material Regulatory Filing, and material correspondence with respect to Regulatory Filings to and from any Regulatory Authority, in each case, Controlled by Licensee or its Affiliates or Sublicensees and in relation to the Licensed Products and in the Licensed Territory.

(ii) Subject to Applicable Laws, Mirati shall provide Licensee with copies of all material correspondence with respect to the Compound or any Licensed Product to and from any Regulatory Authority pertaining to Regulatory Filings Controlled by Mirati or its Affiliates or its or their licensees (other than Licensee) outside of the Licensed Territory promptly so as to permit Licensee to comply with its obligations under Applicable Laws in the Licensed Territory.

(c) Licensee shall hold and own all such Regulatory Filings covering, and all Regulatory Approvals of, Licensed Product in the Licensed Territory, subject to subsection (d) below and to the provisions of Article 15, provided, however, that if Applicable Laws in the Licensed Territory do not allow Licensee (or an Affiliate of Licensee or a Sublicensee) to hold Regulatory Approvals or Regulatory Filings for the Licensed Product in the Field in the Licensed Territory, then during the Term Mirati (i) will hold such Regulatory Approval for Licensee's benefit, (ii) will appoint Licensee (or an Affiliate of Licensee or a Sublicensee) as its exclusive regulatory agent, local legal agent, and local study sponsor, to handle all regulatory activities for the Licensed Product in the Field in the Licensed Territory, and (iii) will promptly transfer such Regulatory Approval to Licensee or its designee when allowed by Applicable Laws.

# (d) Right of Reference.

(i) Licensee hereby grants to Mirati the right of reference to (A) all Regulatory Filings pertaining to the Compound or Licensed Product in the Field submitted by or on behalf of Licensee or its Affiliates or Sublicensees (and all data contained or referenced therein), with the right to grant further rights of reference to Mirati's licensees with respect to the Compound or Licensed Products, and (B) Reference Data, in each case of (A) and (B), Controlled by Licensee or its Affiliates as of the Effective Date or during the Term and to the extent necessary or reasonably useful to Exploit the Compound or Licensed Product in the Field outside the Licensed Territory. Mirati and its Affiliates (and any licensee to whom it may grant a further right of reference) may use the right of reference to such Regulatory Filings in the Field solely for the purpose of seeking, obtaining and maintaining the Regulatory Approval of the Licensed Products outside the Licensed Territory, and shall treat such Regulatory Filings and data provided by Licensee's Confidential Information and handle them in accordance with the best industry practices.

(ii) Subject to and in accordance with Section 5.4, Mirati hereby grants to Licensee the right of reference to (A) all Regulatory Filings pertaining to the Compound or Licensed Product in the Field submitted by or on behalf of Mirati or its Affiliates or licensees (other than Licensee) (and all data contained or referenced therein), with the right to grant further rights of reference to Sublicensees to the extent permitted pursuant to Section 2.2, and (B) Reference Data, in each case of (A) and (B), Controlled by Mirati or its Affiliates as of the Effective Date or during the Term and to the extent necessary or reasonably useful to Exploit the Compound or Licensed Product in the Field in the Licensed Territory. Licensee and its Affiliates (and any Sublicensee to whom it may grant a further right of reference) may use such right of reference to such Regulatory Filings in the Field solely for the purpose of seeking, obtaining and maintaining the Regulatory Approval of the Licensed Products in the Field in the Licensed Territory.

-34-

**6.4 Regulatory Meetings**. Through the JDC, Licensee shall provide Mirati with a schedule of any material in-person meeting or material teleconference with the Regulatory Authorities (or related advisory committees) in the Licensed Territory planned [\*\*\*] that relates to the Development of the Licensed Products in the Licensed Territory (each, a "**Regulatory Meeting**"). Licensee shall be solely responsible for any communications with Regulatory Authorities occurring or required in connection with performing its regulatory responsibilities set forth in this Article 6 with respect to the Licensed Products in the Licensed Territory, and Mirati shall have the right to provide input in preparation for each such Regulatory Meeting and the right at its sole expense and upon reasonable advance written notice, but not the obligation, to have its representatives attend and participate in each such material Regulatory Meeting, unless prohibited or restricted by Applicable Law or a Regulatory Authority, provided that Licensee shall not be obligated to schedule such meetings to specifically enable Mirati's or its representative's attendance.

## 6.5 Safety; Adverse Event Reporting.

- (a) **Database**. Mirati shall establish, hold, and maintain a global drug safety management system and database for the Licensed Products. As between the Parties, Mirati shall enter into such database all pharmacovigilance and other drug safety data for the Licensed Products (including adverse events) used outside the Licensed Territory as required by Applicable Laws (including any such data collected by its other licensees). Each Party shall have the right to access from such global drug safety database all drug safety data necessary for such Party to comply with all Applicable Laws in such Party's territory. Licensee shall provide to Mirati, for incorporation into such database, all safety-related information generated or obtained from use of Licensed Product in the Licensed Territory.
- (b) Licensee Obligations. Licensee shall be responsible, at its expense, for: (i) collecting all pharmacovigilance and other drug safety data for the Licensed Products in the Licensed Territory as required by Applicable Laws; (ii) reporting all such safety data for the Licensed Products in the Licensed Territory, including adverse events in the Licensed Territory, to the applicable Regulatory Authorities in the Licensed Territory as appropriate to be in compliance with all Applicable Laws; (iii) timely reporting all such safety data to Mirati in the format for entry into the global safety database as specified by Mirati; and (iv) providing a copy of all material correspondence with any data and safety management board with respect to safety data for the Licensed Products in the Licensed Territory. The JDC may establish a safety subcommittee, and if so, all pharmacovigilance and other drug safety data for the Licensed Products in the Licensed Territory, including adverse event reports, shall then be submitted to such safety subcommittee concurrently with the reporting of such data to Mirati pursuant to subsection (iii) above.

-35-

- (c) **Sharing of Safety Data**. Licensee expressly acknowledges that Mirati shall have the right to provide all information received by Mirati pursuant to this Section 6.5 to appropriate Regulatory Authorities outside the Licensed Territory, and any of its applicable Affiliates and other licensees engaged in Development and Commercialization activities of the Licensed Products in accordance with all Applicable Laws. Mirati expressly acknowledges that Licensee shall have the right to provide all information received from Mirati by Licensee from the Mirati safety database to appropriate Regulatory Authorities within the Licensed Territory, and any of its applicable Affiliates and other Sublicensees engaged in Development and Commercialization activities of the Licensed Products in the Licensed Territory in accordance with all Applicable Laws.
- (d) **Pharmacovigilance Agreement**. [\*\*\*] the JDC will develop a mutually acceptable pharmacovigilance and safety agreement (to be agreed upon and executed by the Parties) setting forth the Parties' respective obligations in detail regarding pharmacovigilance and the exchange and reporting of drug safety data (the "**Pharmacovigilance Agreement**").
- **6.6 Mirati Inspection Rights**. For purposes of quality control Mirati (or its designee) will have the right not more than [\*\*\*] (except in the event that Mirati has reasonable cause), at its expense and on [\*\*\*] prior notice to Licensee, to inspect the [\*\*\*] established or contracted by Licensee (or its Affiliate or Sublicensee), [\*\*\*] and to audit Licensee's [\*\*\*] procedures with respect to the [\*\*\*] or the [\*\*\*], provided such inspection will take place during regular business hours of the audited party in a manner that does not interfere with the audited party's normal business operations and shall be conducted under obligations of confidentiality.
- **6.7 Governmental Inspections and Inquiries.** Licensee shall advise Mirati promptly after Licensee's receipt of notice thereof, of (i) any planned Regulatory Authority visit to the portion of the facilities of Licensee or the facilities of Mirati or their respective Affiliates where the Compound or any Licensed Product is manufactured, stored or handled, as applicable, or (ii) any material written inquiries by a Regulatory Authority concerning such facilities, Licensee's or its Affiliates' procedures with respect to the manufacture, storage or handling of the Compound or any Licensed Product. If a Regulatory Authority makes an unannounced or unplanned visit, Licensee shall inform Mirati of the visit as soon as practicable after Licensee obtains actual knowledge of the visit. Licensee shall inform Mirati, as soon as practicable, regarding the purpose and result of such visit or inquiry, and will provide to Mirati copies of [\*\*\*] generated by Licensee promptly following such inspection, and any [\*\*\*] provided by Licensee [\*\*\*], as the case may be, to such [\*\*\*] or issued by or provided by such [\*\*\*] to Licensee [\*\*\*] in connection with such visit or inquiry, provided that, if such [\*\*\*] provide Mirati a written English translation of such [\*\*\*]. Further details including notification, timing, response and scope of such audits shall be included in the Pharmacovigilance Agreement.

-36-

#### 7. COMMERCIALIZATION

#### 7.1 Responsibilities and Diligence.

- (a) Licensee shall be responsible, at its sole expense and discretion, for Commercializing the Licensed Products in the Field in the Licensed Territory, in compliance and accordance with the terms and conditions of this Agreement. Licensee shall use Commercially Reasonable Efforts to (i) Commercialize the Licensed Product(s) in the Regions within Licensed Territory where the Regulatory Approval has been obtained, and (ii) achieve the First Commercial Sale in the applicable Region in the Licensed Territory reasonably promptly after obtaining Regulatory Approval for such Licensed Product in such Region. In conducting Commercialization of Licensed Product, Licensee will comply, and will ensure that its Affiliates comply, and will include in each of its Sublicense Agreements an obligation of its Sublicensees to comply, with all Applicable Laws related to its Commercialization of the Licensed Products, including, as applicable, all applicable anti-bribery and anti-corruption laws and regulations. Without limiting the generality of the foregoing, Licensee will not promote or market or sell any of the Licensed Products in a manner that would conflict with Applicable Laws.
- (b) Notwithstanding the foregoing, if, and only if, Mirati has exercised the Co-Commercialization Option, the Parties, under the direction of the JCC and in accordance with the terms and conditions of this Agreement, will participate in the planning and conduct of such Commercialization activities as and to the extent set forth in Section 7.4. In such case, Licensee and Mirati shall each use Commercially Reasonable Efforts to conduct Co-Commercialization activities for the Licensed Products in the Licensed Territory in accordance with Section 7.4 and the Co-Commercialization Plan.

# 7.2 Global Commercialization Strategy for Licensed Products.

- (a) For each Licensed Product, the key Commercialization principles will be set forth in a written summary of the global Commercialization strategy for such Licensed Product, which strategy will be prepared and updated by Mirati (each, a "Global Commercialization Strategy").
- (b) Prior to Mirati's exercise of the Co-Commercialization Option and no later than [\*\*\*] prior to the anticipated date of the First Commercial Sale of a Licensed Product in the Licensed Territory, Licensee shall provide Mirati with reasonable advance notice of [\*\*\*] meeting every [\*\*\*] pertaining to the Commercialization strategy of the Licensed Product in the Licensed Territory, and shall permit Mirati to have, [\*\*\*] a representative of Mirati attend and participate in such internal meetings pertaining to the Commercialization of such Licensed Product in the Licensed Territory.

7.3 Commercialization Plan for the Licensed Territory. Licensee shall prepare and submit to the JCC for its review and comment a plan containing its strategy and proposed Commercialization activities in the Licensed Territory for each Licensed Product (including estimated summary timelines for marketing, promoting and selling the Licensed Product in the Licensed Territory) (the "Commercialization Plan"). Such Commercialization Plan shall be consistent with the requirements of the applicable Global Commercialization Strategy, as such Global Commercialization Strategy may be updated from time to time. At least [\*\*\*] prior to the date Licensee anticipates in good faith the First Commercial Sale of a Licensed Product in a Region in the Licensed Territory, Licensee shall submit to the JCC that date of anticipated First Commercial Sale of such Licensed Product in the Region in the Licensed Territory. Licensee shall submit a proposed draft of the Commercialization Plan for the Licensed Territory to the JCC no later than [\*\*\*] prior to the anticipated date of the First Commercial Sale of the Licensed Product in the Licensed Territory. Licensee shall consider in good faith all comments from the JCC regarding the Commercialization Plan. [\*\*\*] shall have the decision-making authority over the Commercialization Plan. Notwithstanding the foregoing, if any matter related to the Commercialization Plan is a [\*\*\*], [\*\*\*] shall have the decision-making authority. Licensee shall deliver to the JCC an update of the relevant sections of each Commercialization Plan on at least [\*\*\*] during the Term. Updates to the Commercialization Plan will reflect, among other things, [\*\*\*] in the Field for which the relevant [\*\*\*] has received [\*\*\*] and new or modified strategy for [\*\*\*] such [\*\*\*].

### 7.4 Co-Commercialization Option.

(a) **Mirati Co-Commercialization Option**. On a Licensed Product-by-Licensed Product and Region-by-Region basis, Mirati has the right, but not an obligation, to Co-Commercialize as set forth in this Section 7.4, each Licensed Product under the direction of Licensee in the Licensed Territory (the "**Co-Commercialization Option**"); provided that Mirati will provide a written notice to Licensee of its intention to Co-Commercialize on the later of (i) [\*\*\*] or (ii) at least [\*\*\*] before the anticipated date of Regulatory Approval of such Licensed Product in such Region in the Licensed Territory (the "**Co-Commercialization Exercise Notice**"). Mirati's election of the Co-Commercialization Option shall entitle Mirati to during the applicable Royalty Term expend FTEs to conduct Co-Commercialization activities in such Region in the Licensed Territory with respect to such Licensed Product, and to expend FTEs to perform Detailing activities in such Region in the Licensed Territory in an amount up to [\*\*\*] of the total FTEs Licensee designates to perform Detailing activities in such Region in the Licensed Territory for such Licensed Product, the actual percentage Mirati elects to expend shall be provided by Mirati in writing to Licensee as part of the Co-Commercialization Exercise Notice.

# (b) Co-Commercialization Plan.

(i) As further described in Section 7.4(b)(ii), the tactics and strategy for the Co-Commercialization of such Licensed Product in such Region in the Licensed Territory shall be described in a comprehensive plan (a "Co-Commercialization Plan") (1) prepared by the Licensee within [\*\*\*] following Mirati's exercise of the Co-Commercialization Option and (2) presented to the JCC for review, comment and approval. The Co-Commercialization Plan shall describe the Co-Commercialization activities to be undertaken in such Region in the Licensed Territory with respect to such Licensed Product during [\*\*\*], and allocates the responsibilities of the Parties for the Co-Commercialization activities under the Co-Commercialization Plan (it being understood that Mirati's FTEs, in Co-Commercializing in such Region in the Licensed Territory, shall (in the aggregate) be provided a materially equal opportunity to generate Net Sales of the Licensed Product in such Region in the Licensed Territory [\*\*\*] the cohort of FTEs appointed by Licensee against which Mirati's FTEs' opportunity to generate Net Sales shall be compared being identified in the Co-Commercialization Plan (such cohort, the "Licensee Commercialization FTEs")). Without limiting the foregoing, the Co-Commercialization Plan shall [\*\*\*]. The Co-Commercialization Plan shall be consistent with the requirements of the applicable Global Commercialization Strategy, as such Global Commercialization Strategy may be updated from time to time.

- (ii) Licensee shall prepare updates to the Co-Commercialization Plan on [\*\*\*] and provide such updates to the JCC for its review, comment, and approval. In the event of any inconsistency between a Co-Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Each Party shall conduct its activities under the Co-Commercialization Plan in compliance with Applicable Law.
- (iii) Mirati agrees that (a) all Mirati's Co-Commercialization activities in the Licensed Territory after it exercises such Co-Commercialization Option will be in all material respects in compliance with Licensee's Commercialization and Detailing standards generally applicable to Licensee's own employees; and (b) any and all information, procedures and other Know-How of Licensee that are specific to the Commercialization of Licensed Product and that are not Confidential Information of Mirati that Mirati learns or accesses from or as a result of such Co-Commercialization activities will be deemed Licensee Know-How and subject to the terms and conditions of this Agreement.
- (c) **Mirati Opportunity to Additional Royalty Payment.** Upon Mirati's exercise of the Co-Commercialization Option, in relation to the applicable Licensed Product and applicable Region and during the Royalty Term applicable to such Licensed Product:
- (i) If in a Calendar Year, the FTEs Mirati expends to Co-Commercialize the Licensed Product in a Region in the Licensed Territory in accordance with the terms of this Agreement generate on average at least [\*\*\*] more Net Sales than the average Net Sales generated by Licensee Commercialization FTEs expended by Licensee to Co-Commercialize the Licensed Product in such Region in the Licensed Territory, Licensee shall pay Mirati an additional royalty payment equal to [\*\*\*] of the Net Sales of the applicable Licensed Product in such Region in such Calendar Year.

-39-

- (ii) If in a Calendar Year, the FTEs Mirati expends to Co-Commercialize the Licensed Product in a Region in the Licensed Territory in accordance with the terms of this Agreement generate on average at least [\*\*\*] more Net Sales than the average Net Sales generated by Licensee Commercialization FTEs expended by Licensee to Co-Commercialize the Licensed Product in such Region in the Licensed Territory Licensee shall pay Mirati an additional royalty payment equal to [\*\*\*] of the Net Sales of the applicable Licensed Product in such Region in such Calendar Year.
- (iii) If in a Calendar Year, the FTEs Mirati expends to Co-Commercialize the Licensed Product in a Region in the Licensed Territory in accordance with the terms of this Agreement generate on average at least [\*\*\*] more Net Sales than the average Net Sales generated by Licensee Commercialization FTEs expended by Licensee to Co-Commercialize the Licensed Product in such Region in the Licensed Territory, Licensee shall pay Mirati an additional royalty payment equal to [\*\*\*] of the Net Sales of the applicable Licensed Product in such Region in such Calendar Year.
- (iv) For clarity, for any period of time with respect to a Licensed Product and a Region, only one of the above provisions under Sections 7.4(c)(ii), 7.4(c)(iii), or 7.4(c)(iii) shall be in force under the Agreement, and in no event shall the additional royalty payment described above be additive to one or more other additional royalty payments for the same Licensed Product in the same Region.
- (v) Upon Mirati's exercise of the Co-Commercialization Option, within [\*\*\*] after the end of each Calendar Year, Licensee shall notify Mirati in writing if any clause of this Section 7.4(c) shall apply to such just-ended Calendar Year, and if this Section 7.4(c) applies, (1) which of Sections 7.4(c)(ii), 7.4(c)(iii), or 7.4(c)(iii) shall apply, and (2) the corresponding amount of additional royalty payment Licensee owes Mirati due to the application of such clause. Licensee shall prepare and submit to the JCC for JCC's review and approval a report containing Licensee's calculations with respect to the foregoing Sections 7.4(c)(v)(1) and (2), including any supporting documentation. Following the JCC's approval of Licensee's report, to the extent Licensee owes Mirati any additional royalty payment under this Section 7.4(c), Licensee shall make such payment to Mirati within [\*\*\*] after receiving a corresponding invoice from Mirati.
- (vi) For clarity, in the Calendar Year where the Royalty Term for a Licensed Product in a Region starts or ends, if the Royalty Term starts after January 1 of such Calendar Year, or ends prior to December 31 of such Calendar Year (as applicable), the references to Calendar Year in clauses (i) (v) of this Section 7.4(c) for such Calendar Year shall be adjusted to refer to the portion of such Calendar Year within the Royalty Term.
- (d) When determining the Net Sales generated by Mirati's FTEs or the Licensee Commercialization FTEs in Section 7.4(c), Licensee shall provide Mirati along with the written notice pursuant to Section 7.4(c)(v) with (i) the Net Sales generated [\*\*\*] For clarity, Licensee's payment obligations under Section 7.4(c) shall not be subject to any royalty reduction mechanism under Section 9.3(c) through Section 9.3(f).

-40-

- (e) If Mirati does not provide Licensee with the Co-Commercialization Exercise Notice by the later of (i) [\*\*\*] or (ii) at least [\*\*\*] before the anticipated First Commercial Sale of a Licensed Product in a Region in the Licensed Territory, the Co-Commercialization Option shall expire in relation to such Licensed Product in such Region in the Licensed Territory.
- **7.5 Commercialization Costs.** Licensee shall be solely responsible for all Commercialization costs incurred by or on behalf of Licensee in the Commercialization of Licensed Products in the Licensed Territory. If Mirati exercises the Co-Commercialization Option, Mirati will invoice (on a [\*\*\*] basis after each [\*\*\*]) Licensee for [\*\*\*] of the FTEs who performed Detailing activities in the Licensed Territory in the applicable [\*\*\*] at a FTE rate to be agreed to by the Parties, provided such FTE rate on average shall not be greater than the average FTE rate of the corresponding Licensee Detailing FTEs. For Co-Commercialization activities performed by Mirati in addition to Detailing, Licensee shall pay Mirati an amount to compensate Mirati for such activities proposed to the JCC by Mirati and reviewed and approved by the JCC. Licensee shall pay such invoice within [\*\*\*] of its receipt. Mirati's Co-Commercialization activities will be limited to those activities assigned to it under the Co-Commercialization Plan, and Licensee shall be responsible for all other aspects of Commercialization.
- **7.6 Reports**. Licensee shall update the JCC [\*\*\*] regarding Licensee's Commercialization activities for the Licensed Products in the Licensed Territory and the progress and results thereof. In addition, Licensee shall present written summary reports annually to the JCC setting forth Licensee's significant Commercialization activities with respect to Licensed Products (including results thereof) in the Licensed Territory pursuant to this Agreement. Each Party shall keep the JCC informed regarding the progress and results of Co-Commercialization activities for Licensed Products in the Licensed Territory. Each Party shall keep the JCC informed regarding the progress and results of Co-Commercialization activities for Licensed Products in the Licensed Territory, including an annual review of results versus goals (as such goals are set forth in the Co-Commercialization Plan(s)).
- **7.7 Booking of Sales**. For clarity, notwithstanding Mirati's exercise of the Co-Commercialization Option, Licensee shall have the sole right to invoice and book sales with respect to any Licensed Product in the Field in the Licensed Territory and to perform or cause to be performed all related services.
- **7.8 Patent Rights Marking**. To the extent required by Applicable Law and customary in the industry for such products, Licensee will mark all Licensed Products sold in the Licensed Territory by Licensee, its Affiliates, or Sublicensees with appropriate Licensed Product trademarks and patent numbers.

-41-

#### 8. MANUFACTURE AND SUPPLY

**8.1 Clinical Supply**. Mirati shall be solely responsible (itself or through its Affiliate or CMO) for the manufacture and supply to Licensee of Compound and Licensed Product for Development by Licensee and its Affiliates and Sublicensees in the Licensed Territory, provided that, [\*\*\*] shall not be obligated to [\*\*\*] following its good faith determination that any event, incident or circumstance related to material safety issues, quality issues or regulatory concerns has occurred, to the extent such event, incident, or circumstance would reasonably require the suspension or cessation of [\*\*\*] provided further, in such case, [\*\*\*] shall promptly notify [\*\*\*] of such determination and provide [\*\*\*] with the basis for its determination (including supporting documentation), and the Parties shall discuss in good faith alternative arrangements to minimize the interruption on the [\*\*\*] or provide an alternate [\*\*\*] for an actual or expected significant period [\*\*\*], with mechanisms to address the foregoing being set forth in [\*\*\*]. Customary terms of forecasting and ordering procedures, Licensed Product specifications and other operational matters relating to the clinical supply of Compound and Licensed Product under this Section 8.1 shall be set forth in a clinical manufacturing and supply agreement pursuant to be negotiated in good faith and mutually agreed upon by the Parties within [\*\*\*] of the Effective Date or such longer period as agreed by the Parties ("Clinical Supply Agreement"). Subject to the terms of this ARTICLE 8, the Clinical Supply Agreement, and the Quality Agreement, (a) Mirati shall, itself or through one or more CMOs, supply Licensed Product to Licensee [\*\*\*] at [\*\*\*] of Mirati's Manufacturing Costs, and (b) Licensee shall [\*\*\*].

**8.2 Commercial Supply.** Mirati shall be solely responsible (itself or through its Affiliate or CMO) for the manufacture of the commercial supply of Licensed Product for Commercialization by Licensee and its Affiliates and Sublicensees in the Licensed Territory. Customary terms of forecasting and ordering procedures, product specifications, and other operational matters relating to the supply of the Licensed Product under this Section 8.2 shall be set forth in a commercial supply agreement to be negotiated in good faith and mutually agreed upon by the Parties no later than [\*\*\*] prior to Licensee's anticipated date for first commercial launch of a Licensed Product in the Licensed Territory (the "**Mirati Commercial Supply Agreement**") under which Mirati (or its CMO) will manufacture and supply to Licensee the quantities of Licensed Product required by Licensee (provided that, [\*\*\*] shall not be obligated to [\*\*\*] following its good faith determination that any event, incident or circumstance related to material safety issues, quality issues or regulatory concerns has occurred, to the extent such event, incident, or circumstance would reasonably require the suspension or cessation of [\*\*\*] provided further, in such case, [\*\*\*] shall promptly notify [\*\*\*] of such determination and provide [\*\*\*] with the basis for its determination (including supporting documentation), and the Parties shall discuss in good faith alternative arrangements to minimize [\*\*\*] [\*\*\*] with mechanisms to address the foregoing being set forth in the [\*\*\*]), whereby:

- (a) terms and conditions applicable to Mirati (or its Affiliates) pursuant to Third Party contracts relevant to the Mirati 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 forecast mechanisms and principles applicable to Mirati in its contracts with Third Party manufacturers;
  - (c) commercial supply of Licensed Products will be at [\*\*\*] Mirati's Manufacturing Cost and will be delivered [\*\*\*]; and
- (d) [\*\*\*] will obtain and maintain all required export or import licenses or authorizations, and shall serve as importer of record for all Licensed Products delivered in or into any Region in the Licensed Territory pursuant to this Agreement and the [\*\*\*];

all as to be further agreed in the Mirati Commercial Supply Agreement.

- **8.3** Audit by Licensee. Mirati shall (and shall ensure its CMO to) keep complete and accurate records in accordance with U.S. GAAP and in sufficient detail relating to the manufacture of the Compound and Licensed Products supplied to Licensee during the Term and [\*\*\*] thereafter. Upon no less than [\*\*\*] prior notice, Licensee will have the right to have an independent certified public accountant, selected by Licensee and reasonably acceptable to Mirati to inspect such records for the purpose of determining the accuracy of the Manufacturing Cost due within the prior [\*\*\*] period. Such audit may not be conducted more than [\*\*\*] unless Licensee has reasonable cause and will take place at the location(s) where such records, materials, documents are maintained by Mirati during regular business hours and under obligations of confidentiality. If it is determined that any amounts were overpaid during such period, Mirati shall credit such overpayment against future payment owed by Licensee to Mirati (and if no further payments are due, refund Licensee within [\*\*\*] of the date the independent certified public accountant's written report). If it is determined that any such amounts were underpaid during such period, Licensee will pay Mirati the underpaid amounts within [\*\*\*] of the date the independent certified public accountant's written report. The fees charged by such independent certified public accountant will be paid by Licensee, unless it is determined that any overpaid amounts exceed [\*\*\*] of the total amount payable by Licensee to Mirati for the period then being audited, in which case such fees will be paid by Mirati.
- **8.4 Manufacture by Licensee**. Subject to Section 8.5, Licensee shall not be permitted to manufacture Compound or Licensed Products or drug substance of the Licensed Product inside or outside of the Licensed Territory without the prior written consent of Mirati. For clarity, after the completion of the Manufacturing Technology Transfer, Licensee shall be permitted to manufacture or have manufactured the Compound or Licensed Products or drug substance of the Licensed Product in the Licensed Territory.

-43-

**8.5 Manufacturing Technology Transfer Option.** (a) If Licensee reasonably believes it can lower the Manufacturing Costs for the Licensed Product by manufacturing or having manufactured the Compound or Licensed Product in the Licensed Territory, it shall notify Mirati in writing of such belief, the rationale for such belief and that Licensee desires to conduct manufacturing of the Licensed Product in the Licensed Territory, the Parties shall discuss in good faith Licensee's belief and the rationale presented, and if Mirati agrees with such belief (including the opportunity described in Section 8.6.), such agreement not to be unreasonably withheld, delayed or conditioned, or (b) if Mirati decides to cease all development activities pertaining to Compound outside the Licensed Territory and Licensee reasonably considers the further Exploitation of the Compound or Licensed Product in the Licensed Territory is commercially feasible, at Licensee's request, then (c) the Parties shall negotiate in good faith and enter into an agreement on mutually agreeable terms and conditions under which the Parties would conduct a transfer of technology from Mirati to Licensee, or its CMO approved by Mirati in writing (such approval not to be unreasonably withheld, delayed or conditioned), to enable Licensee, or such CMO, to conduct such manufacturing of Compound or Licensed Product (collectively, "Manufacturing Technology Transfer"). Upon reaching such agreement and at Licensee's cost and expense, Mirati should provide reasonable technology transfer and assistance as necessary to complete such Manufacturing Technology Transfer. Licensee would be responsible for all costs and expenses related thereto, including [\*\*\*] provided however, Mirati shall provide without charge [\*\*\*].

**8.6** Manufacture by Licensee for Mirati. In addition, upon Mirati's request provided at any time following completion of the Manufacturing Technology Transfer, Licensee will discuss in good faith the terms pursuant to which Licensee would supply Mirati with the Compound or Licensed Product for clinical use anywhere in the world or commercial sale outside the Licensed Territory by Mirati and its Affiliates and applicable other licensees. If Mirati provides such written notice, the Parties shall discuss in good faith a commercially reasonable supply agreement governing the details of such commercial supply of the Compound or Licensed Product to Mirati by Licensee (the "Licensee Commercial Supply Agreement"). To the extent negotiated and executed, the Licensee Commercial Supply Agreement, as applicable, shall contain commercially reasonable, industry standard terms for similar commercial supply agreements, including that the Compound or Licensed Product would be supplied at [\*\*\*].

**8.7 Quality Agreement**. [\*\*\*], the JDC will develop a mutually acceptable quality agreement (to be agreed upon and executed by the Parties) setting forth the Parties' respective obligations in detail regarding the manufacture, packaging, testing, storage, and release of clinical or commercial Compound and Licensed Product to assure such Compound and Licensed Product is manufactured according to agreed specifications and complies with Applicable Laws (the "Quality Agreement").

-44-

#### 9. FINANCIAL TERMS

**9.1 Upfront License Fee**. Within [\*\*\*] of the Effective Date, Licensee shall pay to Mirati, in cash, sixty-five million USD (\$65,000,000.00), such payment being non-refundable, non-creditable and not subject to set-off.

# 9.2 Milestone Payments.

(a) **Clinical Development Milestones**. After the first achievement of each of the following milestone events with respect to a Licensed Product (each, a "**Clinical Development Milestone Event**"), Licensee shall pay to Mirati the corresponding non-refundable, non-creditable and not subject to set-off, milestone payments set forth in the table below.

Clinical Development Milestone Event	Milestone Payment (USD)
[***]	US \$ [***]
[***]	US \$ [***]

(b) **Regulatory Milestones**. After the first achievement of each of the following milestone events with respect to a Licensed Product (each, a "**Regulatory Milestone Event**"), Licensee shall pay to Mirati the corresponding non-refundable, non-creditable and not subject to set-off, milestone payments set forth in the table below.

Regulatory Milestone Event	Milestone Pay (USD)	ment
[***]	\$ [	***]
[***]	\$ [	***]
[***]	\$ [	***]
[***]	\$ [	***]
[***]	\$ [	***]
[***]	\$ [	***]
[***]	\$ [	***]

-45-

(c) **Sales-Based Milestones**. After the first achievement of each of the following milestone events (each, a "**Sales Milestone Event**"), Licensee shall pay to Mirati the corresponding non-refundable, non-creditable and not subject to set-off, milestone payments set forth in the table below:

Sales Milestone Event	Milestone Paymer (USD)	at
[***]	<u> </u>	*]
[***]	\$ [***	*]
[***]	\$ [***	*]
[***]	\$ [***	*]

### (d) Milestone Conditions.

- (i) Licensee will promptly notify Mirati in writing, but in no event later than (A) [\*\*\*] after the achievement of each Clinical Development Milestone Event and Regulatory Milestone Event and (B) [\*\*\*] after the end of [\*\*\*] in which each Sales Milestone Event is achieved. Mirati shall promptly issue a corresponding invoice thereof to Licensee after receiving such notice.
- (ii) Licensee will pay the corresponding milestone payment to Mirati within [\*\*\*] after receiving the corresponding invoice from Mirati.
- (iii) For clarity, each milestone payment set forth in this Agreement shall be payable only once, regardless of the number of times the corresponding milestone event is achieved or how many Licensed Products achieve a milestone event.

-46-

(iv) If more than one Sales Milestone Event is achieved in the same Calendar Year, then each corresponding sales milestone payment for such Sales Milestone Event shall be payable.

### 9.3 Royalty Payments.

(a) **Royalty Rate**. During the applicable Royalty Term, Licensee shall pay to Mirati non-refundable, non-creditable royalties as a percentage of the Net Sales of all Licensed Products in the Licensed Territory, as calculated by multiplying the applicable royalty rate (as set forth in the following royalty rate schedule) by the amount of Net Sales of all Licensed Products in the Licensed Territory in the applicable Calendar Year (on a by "tier" basis):

Portion of Aggregate Net Sales of all Licensed Products in a Calendar Year	Royalty Rate Applicable to Net Sales Tier
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

- (b) **Terms of Royalty Obligations**. On a Licensed Product-by-Licensed Product and Region-by-Region basis, royalties shall be payable hereunder on sales of a Licensed Product in a Region in the Licensed Territory throughout the Royalty Term applicable to such Licensed Product in such Region. Upon expiration of the Royalty Term with respect to a given Licensed Product (but not in the case of earlier termination of the Agreement) in a particular Region in the Licensed Territory and payment in full of all amounts accrued by the end of the expiration of the Royalty Term and owed to Mirati under this Agreement with respect to such Licensed Product in such Region (for clarity excluding any milestone payments if the milestone event has not occurred prior to the expiration of the Royalty Term), the licenses granted to Licensee under this Agreement with respect to such Licensed Product in such Region shall become perpetual, transferable, sublicensable through multiple tiers, royalty-free, fully-paid up, and irrevocable.
- (c) **Generic Sales**. With respect to a Licensed Product being sold in a Region by Licensee, its Affiliates or Sublicensees, if, at any time during the Royalty Term after a Generic Product for such Licensed Product obtains Regulatory Approval in such Region, then Licensee shall be entitled to reduce the royalties due to Mirati under Section 9.3(a) for such Licensed Product in such Region by (i) [\*\*\*], when a Generic Product [\*\*\*], and (ii) [\*\*\*], when the Generic Products have [\*\*\*] in such Region [\*\*\*] [\*\*\*] (each of the conditions in (i) and (ii), "Generic Competition"). Licensee will promptly notify Mirati of the occurrence of Generic Competition, which notice will specify the apply Generic Product, Indication, and Region in the Licensed Territory.

- (d) **Anti-Stacking.** If Licensee reasonably determines in good faith after advice of counsel that it is necessary for Licensee to obtain a license under any Patents owned or controlled by a Third Party in order to Exploit the Licensed Product in a Region in the Licensed Territory, then Licensee shall be entitled to credit, against royalties owed by Licensee to Mirati on Net Sales of such Licensed Product in such Region under this Agreement, [\*\*\*] of [\*\*\*] any royalty payments paid to such Third Party by Licensee that are in consideration for the grant of such license with respect to such Licensed Product in such Region, provided that Licensee first provides to Mirati written evidence of the agreement establishing Licensee's obligation to make such royalty payments to such Third Party in consideration for the grant of such licensee in the Licensed Territory, provided that [\*\*\*].
- (e) **Valid Claim Expiration**. On a Region-by-Region and Licensed Product-by-Licensed Product basis, if, in any Calendar Quarter during the Royalty Term for such Licensed Product, there are no Valid Claims that Cover the Compound or such Licensed Product in such Region (including any composition of matter, method of use or manufacturing claims thereof), then the royalty rate under Section 9.3(a) shall be reduced by [\*\*\*] in such Calendar Quarter.
- (f) **Cumulative Reductions Floor**. In no event will the royalty rate under Section 9.3(a) in any given Calendar Quarter during the Royalty Term for any Licensed Product be reduced by more than [\*\*\*] of the royalty rate that otherwise would have applied in such Calendar Quarter for such Licensed Product but for the reductions set forth in Section 9.3(c) through Section 9.3(e). For the avoidance of doubt, this provision does not apply to Section 9.3(g).
- (g) **Joint Global Study Enrollment**. With respect to a Joint Global Study, if Mirati requests and Licensee agrees to enroll additional patients in excess of the Minimum Enrollment Threshold, then for the enrollment of each additional [\*\*\*] of the total number of patients to be treated under the applicable protocol for such Joint Global Study in excess of the Minimum Enrollment Threshold, the otherwise then-current royalty rates for each tier shall each be reduced by [\*\*\*]. This provision shall apply after any application of Section 9.3(c) through Section 9.3(f). By way of example, [\*\*\*] [\*\*\*]. The royalty rate reduction pursuant to this Section 9.3(g) is subject to a cap of (i) [\*\*\*] total reduction for each Joint Global Study, and (ii) an aggregate maximum reduction of [\*\*\*] under this Agreement.

-48-

#### 10. PAYMENT; RECORDS; AUDITS

**10.1 Payment; Reports.** The royalty payments due under Section 9.3 shall be calculated and reported on a Calendar Quarter basis. Within [\*\*\*] after the end of each Calendar Quarter, Licensee shall provide to Mirati a complete and accurate report setting forth the on a Licensed Product-by-Licensed Product and Region-by-Region basis the total gross invoiced amount and the calculation of Net Sales of Licensed Products by Licensee and its Affiliates and Sublicensees in the Licensed Territory during such Calendar Quarter and the royalties payable, in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including any reductions taken in the calculation of Net Sales pursuant to Section 1.106 and the exchange rates used. Upon receipt of such royalty report, Mirati shall promptly (within [\*\*\*]) issue a corresponding invoice to Licensee. All royalty payments due under Section 9.3 shall be paid within [\*\*\*] after receiving a corresponding invoice from Mirati.

**10.2** Exchange Rate; Manner and Place of Payment. All references to dollars and "\$" herein shall refer to U.S. dollars. All payments hereunder shall be payable in U.S. dollars. When conversion of payments or amounts received is required for the calculation of Net Sales from any currency other than U.S. dollars, such conversion shall be made by using the exchange rates quoted in the [\*\*\*] on the [\*\*\*] (or such other publication as agreed-upon by the Parties), for the applicable currency exchange, unless otherwise agreed in writing by the Parties. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by the receiving Party, unless otherwise specified in writing by such Party.

### 10.3 Taxes.

(a) Except as otherwise set forth in this Section 10.3(a), each Party shall be entitled to deduct and withhold from any amounts payable under this Agreement such taxes as are required to be deducted or withheld therefrom under any provision of Applicable Law [\*\*\*]. The Party that is required to make such withholding shall: (i) timely remit the taxes to the proper taxing authority; and (ii) send evidence of the obligation, together with proof of tax payment, to the other Party on a timely basis following such tax payment [\*\*\*] [\*\*\*] Each Party shall reasonably cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect to ensure that any amounts required to be withheld pursuant to this Section 10.3 are reduced in amount to the fullest extent permitted by Applicable Law. In addition, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as VAT, sales tax, consumption tax, and other similar taxes) in connection with this Agreement.

(b) [\*\*\*].

10.4 Restrictions on Fund Transfers. In the event that, by reason of Applicable Laws in the Licensed Territory, it becomes impossible or illegal, after reasonable efforts by Licensee to transfer, or have transferred on its behalf, payments owed to Mirati hereunder, Licensee will promptly notify Mirati of the conditions preventing such transfer and, at the request of Mirati, such payments will be deposited in local currency in the Licensed Territory to the credit of Mirati in a recognized banking institution designated by Mirati, or to a local currency account of a Third Party designated by Mirati.

10.5 Royalty Records; Audits. Licensee shall keep, and shall cause its Affiliates and Sublicensees to keep, complete and accurate records pertaining to the sales or other disposition of any Licensed Product in the Licensed Territory and calculation of Net Sales, in sufficient detail to permit Mirati to confirm the accuracy of royalty reports and payments due to it hereunder. Such records shall be kept for at least [\*\*\*] following the end of the Calendar Quarter to which they pertain. Upon no less than [\*\*\*] written notice by Mirati to Licensee, Licensee shall permit, and shall require its Affiliates and Sublicensees to permit, an independent, certified public accountant appointed by Mirati and reasonably acceptable to Licensee to audit such records to confirm Net Sales reports and royalty payments for a period covering not more than [\*\*\*] following the Calendar Quarter to which they pertain. Such audits may be exercised during normal business hours upon reasonable prior written notice to Licensee; provided that such audit right may be exercised [\*\*\*] with respect to sales of a particular Licensed Product in a particular period. All records made available for audit shall be deemed to be Confidential Information of Licensee. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Mirati shall bear the full cost of such audit unless such audit discloses an underpayment by Licensee of more than [\*\*\*] of the amount of royalty payments due under this Agreement for any applicable Calendar Quarter, in which case, Licensee shall bear the cost of such audit and shall promptly remit to Mirati the amount of any underpayment. Any overpayment by Licensee revealed by an audit shall be credited against future payment owed by Licensee to Mirati (and if no further payments are due, shall be promptly refunded by Mirati).

**10.6 Interest on Late Payments**. Any amounts not paid by either Party when due under this Agreement will be subject to interest from and after the date payment is due through and including the date upon which such Party makes such payment at the [\*\*\*] rate equal to the [\*\*\*] on the date such payment is due, plus an additional [\*\*\*].

-50-

#### 11. INTELLECTUAL PROPERTY

#### 11.1 Ownership of Intellectual Property.

(a) Data and Results. All data, results and other Know-How (and all property rights therein) generated in connection with any Development or Commercialization activities with respect to the Compound or Licensed Product (and is not related to another active pharmaceutical ingredient) conducted by or on behalf of Mirati and its Affiliates and other licensees shall, as between Mirati and Licensee, be the sole and exclusive property of Mirati or its Affiliates or licensees (other than Licensee as licensee hereunder), as applicable, subject to the license and use rights granted to Licensee hereunder. To the extent Licensee acquires or obtains any interest to the foregoing data, results and other Know-How (and all property rights therein), Licensee hereby assigns and agrees to assign to Mirati all rights, title and interest in and to all such data, results and other Know-How (and all property rights therein). To the extent permitted by Applicable Laws in the Licensed Territory, all Licensed Territory Data and Results (for clarity, excluding Manufacturing Data) shall, as between Mirati and Licensee, be the sole and exclusive property of Mirati or its Affiliates or licensees (other than Licensee as licensee hereunder), as applicable, and, to the extent permitted by Applicable Laws in the Licensed Territory, Licensee hereby assigns and agrees to assign to Mirati all rights, title and interest in and to all such Licensed Territory Data and Results (and all property rights therein), which rights are subject to the license and use rights granted to Licensee hereunder. All Manufacturing Data generated in connection with any Development or Commercialization activities with respect to the Compound or Licensed Product conducted by or on behalf of Licensee and its Affiliates and Sublicensees shall, as between Mirati and Licensee, be the sole and exclusive property of Mirati, and Licensee hereby assigns and agrees to assign to Mirati all rights, title and interest in and to all such Manufacturing Data (and all property rights therein), which rights are subject to the license and use rights granted to Licensee herein, Licensee shall ensure that its Affiliates and Sublicensees provide Licensee with sufficient rights in all Licensed Territory Data and Results and Manufacturing Data so that Licensee can assign to Mirati all rights and title in and to all Licensed Territory Data and Results, Product Inventions and Manufacturing Data, as provided in this Agreement.

#### (b) Patents, Inventions and other Know-How.

(i) To the extent permitted by Applicable Laws in the Licensed Territory, Mirati (and its Affiliates) shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Licensed Patents, Licensed Know-How, Product Inventions, Product Patents, Mirati Inventions and Mirati Invention Patents. Licensee shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Licensee Know-How and Licensee Patents.

(ii) To the extent permitted by Applicable Laws in the Licensed Territory, (A) Licensee (on behalf of itself and its Affiliates) hereby assigns and agrees to assign to Mirati all of Licensee's (and its Affiliates' and Sublicensees') rights, title and interest in and to the Product Inventions and Product Patents, and (B) Licensee shall ensure that its Affiliates and Sublicensees (including all Third Party subcontractors) provide and assign to Licensee all of such party's rights in Product Inventions and Product Patents so that Licensee can transfer and assign to Mirati all rights, title and interest in and to all Product Inventions and Product Patents, as provided in this Agreement. If, by operation of Applicable Law, Licensee is unable to assign any Product Inventions or Product Patents, then Licensee hereby grants and agrees to grant to Mirati a royalty-free, fully paid-up, exclusive (subject to the terms of this Agreement, including the licenses granted to Licensee pursuant to Article 2), perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers) under such Product Inventions and Product Patents for any and all purposes. Licensee shall promptly disclose to Mirati all Product Inventions that are conceived, discovered, developed or otherwise made by or on behalf of Licensee or its Affiliates and Sublicensees in the course of performing activities or exercising its rights under this Agreement, in each case, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', independent contractors' or sublicensees' (including Sublicensees') directors, officers, employees or agents describing such Inventions.

(iii) The Parties shall jointly own an undivided one-half interest in all Inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of both Parties or their respective Affiliates in the course of performing activities or exercising its rights under this Agreement (referred to herein as "Joint Inventions"), except for Product Inventions and Product Patents. Each Party will and hereby does assign to the other Party a joint interest in and to all Joint Inventions, and the other Party hereby accepts such assignment. Each Party shall ensure that its Affiliates and Sublicensees (including all Third Party subcontractors) provide and assign to such Party all rights in Joint Inventions so that such Party can transfer and assign to the other Party a joint interest in and to all Joint Inventions. If either Party is unable to assign a joint interest in any Joint Inventions, then such Party hereby grants and agrees to grant to the other Party a royalty-free, fully paid-up, non-exclusive (subject to the terms of this Agreement, including the licenses granted to the other Party pursuant to Article 2), perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers) under such Joint Inventions for any and all purposes. All Patents claiming patentable Joint Inventions shall be referred to herein as "Joint Patents", and shall be jointly owned by the Parties, subject to the applicable licenses granted by each Party hereunder. Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign, and otherwise exploit its interest under Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party. At the reasonable written request of a Party, the other Party shall take such further actions to confirm that no such accounting is required or to otherwise effect the foregoing regarding such Joint Inventions. Each Party shall promptly disclose to the other all Joint Inventions, in each case, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', independent contractors' or sublicensees' (including Sublicensees') directors, officers, employees or agents describing such Joint Inventions.

(c) Inventorship for patentable Invention conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement shall be determined on a worldwide basis in accordance with United States Patent laws and, except as expressly set forth herein, ownership of any such patentable Invention shall be determined by inventorship under Applicable Law.

#### 11.2 Patent Prosecution and Maintenance.

### (a) Licensed Patents/Joint Patents.

- (i) Subject to the remainder of this Section 11.2(a), including subsection (ii), Mirati shall have the [\*\*\*] right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates, oppositions,) of the Licensed Patents and Joint Patents, including all Product Patents and Mirati Invention Patents, worldwide, at its sole cost and expense and using counsel of its own choice.
- (ii) In the event that Mirati desires to abandon or cease prosecution or maintenance of any Licensed Patent in the Licensed Territory during the Term, Mirati shall provide reasonable prior written notice to Licensee of such intention to abandon (which notice shall, to the extent possible, be given no later than [\*\*\*] prior to the next deadline for any action that must be taken with respect to any such Licensed Patent in the relevant patent office). In such case, upon Licensee's written election provided to Mirati no later than [\*\*\*] after such notice from Mirati and subject to any rights of any Third Party with respect thereto, Licensee shall have the right to continue prosecution and maintenance of such Licensed Patent at Licensee's direction and expense. If Licensee does not provide such election within [\*\*\*] after such notice from Mirati, Mirati may thereafter, in its sole discretion, continue or discontinue the prosecution and maintenance of such Licensed Patent.
- (iii) Notwithstanding anything to the contrary in this Section 11.2, in the event that any Joint Patent Covers or relates to any proprietary compound of Licensee, the Parties will discuss and agree in good faith upon the allocation between the Parties of prosecution, maintenance and enforcement responsibilities using patent counsel mutually acceptable to the Parties.

# (b) Licensee Patents.

(i) Subject to this Section 11.2(b), Licensee shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of all Licensee Patents worldwide, at its sole cost and expense and by counsel of its own choice.

-53-

(ii) In the event that Licensee desires to abandon or cease prosecution or maintenance of any Licensee Patent outside the Licensed Territory (other than any Licensee Patent that Covers or relates to any proprietary compound of Licensee) during the Term, Licensee shall provide reasonable prior written notice to Mirati of such intention to abandon (which notice shall, to the extent possible, be given no later than [\*\*\*] prior to the next deadline for any action that must be taken with respect to any such Licensee Patent in the relevant patent office). In such case, upon Mirati's written election provided to Licensee no later than [\*\*\*] after such notice from Licensee and subject to any rights of any Third Party with respect thereto, Mirati shall have the right to continue prosecution and maintenance of such Licensee Patent outside the Licensed Territory at Mirati's direction and expense. If Mirati does not provide such election within [\*\*\*] after such notice from Licensee, Licensee may, in its sole discretion, continue or discontinue prosecution and maintenance of such Licensee Patent.

(c) Cooperation of the Parties. The Party that has the responsibility for the preparation, filing, prosecution, and maintenance of any Patents under Section 11.2(a) or 11.2(b) above (the "Prosecuting Party") shall (A) promptly provide the other Party (the "Non-Prosecuting Party") with copies of all material submissions and correspondence with the applicable patent offices with respect to its preparation, filing, prosecution, and maintenance of the applicable Patents, in sufficient time to allow for review and comment by Non-Prosecuting Party, and (B) provide the Non-Prosecuting Party and its patent counsel with an opportunity to consult with the Prosecuting Party regarding such Patents and any amendment, submission or response with respect to such Patents. The advice and suggestions of the Non-Prosecuting Party and its patent counsel shall be taken into consideration in good faith by the Prosecuting Party in connection with such preparation, filing, prosecution, and maintenance; provided, that, if the Non-Prosecuting Party fails to provide any comment on or before the expiration of [\*\*\*] before the proposed date for any amendment, submission or response notified by the Prosecuting Party, the Prosecuting Party's obligations under this Section 11.2(c) shall be deemed to have been fulfilled. The Prosecuting Party shall pursue in good faith all reasonable claims requested by the Non-Prosecuting Party in its preparation, filing, prosecution, and maintenance of any Patents under this Section 11.2(c); provided, that, if the Prosecuting Party incurs any additional cost or expense as a result of any such request, the Non-Prosecuting Party shall be solely responsible for the cost and expense attributable to the pursuit of any such additional claim or taking such other activities. Each Party agrees otherwise to cooperate fully in the preparation, filing, prosecution, and maintenance of Patents under this Section 11.2 and in the obtaining and maintenance of any patent extensions, supplementary protection certificates, and the like with respect thereto, at its own costs. Such cooperation includes, but is not limited to, (i) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to enable the other Party to apply for and to prosecute patent applications in any country or Region as permitted by Section 11.2, and (ii) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution, or maintenance of any such patent applications and the obtaining of any patent term extensions, supplementary protection certificates, and their equivalent.

#### 11.3 Infringement by Third Parties.

- (a) **Notice; Enforcement Generally**. Each Party shall notify the other Party within [\*\*\*] of becoming aware of any infringement or threatened infringement by a Third Party of any Licensed Patents or Joint Patents in the Licensed Territory, which infringement adversely affects or is expected to adversely affect any Licensed Product in the Field in the Licensed 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 or Joint Patents in the Licensed Territory within the scope of the license grant in Section 2.1 (collectively, "**Product Infringement**"). Any such notice shall include evidence to support an allegation of Product Infringement by such Third Party. Except as expressly provided herein, each Party retains exclusive rights to enforce all of its intellectual property rights.
- (b) Subject to this Section 11.3(b), as between the Parties, Licensee shall have the first right, but not the obligation, to bring and control any action or proceeding with respect to such Product Infringement in the Licensed Territory, and the sole right, but not the obligation, to bring and control any action or proceeding with respect to infringement of any Licensee Patent worldwide, in each case at its own expense and by counsel of its own choice. Mirati shall have the right, at its own expense, to be represented in any such action or proceeding with respect to an enforcement of a Licensed Patent (for clarity, including any Product Patent) or Joint Patent in the Licensed Territory by counsel of its own choice, and the Parties shall reasonably cooperate with each other and the other's counsel in strategizing, preparing for, and presenting any such action or proceeding. If Licensee does not bring an action or proceeding with respect to infringement of any Licensed Patent (for clarity, including any Product Patent), or Joint Patent in the Licensed Territory before the earlier of (i) [\*\*\*] following the notice of alleged infringement or (ii) at least [\*\*\*] before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, whichever comes first, Mirati shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Licensee shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Any recovery or damages realized as a result of such action or proceeding with respect to Licensed Patents (for clarity, including any Product Patents) or Joint Patents in the Licensed Territory shall be used (i) first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro-rata basis, (ii) second, if applicable, and if Licensee prosecuted the infringement response, [\*\*\*], and (iii) any remaining amounts shall be allocated [\*\*\*] to the Party that prose
- (c) Mirati shall have the first right, but not the obligation, to enforce the Joint Patents anywhere in the world for any infringement that is not a Product Infringement at its own expense as it reasonably determines appropriate. Licensee shall have the right, at its own expense, to be represented in any such action or proceeding with respect to an enforcement of a Joint Patent anywhere in the world for any infringement that is not a Product Infringement by counsel of its own choice, and the Parties shall reasonably cooperate with each other and the other's counsel in strategizing, preparing for, and presenting any such action or proceeding. If Mirati does not bring an action or proceeding with respect to such infringement of Joint Patent before the earlier of (i) [\*\*\*] following the notice of alleged infringement or (ii) at least [\*\*\*] before the time limit, if any, set forth in the Applicable Laws for the filing of such actions, whichever comes first, Licensee shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Mirati shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Any recovery or damages realized as a result of such action or proceeding with respect to Joint Patents shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro-rata basis, and any remaining amounts shall be allocated [\*\*\*] to the Party that prosecuted the infringement response, and [\*\*\*] to the other Party.

- (d) Mirati 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 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, at its own expense as it reasonably determines appropriate. For clarity, in no event shall Licensee have the right to enforce any Licensed Patent (for clarity, including any Product Patent) outside the Licensed Territory, which right shall be retained solely by Mirati, and Mirati retains sole and exclusive rights, at its discretion, to enforce all Patents of Mirati that are not Licensed Patents, anywhere in the world.
- (e) Mirati shall have the first 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 Licensee Patents, which infringement adversely affects or is expected to adversely affect any Licensed Product in the Field outside the Licensed 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 Licensee Patents outside the Licensed Territory, at its own expense as it reasonably determines appropriate. If Mirati does not bring such legal action prior to the earlier of: (i) [\*\*\*] following receipt or delivery of notice between the Parties regarding such alleged infringement, or (ii) [\*\*\*] 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, Licensee shall have the right to bring and control any legal action in connection with infringement at its own expense as it reasonably determines appropriate. Any recovery or damages realized as a result of such action or proceeding with respect to Licensee Patents shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro-rata basis, and any remaining amounts shall be allocated [\*\*\*] to the Party that prosecuted the infringement response, and [\*\*\*] to the other Party.
- (f) Except as otherwise provided in Section 11.3(e), Licensee 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 Licensee 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 Licensee Patents, at its own expense as it reasonably determines appropriate.
- (g) **Cooperation**. If a Party brings an infringement action in accordance with this Section 11.3, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.

-56-

11.4 Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of Licensee, Mirati, or any of their respective Affiliates or Sublicensees, as applicable, pursuant to this Agreement infringes or may infringe the intellectual property rights of a Third Party, and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties will promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties will assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion. Licensee shall have the sole right to control any defense of any such claim against Licensee (or its Affiliate or Sublicensee) involving alleged infringement of Third Party rights by activities of Licensee or its Affiliate or Sublicensee in the Licensed Territory, at its own expense and by counsel of its own choice, and Mirati shall have the right (if such actions relate to Licensed Product), at its own expense, to be separately represented in any such action by counsel of its own choice. Licensee shall keep Mirati informed on the status of such claim against Mirati involving alleged infringement of Third Party rights by activities of Mirati or its Affiliates or other licensees at its own expense and by counsel of its own choice, and Licensee shall have the right (if such actions relate to Licensed Product activities in the Licensed Territory), at its own expense, to be represented in any such action by counsel of its own choice.

11.5 Consent for Settlement. Neither Party shall enter into any settlement or compromise of any action or proceeding under this Article 11 that would (a) result in the admission of any liability or fault on behalf of the other Party, (b) result in or impose any payment obligations on the other Party, or (c) subject the other Party to an injunction or otherwise limit the other Party's ability to take any actions or refrain from taking any actions under this Agreement or with respect to the Compound or Licensed Product, in each case of (a) to (c), without the prior written consent of such other Party, which shall not be unreasonably withheld, conditioned, or delayed.

11.6 Trademarks. Except as provided below for Regional Marks, and subject to Article 15, Licensee shall own and be responsible for all trademarks, trade names, branding, or logos related to Licensed Product in the Field for use in the Licensed Territory, and will be responsible for selecting, registering, defending, and maintaining the same at Licensee's sole cost and expense. Mirati shall own and be responsible for all trademarks, trade names, branding, or logos related to Licensed Product in the Field for use outside the Licensed Territory, and will have the sole rights for selecting, registering, defending, and maintaining the same at Mirati's sole cost and expense. Notwithstanding the foregoing, the Parties (through the JCC) shall discuss and consider in good faith whether it is commercially valuable to have a single trademark to be used in certain Regions in the Licensed Territory as well as appropriate countries outside the Licensed Territory, and if so, on the details of such a trademark, including the owner and the Party responsible for registering, defending, and maintaining any such trademark (the "Regional Mark").

-57-

#### 12. CONFIDENTIALITY

- 12.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each of the Parties agrees that, during the Term and for [\*\*\*] thereafter, such Party and its Affiliates shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party provided pursuant to this Agreement. Further, each of the Parties and its Affiliates shall keep confidential and, subject to Section 12.4, shall not publish or otherwise disclose the terms of this Agreement, except as otherwise permitted in this Article 12. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own proprietary or confidential information of a similar nature (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors, and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other Party upon discovery of any unauthorized use or disclosure of any Confidential Information of the other Party and shall use diligent, good faith efforts to rectify such issue as soon as practicable.
- **12.2 Authorized Disclosure**. Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
  - (a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;
  - (b) submitting Regulatory Filings for any Compound or Licensed Product in order to obtain or maintain Regulatory Approvals;
  - (c) prosecuting or defending litigation as permitted by this Agreement;
- (d) complying with applicable court or administrative orders or governmental regulations (including regulations promulgated by securities exchanges); and
- (e) disclosure to Affiliates, Sublicensees (as for Licensee) or Mirati's other licensees, collaborators employees, consultants, contractors, or agents, on a need to know basis, or to potential Sublicensees (as to Licensee) or other licensees (as to Mirati), or potential acquirers, merger partners other Third Party strategic partners, and their respective professional advisors, in connection with due diligence or similar investigations by such Third Parties in connection with potential business transactions, disclosure to actual or bona-fide potential Third Party investors in confidential financing documents, and disclosure to actual and bona-fide potential Third Party acquirers of such Party, provided, in each case, that any such Affiliate, Sublicensees (as to Licensee) or other licensees (as to Mirati), collaborator, employee, consultant, contractor, agent, or Third Party agrees to be bound by (or is subject to, pursuant to its professional ethical rules) terms of confidentiality and non-use consistent with those set forth in this Article 12.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 12.2(c) or 12.2(d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to secure confidential treatment of such Confidential Information and at least as diligently as such Party would use to protect its own confidential information. In any event, each of the Parties agrees to take all reasonable action to avoid disclosure of the other Party's Confidential Information hereunder except as needed in furtherance of, and in compliance with the terms of, this Agreement. Any information disclosed pursuant to Section 12.2(c) or 12.2(d) shall still be deemed Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of Article 12.

#### 12.3 Publications.

(a) Subject to Mirati's review and approval as set forth below, Licensee shall have the right to publish Clinical Data pertaining to the Compound or any Licensed Product and generated by or on behalf of Licensee from Local Studies in the Licensed Territory pursuant to this Agreement and subject to this Section 12.3. Mirati shall have the right to review, comment on, and approve any material proposed for disclosure or publication by Licensee regarding any such Clinical Data or results of and other information regarding Licensee's Development activities with respect to the Compound or any Licensed Product, whether by oral presentation, manuscript, or abstract. Before any such material is submitted for publication or presentation of the same is made, Licensee shall deliver a complete copy to Mirati at least [\*\*\*] prior to submitting the material to a publisher or initiating any other disclosure. Mirati shall review any such material and give its comments to Licensee within [\*\*\*] of receipt of such material, which comments Licensee shall implement. With respect to oral presentation materials and abstracts, Mirati shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to Licensee with appropriate comments, if any, but in no event later than [\*\*\*] from receipt. Licensee shall comply with Mirati's request to delete references to its Confidential Information in any such material and agrees to delay any submission for publication or other public disclosure for a period of up to an additional [\*\*\*] for the purpose of preparing and filing appropriate patent applications. Licensee shall have no right to publish outside the Licensed Territory (including in any form or media that may be distributed outside the Licensed Territory) or with respect to any Clinical Data generated from any Global Study, in each case, without Mirati's prior written consent.

(b) Subject to Licensee's review and comment as set forth below, Mirati shall have the right to publish preclinical data and Clinical Data pertaining to the Compound or any Licensed Product that is generated by or on behalf of Licensee or any of its Affiliates or Sublicensees pursuant to this Agreement and subject to this Section 12.3(b). Licensee shall have the right to review and comment on any material proposed for disclosure or publication by Mirati regarding any such preclinical and Clinical Data, whether by oral presentation, manuscript, or abstract. Before any such material is submitted for publication or presentation of the same is made, Mirati shall deliver a complete copy to Licensee at least [\*\*\*] prior to submitting the material to a publisher or initiating any other disclosure. Licensee shall review any such material and give its comments to Mirati within [\*\*\*] of receipt of such material, which comments Mirati shall consider in good faith. With respect to oral presentation materials and abstracts, Licensee shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to Mirati with appropriate comments, if any, but in no event later than [\*\*\*] s from receipt. Mirati shall comply with Licensee's request to delete references to its Confidential Information in any such material and agrees to delay any submission for publication or other public disclosure for a period of up to an additional [\*\*\*] for the purpose of preparing and filing appropriate patent applications. For clarity, Mirati shall have final decision-making authority for publications reviewed by Licensee under this Section 12.3(b).

12.4 Publicity; Public Disclosures. The Parties agree to issue a joint press release promptly after the Effective Date, in the form attached as Exhibit 12.4 of this Agreement. Further, it is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or the activities or results hereunder subject to the prior written consent of the other Party; provided, that (a) the Parties hereby agree to consult with each other with respect to the text and timing of any such subsequent press releases concerning activities or results pursuant to this Agreement (other than any activities or results relating to Joint Global Studies), prior to the issuance thereof and (b) a Party may not unreasonably withhold, condition, or delay its consent to any such releases. Any press releases concerning activities or results relating to Joint Global Studies shall be subject to Mirati's review and approval, in its sole discretion. Each Party may also make such disclosures relating to this Agreement or the activities or results hereunder to the extent required by Applicable Laws; provided, that such Party hereby agrees to use reasonable efforts to consult with the other Party with respect to the text and timing of any such disclosure.

12.5 Required Disclosures. Each Party acknowledges and agrees that the other Party may submit this Agreement to the U.S. Securities and Exchange Commission or any national securities exchange in any jurisdiction (collectively, the "Securities Regulators"), or to other persons as may be required by Applicable Laws, and if a Party does submit this Agreement to any Securities Regulators, or other persons as may be required by Applicable Laws, such Party agrees to reasonably consult and coordinate with the other Party with respect to the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party determines that it is required by Applicable Laws or any Securities Regulator to make a disclosure of the terms of this Agreement in a filing or other submission as required by Applicable Laws or Securities Regulators, then such Party will have the right to make such disclosure at the time and in the manner reasonably determined by its counsel to be required by Applicable Laws or Securities Regulator subject to this Section 12.5. Each Party shall: (a) provide copies of the proposed disclosure to the other Party reasonably in advance of such filing or other disclosure under the circumstances, (b) promptly notify the other Party in writing of such requirement and any respective timing constraints, and (c) give the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon and request confidential treatment for such disclosure; provided, that, the other Party shall promptly review and provide comments regarding the proposed disclosure and the disclosing Party will in good faith consider incorporating such comments.

**12.6 Prior Confidentiality Agreement**. As of the Effective Date, the terms of this Article 12 shall supersede any prior non-disclosure, secrecy, or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

**12.7 Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use, or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 12. In addition to all other remedies, a Party shall be entitled to seek to obtain specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 12.

-60-

#### 13. REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate, partnership or member action; and (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

#### 13.2 Mutual Covenants.

- (a) **Employees, Consultants, and Contractors**. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign inventions in a manner consistent with the provisions of this Agreement.
- (b) **Debarment**. Each Party represents, warrants, and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country, Region, or jurisdiction other than the U.S., and it does not, and will not during the Term, knowingly employ or use the services of any person who is debarred or disqualified in connection with any activities relating to any Licensed Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Sublicensees (as to Licensee) or other licensees (as to Mirati), that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.
- (c) Each Party covenants that all manufacture and Development (including non-clinical studies) related to the Compound or any Licensed Product conducted on behalf of such Party or its Affiliates will be conducted in accordance with all Applicable Laws, including cGCP, cGLP and cGMP.
- (d) Each Party represents, warrants, and covenants that, (i) at the time it delivers the written notice to the other Party in accordance with Section 5.4(f) confirming its Control and rights with respect to a Joint Global Study, it Controls and may grant and provide to, and, (ii) during the remainder of the Term, it will Control, grant a license, and provide to, in each case of (i) and (ii), the other Party the Reference Data, Regulatory Filings, and any other Know-How or Patents resulting from the conduct of such Joint Global Study in such Party's territory as Licensed Technology or Licensee Technology, as applicable, in accordance with the terms of this Agreement (including Sections 2.1, 4.1, 4.2, 5.8, 6.3(b), and 6.3(d)). For clarity, a Party shall not be deemed to have breached this covenant if such Party fails to provide the other Party with a portion of Reference Data, Regulatory Filings, or any other Know-How or Patents resulting from the conduct of such Joint Global Study in such Party's territory as Licensed Technology or Licensee Technology, provided that, upon the other Party's request to do so, the first Party shall reasonably promptly provide such missing item or items to the other Party.

#### (e) Compliance.

- (i) In the performance of its obligations under this Agreement, each Party shall comply, and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws.
- (ii) Each Party, and its and its Affiliates' employees and contractors, shall not, and Licensee will ensure that its Sublicensee's shall not, in connection with the performance of this Agreement, directly or indirectly through Third Parties, pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to any Public Official or other person or entity for the purpose of obtaining or retaining business for or with, or directing business to, any person, including, without limitation, either Party, or with respect to Licensee any Sublicensee (it being understood that, without any limitation to the foregoing, such Party, and to its knowledge, its and its Affiliates' employees and contractors, has not directly or indirectly promised, offered, or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality, or other illegal or unethical benefit to a Public Official or any other person or entity in connection with the performance of such Party's obligations under this Agreement, and shall not, directly or indirectly, engage in any of the foregoing).
- (iii) In connection with the performance of its obligations under this Agreement, each Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with such Party's own anti-corruption and anti-bribery policy, a copy of which shall be provided to the other Party upon such other Party's written request.
- (iv) Each Party will have the right, upon reasonable prior written notice and during the other Party's regular business hours, to audit such other Party's books and records in the event that the first Party reasonably and in good faith suspects that a violation of any of the representations, warranties, or covenants in this Section 13.2(e) has occurred.
- (v) In the event that a Party has violated or been suspected of violating any of the representations, warranties, or covenants in this Section 13.2(e), such Party will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training regarding anti-corruption law compliance.
- (vi) Each Party will, at the other Party's written request, but no more frequently than [\*\*\*], certify to such other Party in writing such Party's compliance, in connection with the performance of such Party's obligations under this Agreement, with the representations, warranties, or covenants in this Section 13.2(e).

- **13.3 Additional Mirati Representations, Warranties, and Covenants**. Mirati represents, warrants, and covenants to Licensee that as of the Effective Date:
  - (a) To the Knowledge of Mirati, all Licensed Patents existing as of the Effective Date are listed on Exhibit 1.84;
- (b) To Mirati's Knowledge, (i) all Licensed Patents, are subsisting and in good standing and being diligently prosecuted in the respective patent offices in accordance with Applicable Laws, and have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment; and (ii) all issued Licensed Patents are valid and enforceable;
- (c) Mirati has not received written notice, including from any Third Party, that the Development of Compound or Licensed Product conducted by or on behalf of Mirati or its Affiliates infringes or misappropriates any Patents or other intellectual property rights of any Third Party in the Licensed Territory;
- (d) Mirati owns or is the exclusive licensee of the rights, title, and interest in and to the Licensed Patents, and have the right to grant the licenses to Licensee set forth in Section 2.1 of this Agreement;
- (e) Neither Mirati nor any of its Affiliates has granted any right or license to any Third Party relating to any of the Licensed Patents or Licensed Know-How that conflicts with, or limits the scope of, any of the rights or licenses granted to Licensee hereunder;
- (f) Neither Mirati nor any of its Affiliates has granted any mortgage, pledge, claim, security interest, encumbrance, lien or other charge of any kind on the Licensed Patents or Licensed Know-How in the Licensed Territory, and the Licensed Patents and Licensed Know-How are free and clear of any mortgage, pledge, claim, security interest, encumbrance, lien or charge of any kind in the Licensed Territory;
- (g) No legal claim or action has been brought or, to Mirati's Knowledge, threatened against Mirati by any Third Party alleging that the Licensed Patents are invalid or unenforceable and no Licensed Patent is the subject of any interference, opposition, cancellation, or other protest proceeding;
- (h) There are no pending legal actions, claims, suits, or proceedings against Mirati or any of its Affiliates, at law or in equity, or before or by any Regulatory Authority or other government authority in the Licensed Territory, and neither Mirati nor any of its Affiliates has received any written notice regarding any pending or threatened legal actions, claims, suits, or proceedings against Mirati, at law or in equity, or before or by any Regulatory Authority or other government authority in the Licensed Territory, in either case with respect to the Licensed Patents or the Development of the Compound or any Licensed Product;

-63-

- (i) Mirati (and any of its Affiliates and to Mirati's Knowledge, Third Parties acting under its authority) has complied in all material respects with all Applicable Laws and applicable governmental regulations and industrial standards (including GLP, GCP, and GMP) in connection with the Development, manufacture, storage and disposition of the Compound and Licensed Product (including information and data provided to Regulatory Authorities);
- (j) All Upstream Agreements as of the Effective Date are listed in **Exhibit 1.145**. With respect to each Upstream Agreement in existence as of the Effective Date, (i) it is in full force and effect; (ii) neither Mirati nor any of its Affiliates is in breach thereof in a manner that could result in the termination of any rights that are sublicensed to Licensee hereunder; (iii) neither Mirati nor any of its Affiliates has received any notice of breach or notice of threatened breach thereof, or any request of a material amendment of, or the termination of any Upstream Agreement; and (iv) neither Mirati nor any of its Affiliates is aware of any other facts that would result in a material amendment or termination of the Upstream Agreement.
- (k) Mirati and its Affiliates (i) will not breach the terms and conditions of each Upstream License in a manner that could result in termination of any rights that are sublicensed to Licensee hereunder; (ii) will ensure that the Upstream Agreements are in full force and effect for so long as any Licensed Technology licensed to Mirati under such Upstream Agreements are necessary or reasonably useful for the Exploitation of the Compound or any Licensed Products in the Field in the Licensed Territory; (iii) will provide prompt notice to Licensee of its receipt of any written notice that alleges breach or default by Mirati of, requests a material amendment of, or termination of any Upstream Agreement in a manner that could result in termination of any rights that are sublicensed to Licensee hereunder and provide to Licensee a copy of each of the foregoing and any amendment to any Upstream Agreement; and (iv) during the Term, will not amend, modify or terminate any Upstream Agreements in a manner that would terminate rights that are sublicensed to Licensee hereunder or otherwise diminish the scope or exclusivity of the licenses granted to Licensee under the technology licensed to Licensee hereunder.
- **13.4 Additional Licensee Covenant**. Neither Licensee nor any of its Affiliates (or any of their respective Sublicensees, employees and contractors), in connection with the exercise of Licensee's rights or performance of Licensee's obligations under this Agreement, shall knowingly cause Mirati to be in violation of any applicable U.S. or foreign export control laws and regulations.
- 13.5 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY MAKES NO AND EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE PRODUCTS, PATENTS, KNOW-HOW, OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. EXCEPT TO THE EXTENT EXPRESSLY PROVIDED FOR HEREIN, NOTHING IN THIS AGREEMENT WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY MIRATI THAT THE LICENSED PATENTS OR LICENSED KNOW-HOW IS NOT INFRINGED BY ANY THIRD PARTY OR THAT THE PRACTICE OF SUCH RIGHTS DOES NOT INFRINGE ANY PUBLISHED INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. Without limiting the generality of the foregoing, (a) neither Party represents or warrants that any data obtained from conducting clinical trials in one country, Region or jurisdiction will comply with the laws and regulations of any other country, Region or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.

### 14. INDEMNIFICATION AND LIMITATION OF LIABILITY

14.1 Indemnification by Licensee. Licensee hereby agrees to defend, indemnify, and hold harmless Mirati and its Affiliates, and their respective directors, officers, employees and agents (each, a "Mirati Indemnitee") from and against any and all liabilities, judgments, damages, expenses, and losses, including reasonable legal expenses and attorneys' fees, (collectively, "Losses") to which any Mirati Indemnitee may become subject as a result of any claim, demand, allegation, suit, action, or other proceeding (each, a "Claim") by any Third Party against any Mirati Indemnitee to the extent such Losses arise directly or indirectly out of: (a) the Development, manufacture, use, handling, storage, sale, offer for sale, import, export or other Commercialization (including Co-Commercialization) of the Compound or any Licensed Product by Licensee or its Affiliates or Sublicensees (excluding, for clarity, Mirati and its Affiliates and their licensees); (b) the breach by Licensee or its Affiliate or Sublicensee of any warranty, representation, covenant, or agreement made by Licensee in this Agreement; or (c) the negligence or willful misconduct of any Licensee Indemnitee; except in each case (a)-(c) above to the extent such Losses or Claim arise out of any activity by Mirati or a Mirati Indemnitee, as applicable, within the criteria set forth in Section 14.2(a)-(d) for which Mirati is obligated to indemnify Licensee under Section 14.2.

14.2 Indemnification by Mirati. Mirati hereby agrees to defend, indemnify, and hold harmless Licensee and its Affiliates, and their respective directors, officers, employees, and agents (each, a "Licensee Indemnitee") from and against any and all Losses to which any Licensee Indemnitee may become subject as a result of any Claim by any Third Party against a Licensee Indemnitee to the extent such Losses arise out of: (a) the Development, manufacture, or if Mirati Exercises the Co-Commercialization Option, Co-Commercialization, of the Compound or any Licensed Product by Mirati or any of its Affiliates or sublicensees (excluding, for clarity, Licensee and its Affiliates and their licensees) in the Licensed Territory; (b) the development, manufacture, use, handling, storage, sale, offer for sale, import, export or other commercialization of the Compound or any Licensed Product by Mirati or any of its Affiliates or sublicensees (excluding, for clarity, Licensee and its Affiliates and their licensees) outside the Licensed Territory; (c) the breach by Mirati of any warranty, representation, covenant, or agreement made by Mirati in this Agreement; or (d) the negligence or willful misconduct of any Mirati Indemnitee; except in each case (a)-(d) above to the extent such Losses or Claim arise out of any activity set forth in Section 14.1 (a)-(c) for which Licensee is obligated to indemnify Mirati under Section 14.1.

14.3 Indemnification Procedures for Claims. The Party claiming indemnity under Section 14.1 or 14.2, either on behalf of itself or its Indemnified Party, with respect to a particular Third Party Claim against such Indemnified Party, shall give written notice to the Party from whom indemnity hereunder is being sought (the "Indemnifying Party", as to such Claim) promptly after learning of such Claim, however, that the failure or delay by an Indemnified Party to give such notice of a Claim shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been prejudiced as a result of such failure or delay to give notice. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party (and including such Party) may participate in and monitor such defense with counsel of its own choosing at its own expense; provided, however, that the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any such Claim without the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, conditioned, or delayed), unless the settlement involves only the payment of money, and no admission of wrong-doing or fault by the Indemnified Party. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Claim in any manner the Indemnified Party may deem reasonably appropriate, all at Indemnifying Party's cost and expense (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party will remain responsible to indemnify and hold harmless the Indemnified Party as provided in this Article 14.

**14.4 Insurance**. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) during the Term and for [\*\*\*] thereafter in an amount consistent with sound business practice and industry standards, and reasonable in light of the risks involved in its activities hereunder and its obligations under this Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

**14.5** Limitation of Liability. NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY, OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED, LOST PROFITS, OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT. Notwithstanding the foregoing, the limitation of liability set forth in this Section 14.5 shall not apply to the extent such liability (a) is subject to indemnification under Section 14.1 or 14.2 or (b) arises in connection with a Party's (i) gross negligence or willful misconduct or (ii) breach of its confidentiality obligations under Article 12.

### 15. TERM AND TERMINATION; CESSATION OF DEVELOPMENT

**15.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier termination of the Agreement as provided in this Article 15 or by mutual written agreement of the Parties, shall continue until it expires as follows (the "**Term**"): (a) on a Licensed Product-by-Licensed Product basis and on a Region-by-Region basis in the Licensed Territory, at the end of the applicable Royalty Term under this Agreement for each Licensed Product, (b) with respect to any Licensed Product for which a Co-Commercialization Option has been exercised pursuant to Section 7.4, on a Region-by-Region basis, the end of the Co-Commercialization Term, and (c) in its entirety, upon the expiration of all payment obligations under this Agreement with respect to all Licensed Product in all Regions in the Licensed Territory.

-66-

#### 15.2 Termination of Agreement.

(a) **Unilateral Right to Terminate**. Licensee may terminate this Agreement at any time by providing not less than twelve (12) months' prior written notice to Mirati.

### (b) Breach.

- (i) **Breach Notice; Cure Period.** Each Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party materially breaches this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail (herein, "**Breach Notice**"), fails to cure such material breach within [\*\*\*] from the date of such Breach Notice. Notwithstanding the foregoing, if such material breach (other than any payment breach), by its nature, is curable, but is not reasonably curable within the applicable cure period and the breaching Party provides a written plan for curing such breach to the non-breaching Party, then such [\*\*\*] cure period will be extended for as long as the breaching Party uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan, but for no longer than an additional [\*\*\*].
- (ii) **Dispute**. If the allegedly breaching Party reasonably and in good faith disagrees that there has been a material breach (that is the subject of the Breach Notice pursuant to this Section 15.2(b)) then the Party that disputes that there has been a material breach may contest the allegation by referring such matter, within [\*\*\*] following receipt of such Breach Notice, for resolution to the Parties' Chief Executive Officers, who will meet promptly to discuss the matter and determine, within [\*\*\*] following referral of such matter, whether or not a material breach has occurred pursuant to this Section 15.2(b). If the Chief Executive Officers are unable to resolve such dispute within such [\*\*\*] period after it is referred to them, (i) the matter and alleged breach will be resolved as provided in Article 16; (ii) the cure period with respect thereto will be tolled through the resolution of such dispute in accordance with the applicable provisions of this Agreement so long as the alleged breaching Party is in good faith participating in the dispute resolution proceedings under Article 16; (iii) this Agreement shall not be terminated and during the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder; (iv) if it is ultimately determined under the dispute resolution process that the breaching Party committed such material breach, then the breaching Party will have the right to cure such material breach for a period not to exceed [\*\*\*] from the date of such determination, and if such material breach is cured by the breaching Party prior to the end of such period, the Agreement shall remain in force (subject to all other terms and conditions), and if not, the other Party may terminate the Agreement on written notice; and (v) if it is ultimately determined under the dispute resolution process that the allegedly breaching Party did not commit such material breach, then the Agreement shal

- (c) **Bankruptcy**. Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if the other Party makes a general assignment for the benefit of creditors, files a petition under bankruptcy or insolvency, petitions for or acquiesces in the appointment of any receiver, trustee, or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above.
- (d) Patent Challenge. If Licensee or its Affiliate conducts or materially participates in any Patent Challenge (as defined below), then Mirati may terminate this Agreement on written notice, unless all such Patent Challenge activities are permanently ceased and terminated within [\*\*\*] of Licensee's receipt of such notice from Mirati. As used herein, a "Patent Challenge" means any direct or indirect through the actions of another person acting on Licensee's or its Affiliate's or Sublicensee's behalf dispute or challenge by Licensee or its Affiliate or Sublicensee, or any willful assistance (other than as compelled by subpoena or other legal process) by Licensee or its Affiliate or Sublicensee in the dispute or challenge by another person or entity, of the validity, patentability, or enforceability of any Licensed Patent, or any equivalent Patent of Mirati outside the Licensed Territory, or any claim thereof, or opposition or assistance in the opposition of the grant of any letters patent within the Licensed Patents, or any equivalent Patent of Mirati outside the Licensed Territory, in any legal or administrative proceedings in a court of law, before any patent office or other similar agency or tribunal with appropriate jurisdiction in any country, Region, territory or jurisdiction, including by reexamination, inter partes review, opposition, interference, post-grant review, nullity proceeding, preissuance submission, third party submission, derivation proceeding or declaratory judgment action. If any Sublicensee of Licensee or its Affiliate conducts or materially participates in any Patent Challenge (as defined above), then Mirati may terminate this Agreement on written notice, unless (i) such Patent Challenge activities are permanently ceased and terminated within [\*\*\*] of Licensee's receipt of such notice from Mirati, (ii) Licensee or its Affiliate terminates the applicable Sublicense Agreement in accordance with Section 2.2 within [\*\*\*] of Licensee's receipt of such written notice from Mirati, or (iii) such P
  - (e) Termination for Mutual Agreement. This Agreement may be terminated by the Parties' mutual written agreement.
  - **15.3 Consequences of Termination**. Upon any termination of this Agreement under Section 15.2 for any reason:
- (a) **License Grants to Licensee**. The licenses granted by Mirati to Licensee pursuant to Section 2.1 shall automatically terminate and Licensee shall have no further right to use or cross-reference Mirati's Regulatory Approvals and Regulatory Filings or to use Licensed Technology for any purpose.
- (b) **License Grants to Mirati**. The licenses granted by Licensee to Mirati in Section 2.4 and 6.3(d)(i) shall continue in full force and effect following such termination.

-68-

(c) **Reversion Licenses**. Effective upon the effective date of termination of this Agreement, Licensee hereby grants to Mirati an exclusive, fully-paid, perpetual, irrevocable, royalty-free, with the right to grant multiple tiers of sublicenses, under the Licensee Know-How, Licensee Patents to Develop, manufacture and Commercialize the Compound and any Licensed Products in the Field in the Licensed Territory.

### (d) Regulatory Materials; Data.

- (i) Within [\*\*\*] of the effective date of such termination, to the extent permitted under Applicable Laws, (A) Licensee shall transfer and assign to Mirati, all Regulatory Filings, Regulatory Approvals, Regulatory Exclusivity, copies of material correspondence and conversation logs, pre-clinical and clinical study reports, clinical study protocols, and all pharmacovigilance data (including all adverse event databases) Controlled by Licensee relating to any Licensed Product in the Licensed Territory, and (B) Licensee shall take all steps necessary to transfer ownership of all such assigned Regulatory Filings, Regulatory Approvals and Regulatory Exclusivity to Mirati, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Mirati) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Filing, Regulatory Approval and Regulatory Exclusivity. In addition, at Mirati's request, Licensee shall provide Mirati with reasonable assistance with any additional inquiries and correspondence with Regulatory Authorities regarding any Licensed Product in the Licensed Territory for up to [\*\*\*] after such termination.
- (ii) Licensee shall grant to Mirati a right of reference under all Regulatory Filings, Regulatory Approvals and Regulatory Exclusivity for any Licensed Products that are Controlled by Licensee or its Affiliates or Sublicensees, unless and until assigned to Mirati pursuant to Section 15.3(d)(i).
- (e) **Know-How Transfer**. Licensee shall provide reasonable consultation and assistance for a period of no more than [\*\*\*] for the purpose of disclosing and providing to Mirati, all Licensee Know-How not already in Mirati's possession that is relevant to the Compound and any Licensed Product.
- (f) **Development Wind-Down**. Licensee shall, as directed by Mirati, either (i) complete or wind-down in an orderly fashion any ongoing Development activities (including any Clinical Trials) with respect to any Licensed Product in the Licensed Territory, and thereafter comply with subclause (ii), or (ii) promptly transfer all Development activities to Mirati or its designee, in any case in compliance with all Applicable Laws.
- (g) Commercial Wind-Down. If at the time of termination any Licensed Products are being Commercialized in the Licensed Territory, then Licensee shall, as directed by Mirati, (i) continue certain ongoing Commercialization activities with respect to such Licensed Products in the Licensed Territory for a period of up to [\*\*\*] as determined by Mirati, or (ii) hand off all, or specified, Commercialization activities to Mirati or its designee, on a timetable to be set by Mirati, not to exceed [\*\*\*], in each case in compliance with all Applicable Laws. During such commercial wind-down period, Licensee shall continue to book sales and pay royalties to Mirati in accordance with Section 9.3, except as otherwise specified by Mirati. Except as necessary to conduct the foregoing activities as directed by Mirati or to exercise its rights to sell inventories for the Sell-Off Period stipulated in Section 15.3(j), Licensee shall immediately discontinue its (and shall ensure that its Affiliates and Sublicensees immediately discontinue their respective) promotion, marketing, offering for sale, and servicing of the Licensed Products. In addition, Licensee shall immediately assign and transfer to Mirati all of Licensee's rights, title, and interests in and to all samples, demonstration equipment, sales materials, catalogs, promotional materials, training materials, medical education materials, packaging and labeling, and all other literature, information or similar materials related to the Licensed Products in Licensee's possession or control and copyrights and any registrations for the foregoing, at Licensee's costs of goods at the end of the Sell-Off Period.

(h) **Transition Assistance**. Licensee shall seek an orderly transition of the Development and Commercialization of the Compound and Licensed Products in the Licensed Territory to Mirati or its designee. Licensee shall provide reasonable consultation and assistance after termination for the purpose of transferring or transitioning to Mirati or its designee all then-existing development and commercial arrangements, including assignment of Licensee's Third Party contracts to Mirati as Mirati shall require, relating to the Licensed Products that Licensee is able to transfer or transition to Mirati or its designee, in each case, to the extent reasonably necessary or useful for Mirati or its designee to continue the Development or Commercialization of the Compound and Licensed Products in the Licensed Territory. If any such contract between Licensee and a Third Party is not assignable to Mirati or its designee (whether by such contract's terms or because such contract does not relate specifically to the Licensed Products) but is otherwise reasonably necessary or useful for Mirati or its designee to continue the Development or Commercialization of the Compound and Licensed Products in the Licensed Territory, or if Licensee is performing such work for the Compound and Licensed Product itself (and thus there is no contract to assign), then Licensee shall reasonably cooperate with Mirati to negotiate for the continuation of such services for Mirati from such entity, or Licensee shall continue to perform such work for Mirati, as applicable, for up to [\*\*\*] after termination at Mirati's cost until Mirati establishes an alternate, validated source of such services.

(i) **Supply Obligations**. Unless and until the necessary Third Party manufacturing agreements are assigned to Mirati pursuant to the preceding sentences, or if Licensee manufactures the Licensed Products itself (and thus there is no contract to assign), Licensee shall: (i) to the extent allowable under such agreements, assign to Mirati or its Affiliates the portion of Licensee's agreement(s) with its Third Party manufacturing provider related to the Licensed Product(s), or alternatively, use Commercially Reasonable Efforts to facilitate Mirati's entering into a direct supply agreement with such Third Party manufacturing provider of Licensed Product(s) on comparable terms to those between Licensee and such Third Party manufacturing provider (in each case assuming Licensee is then obtaining supply of Licensed Products from a Third Party manufacturing provider) and (ii) to the extent Licensee or its Affiliate is producing its own supply of the Licensed Products, supply such bulk finished Licensed Product, as applicable, to Mirati for a reasonable period [\*\*\*]. The cost to Mirati for such supply shall be [\*\*\*] of Licensee's Manufacturing Cost for such Licensed Products. Without limiting the foregoing, in either case Mirati shall additionally have the right to immediately have Licensee commence the transfer of the manufacturing process for such Licensed Product(s) to Mirati or its designee.

-70-

- (j) **Remaining Inventories**. Unless this Agreement is terminated by Mirati pursuant to Section 15.2(b), Licensee will have the right, for a period of [\*\*\*] following termination of this Agreement, to sell or otherwise dispose of any Licensed Products in the Licensed Territory on hand at the time of such termination or in the process of manufacturing(the "Sell-Off Period"). Upon the expiration of the Sell-Off Period, if applicable, Mirati shall have the right, at its discretion, to purchase from Licensee or its Affiliates any or all of the inventory of the Licensed Products held by Licensee or its Affiliates as of the date of termination at a price equal to [\*\*\*] of either (i) the transfer price paid by Licensee or its Affiliates to acquire such inventory from Mirati, or (ii) Licensee's Manufacturing Cost for such inventory of Licensed Product, as applicable. Mirati shall notify Licensee within [\*\*\*] after the date of termination whether Mirati elects to exercise such right.
- (k) **Trademarks**. Licensee shall promptly assign and transfer to Mirati all of Licensee's rights, title, and interest (including all goodwill and related rights) in and to trademarks pertaining to all Licensed Products that are owned by Licensee (or its Affiliate or Sublicensee) and used for such Licensed Products in the Field in the Licensed Territory, but not any house marks, or logos or any trademark of Licensee or its Affiliates, containing the word "Zai" or any such Affiliate.
- (l) **Further Actions**. Licensee shall execute all documents and take all such further actions as may be reasonably requested by Mirati to give effect to the foregoing subsections (c) (k).
- (m) **Transition Costs**. Except as otherwise stipulated in each relevant Sections, Mirati will reimburse Licensee for the internal and external costs incurred in performing such transition activities or providing such assistance under Sections 15.3(d), 15.3(f) through 15.3(i), 15.3(k), 15.3(h) and 15.3(l), unless this Agreement is terminated by Mirati in accordance with Section 15.2(b) or Section 15.2(d) or by Licensee in accordance with Section 15.2(a).
- (n) **Rights in Bankruptcy**. The Parties acknowledge that this Agreement constitutes an executory contract under Section 365 of the Code for the license of "intellectual property" as defined under Section 101 of the Code and constitutes a license of "intellectual property" for purposes of any similar laws in any other country. The Parties further acknowledge that each Party, as licensee of certain rights and licenses under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code, including, but not limited to, Section 365(n) of the Code, and any similar laws in any other country. In the event of the commencement of a bankruptcy proceeding by or against Mirati under the Code and any similar laws in any other country, Licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless Mirati elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of Mirati upon written request therefor by Licensee, provided Licensee elects to retain its rights under the Agreement in accordance with Section 365(n)(1)(B) of the Code and complies with the requirements of Section 365(n)(2) of the Code. All rights, powers and remedies of Licensee provided for in this Section 15.3(n) are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, under the Code and any similar laws in any other country).

- 15.4 Confidential Information. Upon expiration or termination of this Agreement in its entirety, each Party shall promptly return to the other Party or destroy all records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that (i) such Party may keep one copy of such materials for archival purposes to be used in connection with the interpretation and enforcement hereof and subject to continuing confidentiality obligations in accordance with Article 12; and (ii) Mirati shall not be required to return or destroy Licensee's Confidential Information to the extent reasonably necessary or useful for Mirati to continue to Develop, manufacture, and Commercialize the Compound and Licensed Product.
- 15.5 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: Section 8.3 (for the [\*\*\*] specified therein), Section 9.2 (solely with respect to payment obligations accrued prior to such expiration or termination, provided Section 9.3(b) shall only survive upon the expiration of this Agreement or on a Licensed Product-by-Licensed Product and Region-by Region basis, upon the expiration of the Royalty Term and payments to Mirati for such Licensed Product in such Region as stipulated therein), Section 11.1, Section 11.2 through Section 11.5 (solely with respect to Joint Patents), Section 13.5, Section 15.3 through Section 15.7, Article 1, Article 10 (solely with respect to payment obligations accrued prior to such expiration or termination, and for Section 10.5, for the [\*\*\*] specified therein), Article 12 (for the [\*\*\*] specified therein), Article 14 (excluding Section 14.4, which Section 14.4 shall only survive for the [\*\*\*] specified therein), Article 16, Article 17 (as applicable).
- **15.6 Exercise of Right to Terminate**. The use by either Party hereto of a termination right provided for under this Agreement shall not in and of itself give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto; provided, however, that termination of this Agreement shall not preclude either Party from claiming any other damages, compensation, or relief that it may be entitled to upon such termination.
- **15.7 Damages; Relief.** Subject to Section 15.6, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation, or relief that it may be entitled to upon such termination.
- **15.8 Cessation of Development of Compound by Mirati**. Mirati may cease all development activities pertaining to Compound outside the Licensed Territory by providing not less than [\*\*\*] prior written notice to Licensee. In such case, (a) Mirati's ongoing obligations (solely to the extent arising after such cessation) under Sections 5.4, 5.6, 5.8, 6.3(b)(ii), and Article 8 (excluding Section 8.5) herein, and under any Clinical Supply Agreement, Licensee Commercial Supply Agreement and Mirati Commercial Supply Agreement, as applicable, shall cease and be of no further force or effect (for clarity, Mirati's obligation to provide Licensee with access or copies to Reference Data, Regulatory Filing, and correspondence generated prior to such cessation shall be unaffected), (b) all Mirati rights under Sections 5.4 shall cease, and (c) this Agreement shall otherwise continue in full force and effect.

### 16. DISPUTE RESOLUTION

- **16.1 Disputes**. In the event of any dispute, controversy, or claim arising out of or in connection with this Agreement, the Parties shall, through their respective Chief Executive Officers or Chief Operating Officers, first meet and attempt to resolve the dispute in face-to-face negotiations unless otherwise mutually agreed to. This meeting shall occur within [\*\*\*] after either Party provides notice to the other Party that it wishes to invoke such negotiations.
- **16.2 Arbitration**. If the Parties are unable to resolve any dispute through such negotiations as are described in Section 16.1, within [\*\*\*] of notice from a Party about such dispute, then, the dispute shall be resolved by binding arbitration administered by the International Chamber of Commerce ("ICC") in accordance with the ICC's then current rules governing commercial disputes as modified herein.
- (a) Within [\*\*\*] following the commencement of arbitration, each of the Parties shall select a mutually acceptable independent, impartial, and conflicts-free arbitrator to act as an arbitrator, and such two arbitrators shall select a third independent, impartial, and conflicts-free arbitrator who shall serve as the president of the tribunal (such arbitrators, the "**Arbitrators**"). None of the Arbitrators may be current or former employees, officers, or directors of either Party or its Affiliates. Each of the Arbitrators shall have relevant expertise and experience with respect to the matter at issue.
  - (b) The place, or legal seat, of arbitration shall be New York, New York.
- (c) After the Arbitrators are appointed, at the earliest convenient date (not to exceed [\*\*\*] after the Arbitrator's appointment), the Arbitrators shall convene a preliminary conference with the Parties to fix the schedule for the arbitration and determine the discovery that shall take place. Discovery is to be completed within [\*\*\*] of the preliminary conference unless this period of time is extended by the Arbitrator for good cause. The evidentiary hearing on the merits is to commence within [\*\*\*] of the discovery cutoff.
- (d) The hearing shall be conducted on no more than [\*\*\*] unless the Arbitrator determines that the number of witnesses warrants additional hearing days (not to exceed [\*\*\*]). The Parties shall each receive equal time during the hearing, using the chess clock approach. The Arbitrators shall issue a reasoned award, deciding each disputed issue within [\*\*\*] following completion of the hearing. The Arbitrator(s) shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. The arbitral award shall be final and binding, and judgment on the award may be entered in any court having jurisdiction.
- (e) Failure to meet any of the foregoing deadlines will not render the award invalid, unenforceable, or subject to being vacated. The Arbitrators, however, may impose appropriate sanctions and draw appropriate adverse inferences against a Party responsible for the failure to meet any such deadlines.

- (f) Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Arbitrators; provided, however, that the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs, and disbursements (including, for example, expert witness fees and expenses, travel expenses, etc.) or the fees and costs of the Arbitrators.
  - (g) Any arbitration shall be conducted in English and the Arbitrators shall apply the governing law specified in Section 17.1.
- (h) Except to the extent necessary to confirm or enforce an award or as may be required by law, neither a Party nor any Arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Mirati and Licensee. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy, or claim would be barred by the applicable statute of limitations.
- (i) Excluded Claims. As used in this Section 16.2, the term "Excluded Claim" means a dispute, controversy, or claim that concerns (i) the validity, scope, enforceability, or infringement of a patent, trademark, or copyright; (ii) any antitrust, anti-monopoly, or competition law or regulation, whether or not statutory; or (iii) subject to Section 16.3 below, the request for equitable relief. Disputes regarding Excluded Claims shall be brought in a court of competent jurisdiction in which such patent or trademark rights or copyright was granted or arose, or in which such law or regulation applies, or in which equitable relief is properly sought.
- **16.3 Court Actions**. Nothing contained in this Agreement shall deny either Party the right to seek, upon good cause, injunctive or other equitable relief from a court of competent jurisdiction in the context of an emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing dispute resolution discussions or arbitration proceedings.

### 17. GENERAL PROVISIONS

- **17.1 Governing Law**. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding its conflicts of laws principles. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods.
- **17.2 Entire Agreement; Modification.** This Agreement is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written, or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by authorized representatives of the Parties.

**17.3 Relationship Between the Parties**. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture, or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

**17.4 Non-Waiver**. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

### 17.5 Assignment.

- (a) Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party, without the prior written consent of the other Party; provided, however, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent to an Affiliate (for so long as such Person remains an Affiliate), and either Party may assign or otherwise transfer this Agreement without the other Party's consent in connection with the transfer or sale to a Third Party of all or substantially all of the business or assets of such Party relating to the Compound or any Licensed Product whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets, or otherwise. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be null and void.
- (b) Notwithstanding anything to the contrary in Section 17.5(a) or elsewhere in this Agreement, Mirati may assign to a Third Party its right to receive all of the milestone payments and the royalty payments owed under Article 9 (such assignment, a "Securitization Transaction") [\*\*\*]. Further, in connection with a contemplated Securitization Transaction, Mirati may disclose to such Third Party the terms of this Agreement and the royalty reports contemplated under Section 10.1, [\*\*\*] to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (provided that such Third Party is under obligations of confidentiality and non-use with respect to such Confidential Information that are no less stringent than the terms of Article 12), and to allow such Third Party to exercise its rights under this Section 17.5(b). As part of any consummated Securitization Transaction, Mirati may assign, [\*\*\*], its right to receive the royalty reports and to conduct audits under Section 10.1 and Section 10.5 to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such Sections; provided that after such assignment Mirati shall have no further right to receive the royalty reports or to conduct audits under Section 10.1 and Section 10.5.

(c) **Change of Control of a Party**. Notwithstanding anything to the contrary herein, (i) no Patents, Know-How or other intellectual property rights Controlled by an acquiror or successor in a Change of Control of either Party ("**Acquiror**") or any of its Affiliates (as such determination of affiliation is made immediately prior to such Change of Control) will be deemed Controlled by a Party for purposes of this Agreement after such Change of Control and (ii) with respect to the Party undergoing a Change of Control, no compounds, products or other assets or subject matter of an Acquiror or any of its Affiliates (as such determination of affiliation is made immediately prior to such Change of Control), including the items listed in clause (i) above, will be subject to the terms of this Agreement, including Section 2.7 so long as such Acquiror Segregates any Competitive Product until the expiration of such Party's exclusivity obligations in Section 2.7.

**17.6 Performance by Affiliates**. Each Party may discharge any obligations (other than the payment obligations set forth under Article 9) and exercise any right hereunder through any of its Affiliates (for so long as such Person remains an Affiliate), without notice to and without consent from, the other Party, 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.

**17.7 No Third Party Beneficiaries**. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except for the persons expressly entitled to indemnification as provided in Article 14.

17.8 Severability. If for any reason any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect and the Parties will in such an instance use their best efforts to replace the invalid, illegal, or unenforceable provision(s) with valid, legal, and enforceable provision(s) that implement the purposes of this Agreement.

**17.9 Notices**. Any notice to be given under this Agreement must be in writing and delivered either in person, by air mail (postage prepaid) requiring return receipt, or by a recognized overnight courier, to the Party to be notified at its address(es) given below, or at any other address such Party may designate by written notice to the other in accordance with this Section 17.9. Notice shall be deemed sufficiently given for all purposes upon the earliest of the date of actual receipt if personally delivered; if air mailed, [\*\*\*] after the date of postmark; or if delivered by overnight courier, the next Business Day.

If to Mirati, notices must be addressed to:

Mirati Therapeutics, Inc. 3545 Cray Court San Diego, CA 92121 USA Attention: Chief Executive Officer Tel: [\*\*\*]

-76-

With a copy (which shall not constitute notice) to:

Mirati Therapeutics, Inc. 3545 Cray Court San Diego, CA 92121 USA Attention: General Counsel and Corporate Secretary Tel: [\*\*\*]

If to Licensee, notices must be addressed to:

Zai Lab (Hong Kong) Limited Room 2301, 23/F, Island Place Tower 510 King's Road, North Point Hong Kong Attention: Chief Executive Officer

### With copies to:

F. Ty Edmondson Chief Legal Officer Zai Lab Limited 314 Main Street, 4<sup>th</sup> Floor Cambridge, MA 02142 [\*\*\*] + [\*\*\*]

17.10 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control including acts of God, fire, flood, explosion, earthquake, pandemic illness, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the nonperforming Party has not caused such event(s) to occur and uses reasonable efforts to remove the condition. The nonperforming Party shall notify the other Party of a failure or delay in performance due to force majeure event within [\*\*\*] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

-77-

17.11 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all sections, subsections, and paragraphs in such Article, references to any section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means "including without limitation", and shall not be deemed to limit the generality or breadth of any words or phrase preceding such word. The word "or" means "and/or" unless the context dictates otherwise because the subjects of the conjunction are mutually exclusive. The words "herein", "hereof", and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular section or other subdivision. All references to days in this Agreement shall mean calendar days, unless otherwise specified. All references to "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all reports, communications, notices required or permitted to be given hereunder, and all written, electronic, oral, or other communications between the Parties regarding this Agreement shall be in the English language or include an English translation, if applica

**17.12 Counterparts; Electronic or Facsimile Signatures**. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically and upon such delivery such electronic signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

17.13 Exhibits and Schedules. All exhibits or schedules referred to in this Agreement are attached hereto and incorporated herein by this reference.

**{SIGNATURE PAGE FOLLOWS}** 

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed and entered into by their duly authorized representatives as of the Effective Date.

### MIRATI THERAPEUTICS, INC.

By:	/s/ Charles M. Baum
N	Charles M. Paum, MD. DhD.

Title: CEO

## ZAI LAB (HONG KONG) LIMITED

By:	/s/ Samantha Du
Name:	Samantha Du
Title:	CEO



EXHIBIT 1.41

# COMPOUND STRUCTURE

[\*\*\*]

# LICENSED PATENTS

[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]

# **TARGET**

[\*\*\*]

## **UPSTREAM AGREEMENT**

[\*\*\*]

## **CLINICAL DEVELOPMENT PLAN**

[\*\*\*]

## **EXISTING GLOBAL STUDIES**

- KRYSTAL-010: A randomized Phase 3 study of adagrasib in combination with cetuximab versus chemotherapy in second-line colorectal cancer (CRC) patients with KRAS G12C mutations
- KRYSTAL-012: A randomized Phase 3 study of adagrasib versus docetaxel in second-line non-small cell lung cancer (NSCLC) patients with KRAS G12C mutations
- [\*\*\*]
- [\*\*\*]
- [\*\*\*]
- [\*\*\*]

# JOINT PRESS RELEASE

[<u>\*\*\*</u>]

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.

### COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement ("**Agreement**"), effective as of June 15, 2021 (the "**Effective Date**"), is entered into by and between MacroGenics, Inc., a Delaware corporation with a place of business at 9704 Medical Center Drive, Rockville, MD 20850 ("**MacroGenics**"), and Zai Lab US LLC, a limited liability company organized under the laws of the State of Delaware, the United States, with a place of business at 1440 O'Brien Drive, Suite C, Menlo Park, CA 94025 ("**Zai**"). MacroGenics and Zai may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

#### RECITALS

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

WHEREAS, Zai has expertise in the research, development and commercialization of pharmaceutical products;

**WHEREAS,** Zai and MacroGenics desire to enter into a collaboration for the development of certain bi-specific antibodies based on MacroGenics' proprietary DART® and TRIDENT® platforms, and if approved for commercialization, the commercialization of such bi-specific antibodies in the Territory (as defined below), pursuant to the terms and conditions set forth in this Agreement;

WHEREAS, MacroGenics desires to grant to Zai, and Zai desires to receive, an exclusive license to research, develop, manufacture and commercialize bi-specific antibodies based on MacroGenics' proprietary DART® and TRIDENT® platforms in the Field in the Territory, pursuant to the terms and conditions set forth in this Agreement; and

WHEREAS, MacroGenics desires to grant to Zai, and Zai desires to receive, an option to convert a royalty arrangement into a profit and loss sharing arranging with respect to certain bi-specific antibody-based product(s) on a worldwide basis, pursuant to the terms and conditions set forth in this Agreement.

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

### **AGREEMENT**

- 1. **DEFINITIONS.** Unless specifically set forth to the contrary herein, the following capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth below:
- 1.1 "[\*\*\*] **Molecule**" means a therapeutic bi-specific molecule which binds to [\*\*\*] and CD3 and is generated from MacroGenics' proprietary DART or TRIDENT platforms.
  - 1.2 "[\*\*\*] **Opt-In Territory**" means the (a) [\*\*\*] Territory; (b) the countries, regions and territories of [\*\*\*]; and (c) Europe.
  - 1.3 "[\*\*\*] Profit Share Option Payment" means (a) eighty-five million US Dollars (\$85,000,000) [\*\*\*].
  - 1.4 "[\*\*\*] **Product**" means a product that incorporates a [\*\*\*] Molecule as an active ingredient.

- 1.5 "[\*\*\*] **Profit Share Option**" has the meaning set forth in Section 5.1(e).
- 1.6 "[\*\*\*] **Research Costs**" has the meaning set forth in Section 4.2(c)(i).
- 1.7 "[\*\*\*] **Territory**" means Greater China, Japan and Korea.
- 1.8 "[\*\*\*] **Program**" means the program of activities conducted by the Parties under this Agreement for the Development and Commercialization of the [\*\*\*] Molecules and [\*\*\*] Products.
- 1.9 "Accounting Standards" means (a) with respect to MacroGenics, U.S. generally accepted accounting principles ("GAAP"), as consistently applied, and (b) with respect to Zai, International Financial Reporting Standards ("IFRS"), as consistently applied.
  - 1.10 "Acting Improperly" has the meaning set forth in Section 7.3(b)(i).
- 1.11 "Adverse Event" means any adverse medical occurrence in a patient or clinical investigation subject to whom a Licensed Molecule or Product is administered and which could but does not necessarily have a causal relationship with such Licensed Molecule or Product, including any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the administration of such Licensed Molecule or Product, whether or not considered related to such administration.
- 1.12 "Affiliate" means with respect to any Party, any person or entity controlling, controlled by or under common control with such Party. For purposes of this Section 1.12, "control" means (a) in the case of a corporate entity, direct or indirect ownership of at least fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity and (b) in the case of an entity that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.
- 1.13 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.
  - 1.14 "[\*\*\*]" means [\*\*\*].
- 1.15 "Applicable Laws and Regulations" means all international, national, federal, state, regional, provincial, municipal and local government laws, rules, and regulations that apply to either Party or to the conduct of any Development, Manufacturing or Commercialization activities under this Agreement including cGMP, GCP, GBPS, and the laws, rules and regulations of the ICH, the United States and any country or Region in the applicable Territory, each as may be then in effect, as applicable and amended from time to time.
- 1.16 "**Available**" shall mean, with respect to a Target selected by a Party in a written notice pursuant to Section 4.1(a) or Section 4.1(b), [\*\*\*].

- 1.17 "Biosimilar Product" means, with respect to a Product sold in a country or Region, a product that: (a) is marketed by a Third Party that has not obtained the rights to such product as a Sublicensee or distributor of, or through any other contractual relationship with, either Party or any of its Affiliates or Sublicensees; and (b)(i) contains the same or similar amino acid sequence as the applicable Product, or (ii) has been granted Regulatory Approval as a biosimilar or interchangeable biological product by the applicable Regulatory Authority according to a biosimilar regulatory pathway that is materially equivalent to that of Section 351(k) of the US Public Health Service Act (42 U.S.C. § 262(k)), as may be amended, or any subsequent or superseding law, statute or regulation.
- 1.18 "BLA" means a Biologics License Application or New Drug Application ("NDA") filed with the FDA for marketing approval of a Product or any successor applications or procedures, and all supplements and amendments that may be filed with respect to the foregoing, or similar filings with applicable Regulatory Authorities (including the NMPA), for approval to commercially market, import and sell a Product. The term BLA shall exclude pricing and reimbursement approvals.
- 1.19 **"Business Day"** means a day on which banking institutions in Washington, DC, USA, Boston, MA, USA, Hong Kong, and Shanghai, PRC are open for business, excluding any Saturday or Sunday.
- 1.20 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
  - 1.21 "Calendar Year" means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.
- 1.22 "cGMP" means current Good Manufacturing Practices as set forth in the FDCA and the Public Health Service Act (the "PHS Act"), and in regulations at 21 C.F.R. Parts 210, 211 and 600, as in effect at the time when any Product is being manufactured for clinical development or commercial use, when any Product is being sold or when any clinical trial regarding a Product is being conducted, provided, and to the extent applicable to such clinical trial, as such regulations are interpreted and enforced by the FDA, including as set forth in applicable guidance documents issued by the FDA, and in accordance with applicable, generally accepted industry standards, and the equivalent legal requirements in other applicable jurisdictions, all as the same may be amended from time to time.
- 1.23 "[\*\*\*]" means a therapeutic bi-specific molecule which (a) binds to CD3 and [\*\*\*]; (b) is generated from MacroGenics' proprietary DART or TRIDENT platform; and (c)[\*\*\*].
  - 1.24 "[\*\*\*]" means a product that incorporates a [\*\*\*] as an active ingredient.
- 1.25 "[\*\*\*]" means the program of activities conducted by the Parties under this Agreement for the Development, Manufacture and Commercialization of the [\*\*\*] and [\*\*\*].
  - 1.26 "Clinical Data" means all data generated or arising from the conduct of a Clinical Trial under this Agreement.
- 1.27 "Clinical Trial" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Phase IV Clinical Trial or Registration Trial, as applicable.

- 1.28 "CMC" means Chemistry Manufacturing and Controls.
- 1.29 **"CMO"** means a contract manufacturing organization.
- 1.30 "Co-Commercialization Plan" means a written Commercialization plan intended to support Commercialization of [\*\*\*] Molecules and [\*\*\*] Products after the Opt-In in the Field worldwide, as may be updated and amended periodically in form and substance approved by the JSC in accordance with Section 7.1(c).
- 1.31 "Co-Development Plan" means a written Development plan intended to support Development and Regulatory Approval of [\*\*\*] Molecules and [\*\*\*] Products after the Opt-In in the Field worldwide, as may be updated and amended periodically in form and substance approved by the JSC in accordance with Section 5.1(a)(ii).
  - 1.32 "Collaboration Molecule" means each of the [\*\*\*] Molecule and the MGNX Option Molecule.
  - 1.33 "Collaboration Product" means each of the [\*\*\*] Product and the MGNX Option Product.
- 1.34 "Collaboration Program" means each program of activities conducted by the Parties under this Agreement for the Development and Commercialization of the Collaboration Molecules and Collaboration Products.
- 1.35 "Collaboration Territory" means (a) with respect to the [\*\*\*] Molecule and the [\*\*\*] Product before the Opt-In, the [\*\*\*] Territory, (b) with respect to the [\*\*\*] Molecule and the [\*\*\*] Product after the Opt-In, the [\*\*\*] Opt-In Territory, and (b) with respect to the MGNX Option Molecule and MGNX Option Product, the MGNX Option Territory.
- 1.36 "Combination Product" mean (a) any single product comprising both (i) a Licensed Molecule and (ii) one or more other therapies or pharmaceutically active compounds or substances that is not a Licensed Molecule; (b) any sale of a Product with one or more other therapies or products for a single invoice price; or (c) any sale of a Product as part of a bundle with one or more other therapies, products or services (i.e., where a Product and such other therapies, products or services are sold for a single invoice price or where a discount, rebate or other amount that reduces the price of a Product is provided in exchange for, or otherwise conditioned upon, the purchase of such other therapies, products or services), to the extent not described in clause (a) or (b). The Licensed Molecule portion of any Combination Product shall be deemed the "Licensed Component" and the other portion of such Combination Product shall be deemed a Product hereunder.
- 1.37 "Commercialization" or "Commercialize" means activities taken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, sales force recruitment, sale, offering for sale, and distribution of a pharmaceutical product and post-launch medical activities, including: (a) distribution, storage, transportation, importation and exportation; (b) strategic marketing, sales force, detailing, advertising, and market and product support; (c) medical education and liaison and any Phase IV Clinical Trials unless required as a condition for approval, to the extent permitted by this Agreement; (d) all customer support and product distribution, invoicing and sales activities; and (e) all post-approval regulatory activities, including those necessary to maintain Regulatory Approvals. For clarity, "Commercialization" or "Commercialize" does not include any related Manufacturing activities.

- 1.38 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective of such Party under similar circumstances, it being understood and agreed that with respect to the Commercialization of Licensed Molecule and Products, such efforts shall be similar to those efforts and resources commonly used by a pharmaceutical or biopharmaceutical company, as applicable, of comparable size and resources to such Party in the applicable country or Region for a similar biological or pharmaceutical product owned by it or to which it has exclusive-rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, other medical and clinical considerations, anticipated or approved labeling, the competitiveness of alternative products in the marketplace, market exclusivity, market potential, financial return, the patent and other proprietary position of the product, and the likelihood of Regulatory Approval given the regulatory structure involved, regulatory environments and other technical, legal, scientific, medical or commercial factors that such a company would reasonably deem to be relevant.
- 1.39 "Confidential Information" means any and all non-public scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information and data, in any tangible or intangible form.
- 1.40 "Control", "Controls" or "Controlled by" means, with respect to any item of or right under Patents or Know-How, the extent of the ability of a Party (whether through ownership or license, other than pursuant to this Agreement) to grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party or creating a payment obligation upon such Party, unless the other Party agrees to bear the applicable Triggered Third Party Payment pursuant to Section 3.8 or otherwise.
- 1.41 "Cover" means, with respect to a product, technology, process or method, that, in the absence of possession of the right (by ownership, license or otherwise) under a Valid Claim, the practice or exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).
  - 1.42 "CRO" means a clinical research organization.
- 1.43 "**Data Exclusivity Period**" means the period, if any, during which the applicable Regulatory Authority (including the FDA and the NMPA) prohibits reference, without the consent of the owner of a BLA, to the clinical and other data that is contained in such BLA and that is not published or publicly available outside of such BLA.
  - 1.44 "**Deadlock**" has the meaning set forth in Section 2.2(c).
- 1.45 **"Depot Subcontractor"** means any subcontractor engaged by Zai to store, distribute, handle or otherwise possess Licensed Molecule or Product that was provided by MacroGenics to supply a Clinical Trial.
- 1.46 "**Develop"**, "**Development**" or "**Developing**" means research, discovery, and preclinical and clinical drug or biological development activities, including toxicology, formulation, statistical analysis, preclinical and Clinical Trials (but excluding Phase IV Clinical Trials unless required as a condition for Regulatory Approval) and regulatory affairs, approval and registration, in each case, of a Licensed Molecule or a Product in the Field. For clarity, "**Development**" or "**Developing**" does not include any related Manufacturing activities.

- 1.47 "**Development Costs**" means all costs incurred in connection with any Development activities, including (a) site investigator fees and monitoring costs, (b) contract research organization and site management organization fees, (c) data management costs, (d) safety surveillance and reporting costs (e) patient costs, (f) drug comparator and standard-of-care drug costs, (g) drug administration costs, (h) development, validation, and procurement costs related to any companion diagnostic product, and (i) central and local lab costs.
  - 1.48 "**Development Plan Activities**" has the meaning set forth in Section 5.1(c)(i).
- 1.49 "**Dispute**" means any dispute, claim, or controversy (other than matters that are within the decision-making authority of a Party pursuant to Section 2.2(c), or are expressly stated herein to require the consent of both Parties) arising from or related to this Agreement or to the interpretation, application, breach, termination, or validity of this Agreement, including any claim of inducement of this Agreement by fraud or otherwise.
  - 1.50 "EMA" means the European Medicines Agency, or any successor agency thereto.
- 1.51 **"Europe"** means all countries that are officially recognized as member states of the European Union as of the Effective Date, the United Kingdom, Switzerland, Iceland, Norway and Liechtenstein.
- 1.52 "Executive Officer" means, with respect to either Party, the Chief Executive Officer of such Party (or his or her designee who will be a senior executive directly reporting to the Chief Executive Officer of such Party and with authority to bind such Party).
- 1.53 **"Failure to Supply**" means the failure of MacroGenics or its Affiliates to supply Zai, its Affiliates or Sublicensees with [\*\*\*]percent ([\*\*\*]%) [\*\*\*] be supplied to Zai, its Affiliates or Sublicensees pursuant to a supply agreement between the Parties[\*\*\*].
  - 1.54 "FDA" means the United States Food and Drug Administration, or any successor agency thereto.
  - 1.55 "FDCA" means the Federal Food, Drug and Cosmetic Act, as amended.
- 1.56 "Field" means the treatment, prevention and diagnosis of all Indications; provided that, in the case of any Licensed Molecule or Product Covered by a Patent or other intellectual property right licensed in one or more MacroGenics Third Party Agreement or Zai Third Party Agreement, "Field" in which such Patent or other intellectual property right may be practiced with respect to such Licensed Molecule or Product shall be limited to the minimum extent necessary to comply with the terms of such MacroGenics Third Party Agreement or Zai Third Party Agreement for so long as such limitation is necessary to avoid a breach of the MacroGenics Third Party Agreement or Zai Third Party Agreement.
- 1.57 "**First Commercial Sale**" means, with respect to any Product, the first sale to a Third Party for end use or consumption of such Product in a country or Region after Regulatory Approval has been granted by the Regulatory Agency for the Product in such country or Region.
- 1.58 "FTE" means, with respect to a Party, [\*\*\*] hours of work devoted to or in direct support of specified activities under this Agreement, conducted by one or more qualified employees of such Party or its Affiliate. For clarity, any individual contributing less than [\*\*\*] hours per Calendar Year (or equivalent pro-rata portion thereof for the period beginning on the Effective Date and ending on the last day of the first Calendar Year) shall be deemed a fraction of an FTE on a pro-rata basis.

- 1.59 "FTE Cost" means, with respect to any period and a Party or its Affiliate, the FTE Rate multiplied by the number of FTEs expended by such Party or its Affiliate during such period; provided that a Party shall not charge the other Party more than once for any FTE Cost if such FTE Cost is already included as a component of other expenses payable to such charging Party under this Agreement.
- 1.60 "FTE Rate" means a rate of [\*\*\*] US Dollars (US\$[\*\*\*]) per FTE per Calendar Year, pro-rated for the period beginning on the Effective Date and ending on the last day of the first Calendar Year; provided, however, that such rate shall be increased or decreased annually beginning on [\*\*\*], by the applicable CPI Adjustment.
- 1.61 "Fully-Burdened Manufacturing Cost" means, with respect to a particular Collaboration Molecule or Collaboration Product, whether as active pharmaceutical ingredient or finished form, supplied by a Party, [\*\*\*] percent ([\*\*\*]%) of either: (i) if Manufactured by a Third Party, [\*\*\*] for the Manufacture of such Collaboration Molecule or Collaboration Product without mark-up (for clarity, [\*\*\*]); or (ii), if Manufactured by such Party or its Affiliate, [\*\*\*] and applicable FTE costs, and in accordance with such Party's Accounting Standards, including the following incurred by or on behalf of such Party or its Affiliate and reasonably allocated to such Collaboration Molecule or Collaboration Product:

[\*\*\*]

- 1.62 **"Future Third Party Agreement"** has the meaning set forth in Section 3.8(a).
- 1.63 "Gatekeeper" has the meaning set forth in Section 4.1(c).

- 1.64 "GBPS" means the General Biological Products Standards as set forth in 21 C.F.R. Part 610, to the extent applicable.
- 1.65 "GCP" or "Good Clinical Practices" means current Good Clinical Practices as set forth in the Applicable Laws and Regulations, such as FDCA and the PHS Act and regulations set forth at 21 C.F.R. Part 312, as well as (but not limited to) the requirements set forth in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and Commission Directive 2005/28/EC of 8 April 2005, to the extent applicable to a clinical trial regarding any Product, as such obligations are interpreted and enforced by the applicable Regulatory Authority (e.g., FDA and Member States of the European Union), and as interpreted under prevailing industry standards, including standards of medical ethics, applicable guidance documents issued by the FDA and any other Regulatory Authority, including ICH GCP, the informed consent requirements set forth in 21 C.F.R. Part 50 and the equivalent legal requirements in other applicable jurisdictions, as the same may be amended from time to time.
  - 1.66 **"Global Branding Strategy"** has the meaning set forth in Section 7.1(d).
- 1.67 "Global Development Plan" means a written Development plan intended to support Development and Regulatory Approval of Collaboration Molecules and Collaboration Products (other than [\*\*\*] Molecules and [\*\*\*] Products after the Opt-In) in the Field both within the Collaboration Territory and outside of the Collaboration Territory, as may be updated and amended periodically in form and substance approved by the JSC in accordance with Section 5.1(a).
  - 1.68 **"Global Product Brand"** has the meaning set forth in Section 7.1(d).
- 1.69 "GLP" or "Good Laboratory Practices" means the recognized rules governing the conduct of non-clinical safety studies and ensuring the quality, integrity and reliability of study data as set forth in Applicable Laws and Regulations, such as 21 C.F.R. Part 58, and the equivalent legal requirements in other applicable jurisdictions, as the same may be amended from time to time.
- 1.70 "Government Official" means any Person employed by or acting on behalf of a government, government-owned or -controlled entity or public international organization; any political party, party official or candidate; any Person who holds or performs the duties of an appointment, office or position created by custom or convention; and any Person who holds himself out to be the authorized intermediary of any of the foregoing.
  - 1.71 "Greater China" means the PRC, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan.
  - 1.72 "ICC Rules" has the meaning set forth in Section 15.3.
  - 1.73 "ICH" means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
  - 1.74 "**In-License Party**" has the meaning set forth in Section 3.8(a).
- 1.75 **"IND"** means an Investigational New Drug application, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

- 1.76 "Indemnifying Party" means the Party that is obligated to indemnify the Indemnitee under Article 13.
- 1.77 **"Indemnitee"** means either the Zai Indemnitee or the MacroGenics Indemnitee, as applicable.
- 1.78 "**Indication**" means a separate and distinct disease, disorder or medical condition in humans or non-human animals with different tissue origin classified as a three-character category in International Statistical Classification of Diseases and Related Health Problems (or "**ICD**") 10-CM published by the World Health Organization, for which a Product can be used to diagnose, treat or prevent, which use is the subject of a separate Regulatory Filing to support a Regulatory Approval for such use. Notwithstanding the foregoing, [\*\*\*].
- 1.79 **"Initiation"** means, with respect to a clinical trial of a Product, the first dosing of such Product in the first subject in such clinical trial.
  - 1.80 "[\*\*\*]" shall mean an [\*\*\*] conducted by a Party or its Affiliates that (a) [\*\*\*], and (b) has a [\*\*\*].
  - 1.81 "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 2.4(a).
  - 1.82 "Joint Research and Development Committee" or "JRDC" has the meaning set forth in Section 2.3(a).
  - 1.83 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 2.2(a).
- 1.84 "**Jointly Owned IP**" means, collectively, all Know-How and inventions, whether patentable or not, that are (a) conceived or reduced to practice in the course of conducting activities under this Agreement and (b) jointly owned by the Parties pursuant to this Agreement, together with all intellectual property rights therein. For clarity, Jointly Owned IP shall include the Research IP.
  - 1.85 "Jointly Owned Patents" has the meaning set forth in Section 14.2(b)(iv).
- 1.86 "Know-How" means (a) any proprietary scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data, and (b) any proprietary biological, chemical or physical materials.
  - 1.87 "License-Only Molecule" means [\*\*\*].

- 1.88 "License-Only Product" means [\*\*\*].
- 1.89 "License-Only Program" means each program of activities conducted by the Parties under this Agreement for the Development, Manufacture and Commercialization of the License-Only Molecules and License-Only Products.
  - 1.90 "License-Only Territory" means worldwide.
  - 1.91 "Licensed Molecule" means each of the [\*\*\*] Molecule, the MGNX Option Molecule, the [\*\*\*] and the Zai Selection Molecule.
  - 1.92 "Losses" has the meaning set forth in Section 13.1.
  - 1.93 "MacroGenics Audit" has the meaning set forth in Section 7.3(c)(vi).
  - 1.94 "MacroGenics Improvement Plan" has the meaning set forth in Section 7.3(c)(iii)(1).
  - 1.95 "MacroGenics Improvement IP" has the meaning set forth in Section 14.1(c).
  - 1.96 "MacroGenics Indemnitee" has the meaning set forth in Section 13.1.
- 1.97 "MacroGenics Manufacturing In-Licenses" means agreements executed prior to the Effective Date by MacroGenics with Third Parties to the extent such agreements grant MacroGenics the right to use Patents and/or Know-How controlled by such Third Party for Manufacturing any Licensed Molecule or Product.
- 1.98 "MacroGenics Licensed Know-How" means any Know-How (excluding any Patents) that is (a) Controlled by MacroGenics or any of its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or reasonably useful for Zai to Develop, Manufacture and Commercialize Licensed Molecules and Products in accordance with this Agreement, including MacroGenics' interest in any Know-How with the Jointly Owned IP or MacroGenics Improvement IP; provided that, MacroGenics Licensed Know-How shall exclude any Know-How [\*\*\*].
- 1.99 "MacroGenics Licensed Patent" means any Patent that is (a) Controlled by MacroGenics or any of its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or reasonably useful for Zai to Develop, Manufacture and Commercialize Licensed Molecules and Products in accordance with this Agreement, including any MacroGenics' interest in any Patent within the Jointly Owned IP or MacroGenics Improvement IP; provided that, MacroGenics Licensed Patent shall exclude [\*\*\*]. The MacroGenics Licensed Patents Controlled by MacroGenics or any of its Affiliates as of the Effective Date are listed in Exhibit A attached hereto.
  - 1.100 "MacroGenics Licensed Technology" means the MacroGenics Licensed Patents and the MacroGenics Licensed Know-How.
  - 1.101 "MacroGenics Licensed Trademarks" means any and all Trademarks [\*\*\*].

- 1.102 "MacroGenics Platform" means MacroGenics' proprietary DART, TRIDENT and other MacroGenics' proprietary platforms that are used to generate, evaluate and select bi-specific molecules comprising one or more covalently-bonded diabody domains including, but not limited to those disclosed in the Patents listed in Exhibit A, which may be updated from time to time by MacroGenics.
- 1.103 "MacroGenics Product-Specific Patent" means any MacroGenics Licensed Patent that solely and exclusively Covers the (a) composition of matter of a License-Only Molecule or License-Only Product or (b) the method of using such License-Only Molecule or License-Only Product as a therapeutic, prophylactic or diagnostic, in each case (a)-(b) in the applicable Territory, and does not also Cover the composition of matter of, or the method of using, any other product that is not a License-Only Molecule or License-Only Product. For clarity, MacroGenics Product-Specific Patent shall exclude [\*\*\*].
  - 1.104 "MacroGenics Representatives" has the meaning set forth in Section 7.3(c).
- 1.105 "MacroGenics Third Party Agreements" means any agreement between MacroGenics and its Third Party licensor that is entered into after the Effective Date and for which Zai elects to obtain a sublicense under Section 3.8.
  - 1.106 "Major European Country" means the [\*\*\*].
- 1.107 "Major Safety Issue" means, with respect to a Product, any of the following: (a) an adverse safety profile of a Product, or receipt or generation by a Party of any safety, tolerability or other data, indicating, as measured by safety and efficacy evaluation criteria and methodology customarily used by a majority of clinicians conducting studies on similar products for the same or substantially the same Indication as being pursued by such Party for such Product in the applicable country or Region, that such Product has or is reasonably likely to have serious risks for medical applications in humans to require a recall, withdrawal, or similar action; or (b) any notice, information or correspondence received by a Party from [\*\*\*\*], or any action taken by any such Regulatory Authority, in each case, indicates that Regulatory Approval is reasonably unlikely to be granted therefor or, if already granted, the Regulatory Approval therefor would reasonably likely be revoked, or causes the Regulatory Approval therefor not to be granted or, if already granted, to be revoked.
- 1.108 "Manufacture" or "Manufacturing" means all operations involved in the manufacturing (including process development activities, quality assurance and quality control testing (including test method development and in-process, release and stability testing, if applicable), storage, releasing, packaging and importation of a Licensed Molecule or a Product) to supply Licensed Molecule and Product for Development and Commercialization under this Agreement. For purposes of clarification, "Manufacturing" is not included in Development or Commercialization.
- 1.109 "**Marketing Authorization Application**" or "**MAA**" means a New Drug Application ("**NDA**") or any other application to the appropriate Regulatory Authority for approval to market a Product, but excluding pricing approvals.
- 1.110 "MGNX Option Molecule" means a therapeutic bi-specific molecule which (a) binds to (i) a Target selected by MacroGenics pursuant to Section 4.1(a) and (ii) CD47; (b) is generated from MacroGenics' proprietary DART or TRIDENT platform; and (c) comprises a sequence that is the same as or similar to a sequence provided by Zai and encodes a CD47 binding moiety.

- 1.111 "MGNX Option Product" means a product that incorporates a MGNX Option Molecule as an active ingredient.
- 1.112 **"MGNX Option Program"** means the program of activities conducted by the Parties under this Agreement for the Development and Commercialization of the MGNX Option Molecules and MGNX Option Products.
  - 1.113 "MGNX Option Territory" means Greater China, Japan and Korea.
  - 1.114 "NMPA" means National Medical Products Administration, or any successor agency thereto.
- 1.115 "**Net Sales**" means the gross amount invoiced for Products sold by Zai or its Related Parties directly to Third Parties which are not Related Parties after deducting, if not previously deducted, from the amount invoiced, the following, in each case to the extent included in the gross invoice price:
- (a) reasonable trade, quantity and cash discounts and rebates (including wholesaler inventory management fees), chargebacks, and retroactive price reductions or allowances actually allowed or granted from the billed amount;
- (b) credits or allowances actually granted upon claims, rejections or returns of such sales of Products, including recalls and amounts credited or repaid because of retroactive price reductions specifically identifiable to the Product;
- (c) bad debts written off which are attributable to sales of Products (subject to cap equal to [\*\*\*] percent ([\*\*\*]%) of gross amount invoiced for Products sold);
- (d) taxes imposed on the production, sale, import, delivery or use of the Product (including sales, use, excise or value added taxes but excluding income taxes), duties or other governmental charges (including charges for product testing required for importation) levied on or measured by the billing amount when included in billing, as adjusted for rebates and refunds; and
- (e) costs actually incurred for distribution or importing (including transportation, freight and insurance, and warehousing in the Territory).

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

If Zai or any of its Related Parties sells a Product as a Licensed Component of a Combination Product in a country or Region 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 such country or Region during such Calendar Quarter (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 in such country or Region during such Calendar Quarter (calculated by determining the Net Sales of such Other Component(s) sold during such Calendar Quarter by applying the definition of Net Sales set forth herein as if it applied to sales of such Other Component(s) and dividing such Net Sales by the number of units of such Other Component(s) sold during such Calendar Quarter).

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

In the event that no separate sales of the Licensed Component or any Other Component(s) included in a Combination Product are made by Zai or its Related Parties, during a Calendar Quarter in which such Combination Product is sold, the average Net Sales per unit sold shall be determined by mutual agreement of the Parties in good faith based on the relative economic value contributions of the Licensed Component and each of the Other Component(s) included in such Combination Product.

- 1.116 "Opt-In" means Zai's exercise of the [\*\*\*] Profit Share Option in accordance with Section 5.1(e).
- 1.117 "Patents" means (a) all patents and patent applications in any country, region (including Region) or supranational jurisdiction and (b) any provisionals, substitutions, divisions, continuations, continuations in part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like, of any such patents or patent applications.
- 1.118 **"Patent Prosecution"** means the responsibility for (a) preparing, filing, prosecuting, and pursuing registration of, applications (of all types) for any Patent (b) for maintaining any Patent, and (c) for managing any interference or opposition proceeding relating to the foregoing.
  - 1.119 "Payment Taxes" means VAT and income taxes withholding required under Applicable Law to be paid to a tax authority.
  - 1.120 "**Permitted Subcontractor**" has the meaning set forth in Section 5.1(f)(i).
- 1.121 **"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.
- 1.122 "Phase I Clinical Trial" means a human clinical trial, or the relevant portion of such trial, of a Product in patients in any country (including country or Region) in accordance with GCP that generally provides for the first introduction into humans of a Product and intended to determine safety, metabolism and pharmacokinetic properties and clinical pharmacology of a Product in health patients, or that would otherwise satisfy the requirements of Applicable Laws and Regulations for such country in which such human clinical trial is conducted, such as 21 C.F.R. § 312.21(a), relating to human clinical trials conducted in the United States, or any successor regulation thereto or foreign equivalents.

- 1.123 "Phase II Clinical Trial" means a human clinical trial, or the relevant portion of such trial, conducted in patients with a Product, in accordance with GCP and intended to demonstrate efficacy and a level of safety in the particular Indication tested, as well as to obtain a preliminary Indication of the unit or daily dosage regimen required, or that would otherwise satisfy the requirements of Applicable Laws and Regulations of the country or Region in which such human clinical trial is conducted, such as 21 C.F.R. § 312.21(b), relating to human clinical trials conducted in the United States, or any successor regulation thereto or foreign equivalents. For clarity, a Phase I Clinical Trial with an expansion cohort of patients that meets the descriptions or otherwise satisfies the requirements in the foregoing shall be deemed a Phase II Clinical Trial.
- 1.124 **"Phase III Clinical Trial"** means a human clinical trial, or the relevant portion of such trial, in any country that is conducted in accordance with GCPs and the results of which are intended to be used as a pivotal study to establish both safety and efficacy of a Product as a basis for a BLA submitted to the FDA, the NMPA or the appropriate Regulatory Authority of such other country or Region, or that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(c), or any successor regulation thereto or foreign equivalents.
- 1.125 "**Phase IV Clinical Trial**" means a human clinical trial conducted after the Regulatory Approval of a Product in a country or Region, which trial is conducted (a) voluntarily to enhance scientific knowledge of such Product (e.g., for expansion of product labeling or dose optimization); or (b) conducted due to a request or requirement of a Regulatory Authority of a country or Region.
- 1.126 **"Plan"** means individually and collectively the Research Plans, Global Development Plans, Territory Specific Development Plans, Co-Development Plan and Co-Commercialization Plan.
- 1.127 "**POC Clinical Trial**" means one or more Clinical Trials in which patients are treated with the [\*\*\*] Product that has in aggregate either: (a) [\*\*\*], or (b) [\*\*\*].
  - 1.128 "POC Data Package" means [\*\*\*].
- 1.129 "PRC" means the People's Republic of China, which for purposes of this Agreement, excludes the Hong Kong Special Administrative Region, the Macau Special Administrative Region, and Taiwan.
  - 1.130 "Product" means each of the Collaboration Products and the License-Only Products.
  - 1.131 "**Program**" means a Collaboration Program or a License-Only Program.

- 1.132 "[\*\*\*]" means [\*\*\*].
- 1.133 "Region" means each of Hong Kong Special Administrative Region and Macau Special Administrative Region.
- 1.134 **"Registration Trial**" means the first clinical trial which is designed to support Regulatory Approval for the Product in a country or Region. Notwithstanding, any Phase III Clinical Trial shall be deemed a Registration Trial.
- 1.135 **"Regulatory Approval"** means a BLA approval from the relevant Regulatory Authority in a country or Region to market and sell a Product in such country or Region.
- 1.136 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the conduct of clinical trials or the manufacturing, marketing, reimbursement or pricing, as applicable, of a Product, including in the United States, the FDA and in the PRC, the NMPA, and any successor governmental authority having substantially the same function.
- 1.137 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including INDs, BLAs, NDAs, and Regulatory Approvals, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to a Product.
  - $1.138 \quad \hbox{``Related Party''} \ means, with \ respect to \ a \ Party, its \ Affiliates \ and \ Sublicensees.$
  - 1.139 "Requesting Party" has the meaning set forth in Section 10.7.
  - 1.140 "**Research IP**" has the meaning set forth in Section 14.1(f).
  - 1.141 "Research Plan" has the meaning set forth in Section 4.2(a).
  - 1.142 "Research Plan Activities" has the meaning set forth in Section 4.2(b).
  - 1.143 "**Research Term**" means [\*\*\*].
  - 1.144 "ROW" means all countries in the world except those in the [\*\*\*] Opt-In Territory.
- 1.145 "**Royalty Term**" means, on a Product-by-Product and country-by-country or Region-by- Region basis, the time period beginning on the First Commercial Sale of such Product in such country or Region and expiring on the latest of the following dates: (a) the twelfth (12<sup>th</sup>) anniversary of the date of First Commercial Sale of the Product in the applicable country or Region, (b) the expiration of the last-to-expire MacroGenics Licensed Patent having a Valid Claim Covering the composition, Manufacture, use, sale or importation of the Product in the applicable country or Region, or (c) the expiration of the last-to-expire Data Exclusivity Period for the Product in the applicable country or Region.

- 1.146 "Safety Data" means any data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities, including any "adverse events", "adverse drug reactions", and "unexpected adverse drug reactions" as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.
- 1.147 **"Sublicensee"** means a Third Party that is granted a sublicense under the licenses granted to a Party under this Agreement, as permitted herein.
  - 1.148 "**Target**" shall [\*\*\*].
  - 1.149 "**Term**" has the meaning set forth in Section 16.1.
- 1.150 **"Terminated Program"** means any Program that is terminated by a Party pursuant to Section 16.2, Section 16.3, Section 16.4, Section 16.5, Section 16.6 or Section 16.7.
  - 1.151 "[\*\*\*]" means each of (a) [\*\*\*], (b) [\*\*\*], (c) [\*\*\*], (d) [\*\*\*], (e) [\*\*\*], and (f) [\*\*\*] (a)-(e).
- 1.152 "**Territory**" means (a) with respect to the Collaboration Molecules and Collaboration Products, the applicable Collaboration Territory, and (b) with respect to the License-Only Molecules and License-Only Products, the License-Only Territory.
- 1.153 "**Territory-Specific Development Plan**" means a written plan for Development of the Collaboration Molecules and Collaboration Products (other than [\*\*\*] Molecules and [\*\*\*] Products after the Opt-In) in the Field in the applicable Collaboration Territory that is primarily intended to support Regulatory Approval of the Collaboration Product in such Collaboration Territory (and not outside such Collaboration Territory) and not otherwise included within the Global Development Plan, as may be updated and amended periodically in form and substance approved by the JSC in accordance with Section 5.1(a).
  - 1.154 "Third Party" means an entity other than (a) Zai and its Affiliates, and (b) MacroGenics and its Affiliates.
- 1.155 "**Trademark**" means all trade names, logos, common law trademarks and service marks, trademark and service mark registrations and applications throughout the world.
- 1.156 "**Trademark Prosecution**" means the responsibility for (a) preparing, filing, and seeking registration of, trademark applications (of all types) for any Trademark, (b) for maintaining any Trademark, and (c) for managing any interference or opposition proceeding relating to the foregoing.
- 1.157 "**Triggered Third Party Payment**" means, with respect to a Future Third Party Agreement for which a Party elects to obtain a sublicense under Section 3.8, [\*\*\*] percent ([\*\*\*]%) of any payments that the In-License Party would be obligated to pay the Third Party licensor of such Future Third Party Agreement as a result of the grant of a sublicense to the other Party, including all royalty payments, milestone payments, license maintenance (or similar payment) or sublicense payments payable by the In-License Party pursuant to such Future Third Party Agreement.

- 1.158 **"United States"** or **"US"** means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands.
  - 1.159 "US Dollars" means United States Dollars, the lawful currency of the US.
- 1.160 "Valid Claim" means a claim of: (a) an issued and unexpired Patent included within the MacroGenics Licensed Patents in a country or Region which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) a pending patent application that has been filed in good faith and that has not been cancelled, withdrawn, or abandoned and has not been pending for more than [\*\*\*] from the earliest priority date, provided that, if a claim ceases to be a Valid Claim by reason of the foregoing subclause (b), then such claim shall again be deemed a Valid Claim in the event such claim subsequently issues.
  - 1.161 "**Zai Audit**" has the meaning set forth in Section 7.3(b)(vi).
  - 1.162 "**Zai Improvement IP**" has the meaning set forth in Section 14.1(d).
  - 1.163 "**Zai Improvement Plan**" has the meaning set forth in Section 7.3(b)(iii)(1).
  - 1.164 "**Zai Indemnitees**" has the meaning set forth in Section 13.2.
  - 1.165 "Zai License-Only IP" has the meaning set forth in Section 14.1(e).
- 1.166 "Zai Licensed Know-How" means any Know-How (excluding any Patent) Controlled by Zai or any of its Affiliates as of the Effective Date or at any time during the Term that is necessary or reasonably useful for MacroGenics to (a) conduct the Development activities allocated to it under the applicable Research Plans or (b) Develop, Manufacture and Commercialize Collaboration Molecules and Collaboration Products in accordance with this Agreement, including Zai's interest in any Know-How with the Jointly Owned IP or Zai Improvement IP.
- 1.167 "Zai Licensed Patent" means any Patent Controlled by Zai or any of its Affiliates as of the Effective Date or at any time during the Term that is necessary or reasonably useful for MacroGenics to (a) conduct the Development activities allocated to it under the applicable Research Plans or (b) Develop, Manufacture and Commercialize Collaboration Molecules and Collaboration Products in accordance with this Agreement, including Zai's interest in any Patent with the Jointly Owned IP or Zai Improvement IP. [\*\*\*] and are Controlled by Zai or any of its Affiliates as of the Effective Date are listed in Exhibit C attached hereto.
  - 1.168 "Zai Licensed Technology" means the Zai Licensed Patents and the Zai Licensed Know-How.
  - 1.169 "**Zai Platform**" means [\*\*\*].

- 1.170 "Zai Product-Specific Patent" means [\*\*\*].
- 1.171 "**Zai Representatives**" has the meaning set forth in Section 7.3(b).
- 1.172 "**Zai Selection Molecule**" means [\*\*\*].
- 1.173 "Zai Selection Product" means a product that incorporates a Zai Selection Molecule as an active ingredient.
- 1.174 **"Zai Selection Program"** means the program of activities conducted by the Parties under this Agreement for the Development, Manufacture and Commercialization of the Zai Selection Molecules and Zai Selection Products.
- 1.175 **"Zai Third Party Agreements"** means any agreement between Zai and its Third Party licensor that is entered into after the Effective Date and for which MacroGenics elects to obtain a sublicense under Section 3.8.

# 2. OVERVIEW; GOVERNANCE

- 2.1 **Overview**. The Parties intend and have agreed to undertake the Development, Manufacturing and Commercialization activities under this Agreement, consisting of the following components:
  - (a) [\*\*\*] Collaboration Programs, pursuant to which
    - (i) the Parties will jointly conduct [\*\*\*] Development activities in accordance with the applicable Research Plans;
  - (ii) with respect to any [\*\*\*] the Parties will jointly conduct [\*\*\*] Development activities in accordance with the applicable Global Development Plan and Territory-Specific Development Plan[\*\*\*] will have the [\*\*\*] Development and Commercialization of [\*\*\*] MGNX Option Territory [\*\*\*] Development and Commercialization of [\*\*\*] MGNX Option Territory, in each case of (B) and (C), [\*\*\*] in the applicable Research Plan, Global Development Plan and Territory-Specific Development Plan;
  - (iii) with respect to any [\*\*\*] Molecule and [\*\*\*] Product [\*\*\*] the Parties will jointly conduct certain Development activities in accordance with the applicable Global Development Plan and Territory-Specific Development Plan [\*\*\*] Development and Commercialization of such [\*\*\*] Molecule and [\*\*\*] Product Development and Commercialization of such [\*\*\*] Molecule and [\*\*\*] Product [\*\*\*], in each case of (B) and (C), [\*\*\*] in the applicable Research Plan, Global Development Plan and Territory-Specific Development Plan; and

- (iv) with respect to any [\*\*\*] Molecule and [\*\*\*] Product [\*\*\*] the Parties will jointly Develop and Commercialize such [\*\*\*] Molecule and [\*\*\*] Product worldwide in accordance with the Co-Development Plan and Co-Commercialization Plan, [\*\*\*] Development and Commercialization of such [\*\*\*] Molecule and [\*\*\*] Product [\*\*\*] Development and Commercialization of such [\*\*\*] Molecule [\*\*\*], in each case of (B) and (C), [\*\*\*]Co-Development Plan and Co-Commercialization Plan; and
- (b) [\*\*\*] License-Only Programs, pursuant to which [\*\*\*] Development activities in accordance with the applicable Research Plans [\*\*\*] Zai will have the exclusive rights and be solely responsible for the Development, Manufacturing and Commercialization of License-Only Molecules and License-Only Products in the License-Only Territory.

# 2.2 **Joint Steering Committee**

- (a) **Membership**. The Parties hereby establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**"), to coordinate and oversee (i) the Parties' conduct of the Research Plan and subsequent conduct of each Collaboration Program and (ii) the Parties' conduct of the Research Plan of each License-Only Program during the applicable Research Term. For clarity, neither the JSC nor any other committee established pursuant to this Agreement shall have the right to oversee or have any decision making authority with respect to the Development, Manufacturing or Commercialization of any License-Only Program other than the Parties' conduct mentioned in (ii) above. The JSC shall consist of [\*\*\*] representatives [\*\*\*] shall designate [\*\*\*] of its representatives as the initial chairperson of the JSC. Thereafter, the role of chairperson shall alternate between MacroGenics and Zai representatives on a [\*\*\*]. Each Party may replace its appointed JSC representatives at any time upon reasonable written notice to the other Party. The initial representatives and chair of the JSC shall be established within [\*\*\*] after the Effective Date. The chair shall have the responsibility to call regular meetings, circulate meeting agendas at least [\*\*\*] prior to each regular JSC meeting, draft minutes for each JSC meeting and circulate such minutes for both Parties' written approval. The chair shall have no other authority or special voting power.
  - (b) **Responsibilities**. The responsibilities of the JSC shall be:
  - (i) to provide a forum by which the Parties may share information regarding the overall strategy for the Collaboration Programs;
  - (ii) to facilitate the exchange of information between the Parties with respect to the activities hereunder and to establish procedures for the efficient sharing of information necessary for the Parties to fulfill their respective responsibilities with respect to the Collaboration Programs;
  - (iii) review, discuss and approve each Research Plan, Global Development Plan and Territory-Specific Development Plan and the Co-Development Plan and Co-Commercialization Plan, and updates or amendments thereto and to share and discuss the progress of activities under the Research Plans, Global Development Plans, Territory-Specific Development Plans, Co-Development Plan and Co-Commercialization Plan on a quarterly basis;

- (iv) to share and discuss the data generated by or on behalf of the Parties in the course of performance towards the goals set forth in the Research Plans, Global Development Plans, Territory-Specific Development Plans, Co-Development Plan and Co-Commercialization Plan;
- (v) to coordinate Development and Commercialization strategies of the Collaboration Programs, and allocate resources and set timelines for Development and Commercialization activities with respect to the Collaboration Programs;
- (vi) to establish an overall regulatory strategy for (1) each [\*\*\*] Molecule and [\*\*\*] Product before the Opt-In or (2) any MGNX Option Molecule and MGNX Option Product, in each case of (1) and (2), in the applicable Collaboration Territory that is consistent with and complements the worldwide regulatory strategy being implemented by MacroGenics for the applicable Collaboration Molecule and Product;
  - (vii) to establish an overall worldwide regulatory strategy for any [\*\*\*] Molecule and [\*\*\*] Product after the Opt-In;
- (viii) to create any subcommittees (including the JRDC and JCC) as agreed in writing by both Parties, to oversee the activities of such subcommittees, and to seek to resolve any issues that such subcommittees cannot resolve;
- (ix) to establish an overall strategy for the filing, prosecution and maintenance of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks and Zai Licensed Patents in the Territory and any applicable Patent and Trademark term extensions; and
- (x) to perform such other functions as expressly set forth in this Agreement or as appropriate to further the purposes of this Agreement, as determined by the Parties.
- (c) **Decision-Making**. The JSC shall make decisions unanimously, with each Party's representatives collectively having one (1) vote and at least one (1) representative from each Party present. In the event the JSC cannot reach an agreement regarding any matter within the JSC's authority for a period of [\*\*\*] (a "**Deadlock**"), then either Party may elect to [\*\*\*], and if a Party makes an [\*\*\*], [\*\*\*] to resolve promptly such matter, which such [\*\*\*]shall include at least [\*\*\*]. If any Deadlock is not resolved after [\*\*\*]within [\*\*\*] after its submission to them, such Deadlock shall be finally determined by the applicable Party in accordance with Sections 2.2(c)(i) and 2.2(c)(ii), respectively.
  - (i) With respect to any Deadlock pertaining to (A) any [\*\*\*] Molecule and [\*\*\*] Product arising at any time before the Opt-In or (B) any MGNX Option Molecule and MGNX Option Product arising at any time during the Term, if the [\*\*\*] on any such matter within [\*\*\*] after its submission to them, the Deadlock shall be resolved in accordance with the provisions of this Section 2.2(c)(i):
  - (1) Except for those Deadlocks set forth in Section 2.2(c)(i)(2) for which Zai has the final decision-making authority, MacroGenics shall have the final decision-making authority with respect to all Deadlocks pertaining to any [\*\*\*] with respect thereto; provided that such decision shall [\*\*\*].
  - (2) Zai shall have the final decision-making authority on all Deadlocks pertaining to any of the following: (A) all Deadlocks [\*\*\*], (B) [\*\*\*], and (C) [\*\*\*] in accordance with Section [\*\*\*]; provided that such decision pursuant to (B) or (C) shall[\*\*\*].

- (3) Notwithstanding Section 2.2(c)(i)(1) and Section 2.2(c)(i)(2), no exercise of a Party's unilateral decision-making authority on any such matters may, without the other Party's prior written consent, be used to (A) make a determination as to whether a particular milestone or other criteria has been achieved or that any of its obligations under this Agreement has been fulfilled, (B) amend or add to such Party's consent or approval rights or otherwise expand or reduce its obligations provided under this Agreement, (C) impose any requirements that the other Party take or decline to take any action that would result in a violation of Applicable Laws and Regulations or any agreement with any Third Party (including any MacroGenics Third Party Agreements and Zai Third Party Agreements) or the infringement of intellectual property rights of any Third Party, (D) make a decision that is expressly stated to require the consent or approval of the other Party, (E) otherwise conflict with this Agreement, or (F) reduce the other Party's rights under this Agreement without such other Party's written consent.
- (ii) With respect to any Deadlock pertaining to any [\*\*\*] Molecule and [\*\*\*] Product arising at any time after the Opt-In, if the [\*\*\*] are unable to reach consensus on any such matter within [\*\*\*] after its submission to them, the Deadlock shall be resolved in accordance with the provisions of this Section 2.2(c)(ii):
- (1) Subject to Section 2.2(c)(ii)(3) and Section 2.2(c)(ii)(4), [\*\*\*]shall have the final decision-making authority on all Deadlocks pertaining to all [\*\*\*]in accordance with Section [\*\*\*]for [\*\*\*] Molecules and [\*\*\*] Products in the [\*\*\*]; provided that such decision shall [\*\*\*].
- (2) Subject to Section 2.2(c)(ii)(3) and Section 2.2(c)(ii)(4), [\*\*\*]shall have the final decision-making authority on all Deadlocks pertaining to all [\*\*\*]in accordance with Section [\*\*\*]for [\*\*\*] Molecules and [\*\*\*] Products in the Field in the [\*\*\*] Opt-In Territory; provided that such decision shall[\*\*\*].
- (3) In the event that a Party [\*\*\*] which would cause the [\*\*\*] percent ([\*\*\*]%) of the [\*\*\*] in the [\*\*\*] (as the case may be), the Parties will discuss any such proposal in good faith and attempt to resolve and mitigate such overages related thereto through good faith negotiation.

- (4) Notwithstanding Section 2.2(c)(ii)(1) and Section 2.2(c)(ii)(2), no exercise of a Party's unilateral decision-making authority on any such matters may, without the other Party's prior written consent, be used to (A) [\*\*\*] that includes at least [\*\*\*] and where the [\*\*\*] is expected to [\*\*\*] of the total [\*\*\*], (B) make a determination as to whether a particular milestone or other criteria has been achieved or that any of its obligations under this Agreement has been fulfilled, (C) amend or add to such Party's consent or approval rights or otherwise expand or reduce its obligations provided under this Agreement, (D) impose any requirements that the other Party take or decline to take any action that would result in a violation of Applicable Laws and Regulations or any agreement with any Third Party (including any MacroGenics Third Party Agreements and Zai Third Party Agreements) or the infringement of intellectual property rights of any Third Party, (E) make a decision that is expressly stated to require the consent or approval of the other Party, (F) otherwise conflict with this Agreement, or (G) reduce the other Party's rights under this Agreement without such other Party's written consent.
- (d) **JSC Meetings**. JSC meetings shall be held [\*\*\*], or on any other schedule mutually agreed by the Parties. With the consent of the representatives of each Party serving on the JSC, other representatives of each Party may attend meetings as non-voting observers (provided such non-voting observers have confidentiality obligations to such Party that are at least as stringent as those set forth in this Agreement). A JSC meeting may be held either in person or by audio, video or internet teleconference with the consent of each Party. Meetings of the JSC shall be effective only if at least one (1) representative of each Party is present or participating. Each Party shall be responsible for all of its own expenses of participating in the JSC meetings. The Parties shall alternate hosting the in-person meeting, and the Party hosting is responsible for preparing and circulating the minutes of the JSC meetings.
- (e) **Duration of JSC**. The JSC shall continue to exist until the first to occur of (i) the Parties mutually agreeing in writing to disband the JSC or (ii) termination of this Agreement in accordance with the terms hereof.
- (f) **Limitations**. The JSC shall have no authority other than that expressly set forth in this Section 2.1 and, specifically, shall have no authority (i) to amend or interpret this Agreement, or (ii) to determine whether or not a breach of this Agreement has occurred.
- (g) **Subcommittees**. Any subcommittee (including the JRDC and JCC) established hereunder shall be composed of an equal number of representatives from each Party. Each Party may replace its subcommittee representatives upon written notice to the other Party. All decisions of a subcommittee shall be made by unanimous vote, with each Party's representatives having one vote. In the event the Parties are unable to reach a unanimous vote with respect to a matter, such matter shall be referred to the JSC for resolution in accordance with Section 2.2(c).

# 2.3 Joint Research and Development Committee

(a) **General.** Within [\*\*\*] of the Effective Date, the Parties shall establish a joint development committee (the "**Joint Research and Development Committee**" or the "**JRDC**") to oversee (i) the day-to-day Development of the Collaboration Molecules and Collaboration Products, (ii) the day-to-day Development of the License-Only Molecules and License-Only Products as described in the applicable Research Plan(s) during the Research Term, (iii) the execution of the Research Plans, Global Development Plans, Territory-Specific Development Plans and Co-Development Plan, (iv) the progress of the Regulatory Approvals and Regulatory Submissions for the Collaboration Molecules and Collaboration Products, (v) sharing of information regarding proposed sites for Clinical Trials of Collaboration Molecules and Collaboration Products in the Territories, and (vi) such other Development related activities pertaining to the Collaboration Molecules and Collaboration Products delegated to it by the JSC. Each Party shall appoint [\*\*\*] representatives to the JRDC, each of whom shall be an officer or employee of the applicable Party having sufficient knowledge regarding Development of the Collaboration Molecules and Collaboration Products.

(b) **Meetings**. While the Parties are developing and conducting Clinical Trials for Collaboration Molecules and Collaboration Products in the Territory, the JRDC shall meet at least [\*\*\*]. The Parties shall endeavor to schedule meetings of the JRDC at least [\*\*\*] in advance.

#### 2.4 Joint Commercialization Committee

- (a) **General**. Within [\*\*\*] of initiating a Registration Trial for a Collaboration Product, the Parties shall establish a joint commercialization committee (the "**Joint Commercialization Committee**" or the "**JCC**") to oversee and coordinate (i) the day-to-day Commercialization of Collaboration Products in the applicable Collaboration Territory and, in the case of [\*\*\*] Products after Opt-In, both in and outside the [\*\*\*] Opt-In Territory, including review of branding, marketing strategy, Product positioning, pricing and reimbursement strategy (to the extent legally permissible), (ii) the progress of Commercialization activities for Collaboration Products in the applicable Collaboration Territory and, in the case of [\*\*\*] Products after Opt-In, both in and outside the [\*\*\*] Opt-In Territory, (iii) the execution of the Co-Commercialization Plan, and (iv) such other Commercialization related activities delegated to it by the JSC. Each Party shall appoint [\*\*\*] representatives to the JCC, each of whom shall be an officer or employee of the applicable Party having sufficient knowledge regarding Commercialization of the Collaboration Products.
- (b) **Meetings.** While the Parties are Commercializing Collaboration Products in the applicable Collaboration Territory, the JCC shall meet at least [\*\*\*] . The Parties shall endeavor to schedule meetings of the JCC at least [\*\*\*] in advance.

#### 3. LICENSES

#### 3.1 Licenses to Zai

(a) **Research and Development License**. Subject to the terms and conditions of this Agreement, MacroGenics hereby grants to Zai a worldwide, royalty-free, co-exclusive (with MacroGenics) license, with the right to grant sublicenses to its Affiliates only, under the MacroGenics Licensed Technology to conduct the Development activities allocated to Zai under the applicable Research Plans, Co-Development Plan, Global Development Plans and Territory-Specific Development Plans.

# (b) Development and Commercialization Licenses for Collaboration Products.

(i) [\*\*\*] **Products**. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, MacroGenics hereby grants to Zai an exclusive (even as to MacroGenics except to the extent needed by MacroGenics to perform its assigned responsibilities under the Plans), royalty-bearing license, with the right to grant sublicenses to its Affiliates and Third Party (subject to Section 3.3), under the MacroGenics Licensed Technology and the MacroGenics Licensed Trademarks for the Development, Commercialization, use and otherwise exploitation of [\*\*\*] Molecules and [\*\*\*] Products in the Field in the [\*\*\*] Territory; provided that, after the Opt-In, the license under this Section 3.1(b)(i) shall become royalty-free and the Territory for such license shall be expanded to the [\*\*\*] Opt-In Territory. Notwithstanding the foregoing, to the extent needed by Zai to perform any responsibility assigned to it under the Co-Development Plan, Co-Commercialization Plan or this Agreement in any country outside the [\*\*\*] Opt-In Territory after the Opt-In, the license under this Section 3.1(b)(i) shall become royalty-free and co-exclusive (with MacroGenics) for the purpose of performing such responsibility in such country outside the [\*\*\*] Opt-In Territory.

(ii) MGNX Option Products. Subject to the terms and conditions of this Agreement, effective as of the MGNX Option Target Date, MacroGenics hereby grants to Zai an exclusive (even as to MacroGenics except to the extent needed by MacroGenics to perform its assigned responsibilities under the Plans), royalty-bearing license, with the right to grant sublicenses to its Affiliates and Third Party (subject to Section 3.3), under the MacroGenics Licensed Technology and the MacroGenics Licensed Trademarks for the Development, Commercialization, use and otherwise exploitation of MGNX Option Molecules and MGNX Option Products in the Field in the MGNX Option Territory.

For clarity, the licenses granted to Zai under this Section 3.1(b) shall (A) [\*\*\*]; (B) [\*\*\*]; and (C) be subject to the [\*\*\*] in the event any such [\*\*\*] are subject to [\*\*\*] for which Zai elects to [\*\*\*].

# (c) Manufacturing License for Collaboration Products.

- (i) [\*\*\*] **Products**. Subject to the terms and conditions of this Agreement, [\*\*\*] with respect to a [\*\*\*] Product, MacroGenics hereby grants to Zai a co-exclusive (with MacroGenics) license, with the right to grant sublicenses to its Affiliates and Third Parties, under the MacroGenics Licensed Technology for the Manufacture of [\*\*\*] Molecules and [\*\*\*] Products in the Field worldwide, solely to Develop, Commercialize, use and otherwise exploit [\*\*\*] Molecules and [\*\*\*] Products within the scope of the license grant in Section 3.1(b)(i).
- (ii) MGNX Option Products. Subject to the terms and conditions of this Agreement, [\*\*\*] with respect to a MGNX Option Product, MacroGenics hereby grants to Zai a co-exclusive (with MacroGenics) license, with the right to grant sublicenses to its Affiliates and Third Party, under the MacroGenics Licensed Technology for the Manufacture of the applicable MGNX Option Molecule and MGNX Option Product in the Field in the MGNX Option Territory.

# (d) Development, Manufacturing and Commercialization License for License-Only Products.

(i) [\*\*\*]. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, MacroGenics hereby grants to Zai an exclusive (even as to MacroGenics), royalty-bearing license, with the right to grant sublicenses to its Affiliates and Third Party (subject to Section 3.3) under the MacroGenics Licensed Technology, for the Development (other than the Development activities allocated to MacroGenics under the Research Plan for the [\*\*\*]), Manufacture, Commercialization, use and otherwise exploitation of [\*\*\*] and [\*\*\*] in the Field in the License-Only Territory.

(ii) **Zai Selection Product**. Subject to the terms and conditions of this Agreement, effective as of the Zai Selection Target Date, MacroGenics hereby grants to Zai an exclusive (even as to MacroGenics), royalty-bearing license, with the right to grant sublicenses to its Affiliates and Third Parties (subject to Section 3.3), under the MacroGenics Licensed Technology, for the Development (other than the Development activities allocated to MacroGenics under the Research Plan for the Zai Selection Program), Manufacture, Commercialization, use and otherwise exploitation of Zai Selection Molecules and Zai Selection Products in the Field in the License-Only Territory.

For clarity, the licenses granted to Zai under this Section 3.1(d) shall [\*\*\*].

#### 3.2 License to MacroGenics.

(a) **Research and Development License**. Subject to the terms and conditions of this Agreement, Zai hereby grants to MacroGenics a worldwide, royalty-free, co-exclusive (with Zai) license, with the right to grant sublicenses to its Affiliates only, under the Zai Licensed Patents and Zai Licensed Know-How to conduct the Development activities allocated to MacroGenics under the applicable Research Plans, Co-Development Plan, Global Development Plans and Territory-Specific Development Plans.

### (b) Development and Commercialization Licenses for Collaboration Products.

- (i) [\*\*\*] **Products**. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Zai hereby grants to MacroGenics an exclusive (even as to Zai except to the extent needed by Zai to perform its assigned responsibilities under the Plans), royalty-free (except as set forth in Section 16.8) license, with the right to grant sublicenses to its Affiliates and Third Party (subject to Section 3.3), under the Zai Licensed Technology for the Development, Commercialization, use and otherwise exploitation of [\*\*\*] Molecules and [\*\*\*] Products in the Field outside the [\*\*\*] Territory; provided that, after the Opt-In, the Territory for the license under this Section 3.2(b)(i) shall be revised to the ROW. Notwithstanding the foregoing, to the extent needed by MacroGenics to perform any responsibility assigned to it under the Co-Development Plan, Co-Commercialization Plan or this Agreement in any country outside the ROW after the Opt-In, the license under this Section 3.1(b)(i) shall become co-exclusive (with Zai) for the purpose of performing such responsibility in such country outside the ROW.
- (ii) MGNX Option Products. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Zai hereby grants to MacroGenics an exclusive (even as to Zai except to the extent needed by Zai to perform its assigned responsibilities under the Plans), royalty-free (except as set forth in Section 16.8) license, with the right to grant sublicenses to its Affiliates and Third Party, under the Zai Licensed Patents and Zai Licensed Know-How for the Development (other than the Development activities allocated to MacroGenics under the Research Plan, Global Development Plan and Territory-Specific Development Plan for the MGNX Option Program), Commercialization, use and otherwise exploitation of MGNX Option Molecules and MGNX Option Products in the Field outside the MGNX Option Territory.

For clarity, the license granted to MacroGenics under this Section 3.2 shall (i) [\*\*\*] by reason of [\*\*\*], and (ii) be subject to [\*\*\*]in the event any such [\*\*\*].

#### 3.3 Sublicensees.

(a) **Sublicenses to Affiliates**. Each Party shall have the right to grant sublicenses of the licenses granted to such Party in Section 3.1 or Section 3.2 (as applicable), including sublicenses to a subset of the rights granted thereunder, to any of its Affiliates without the other Party's consent.

### (b) Sublicenses to Third Parties.

- (i) [\*\*\*] **Product Before Exercise of the** [\*\*\*] **Profit Share Option**. Before the Opt-In, each Party shall have the right to grant sublicenses of the license granted in Section 3.1(b)(i) or Section 3.2(b)(i) (as applicable), including sublicenses to a subset of the rights granted thereunder, to a third party only with the other Party's express prior written consent.
- (ii) [\*\*\*] **Product After Exercise of the** [\*\*\*] **Profit Share Option**. After the Opt-In, the Parties will jointly decide on any matter in connection with grant of sublicenses of the license granted in Section 3.1(b)(i) or Section 3.2(b)(i) (as applicable), including sublicenses to a subset of the rights granted thereunder.
- (iii) **MGNX Option Product**. Zai shall have the right to grant sublicenses of the license granted in Section 3.1(b)(ii) or Section 3.2(b)(ii) (as applicable), including sublicenses to a subset of the rights granted thereunder, to a Third Party only with the MacroGenics' express prior written consent, not to be unreasonably withheld, conditioned or delayed.
- (iv) **License-Only Product**. Zai shall have the right to grant sublicenses of the license granted in Section 3.1(d), including sublicenses to a subset of the rights granted thereunder, to any Third Party without MacroGenics' consent.
- (v) **Contractor Sublicenses**. Notwithstanding anything to the contrary in this Section 3.3(b), but subject to Section 5.1(f), a Party shall not be required to obtain the other Party's consent to grant sublicenses under this Section 3.3(b) to subcontractors subcontracted by such Party to perform responsibilities assigned to such Party under a Plan.
- (c) **Sublicense Requirements**. Each sublicense granted by any party (a "**Licensor**") shall be consistent with this Agreement and subject thereto, and the Licensor shall remain responsible to the other Party for the compliance of each such Sublicensee with the terms and conditions of this Agreement, including, with respect to the financial and other obligations due under this Agreement. Except with respect to sublicenses granted under Section 3.3(b)(v), each sublicense granted by a Licensor pursuant to Section 3.3(b) shall be in writing and the Licensor shall provide a complete copy of each such sublicense (and all amendments or restatements thereof) to the other Party so that the other Party can confirm the Licensor's compliance with the foregoing. Each sublicense granted to a Third Party by a Licensor under this Agreement shall permit the conversion of such sublicense to a direct license with the other Party at the other Party's sole discretion in the event this Agreement is terminated and, upon such conversion, the other Party shall be responsible for all former obligations of the Licensor under such sublicense. The Licensor shall include in each such sublicense a requirement obligating such Sublicensee to cooperate with the other Party.
- 3.4 **Limitations**. During the Term, neither Party may, either by itself or with or through a Related Party or Third Party, (a) Develop or Commercialize any Collaboration Product, (b) [\*\*\*] or (c) with respect to Zai, practice the MacroGenics Licensed Technology or, with respect to MacroGenics, practice the Zai Licensed Technology, in each case (a)-(c), outside of the scope of this Agreement; provided that MacroGenics shall have the right to practice the Zai Licensed Technology, and Zai shall have the right to practice the MacroGenics Licensed Technology, in each pursuant to the licenses granted under the Collaboration Agreement entered into by the Parties on November 29, 2018.

- 3.5 **Retained Rights**. Each Party shall retain all rights not otherwise granted to the other Party. For clarity, notwithstanding the licenses granted to Zai pursuant to Section 3.1, no right or license is granted by MacroGenics to Zai under the MacroGenics Licensed Technology or MacroGenics Licensed Trademarks with respect to any molecule or product Covered by such MacroGenics Licensed Technology or MacroGenics Licensed Trademarks other than the Licensed Molecules and Products (including any Other Component of a Combination Product) solely in accordance with Section 3.1, and notwithstanding the licenses granted to MacroGenics pursuant to Section 3.2, no right or license is granted by Zai to MacroGenics under the Zai Licensed Technology with respect to any molecule or product Covered by such Zai Licensed Technology other than the Collaboration Molecules and Collaboration Products (including any Other Component of a Combination Product) solely in accordance with Section 3.2.
- 3.6 **Negative Covenant; No Implied Licenses.** Each Party covenants that, except to the extent Third Parties generally are lawfully permitted to do so without a granted license from or other contractual right with the other Party, it shall not use or practice any of the other Party's intellectual property rights licensed to it under this Article except for the purposes expressly permitted in the applicable license grant. Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

# 3.7 Third Party Agreements.

- (a) All licenses and other rights granted to Zai under this Agreement are subject to the rights and obligations of MacroGenics under the MacroGenics Third Party Agreements. Zai will comply with all applicable provisions of the MacroGenics Third Party Agreements and Zai agrees to (and shall cause its Related Parties to) timely perform and take such actions as may be required to allow MacroGenics to comply with its obligations thereunder, including to provide to MacroGenics such information and reports as it reasonably requires, comply with reasonable requests for access to Zai's (and its Related Parties') records or facilities or otherwise cooperate with MacroGenics, including with respect to any financial and regulatory reporting, audit and payment obligations under each MacroGenics Third Party Agreement, insofar as they pertain to a Licensed Molecule or any Product or Zai's (and its Related Parties') activities hereunder.
- (b) All licenses and other rights granted to MacroGenics under this Agreement are subject to the rights and obligations of Zai under the Zai Third Party Agreements. MacroGenics will comply with all applicable provisions of the Zai Third Party Agreements and MacroGenics agrees to (and shall cause its Related Parties to) timely perform and take such actions as may be required to allow Zai to comply with its obligations thereunder, including to provide to Zai such information and reports as it reasonably requires, comply with reasonable requests for access to MacroGenics' (and its Related Parties') records or facilities or otherwise cooperate with Zai, including with respect to any financial and regulatory reporting, audit and payment obligations under each Zai Third Party Agreement, insofar as they pertain to a Licensed Molecule or any Product or MacroGenics' (and its Related Parties') activities hereunder

#### 3.8 Future Third Party Agreements

- (a) If, after the Effective Date, either Party enters into a license agreement in which it would Control any Patents or Know-How licensed from a Third Party that would fall under the definitions of (i) in the case of MacroGenics, MacroGenics Licensed Patents or MacroGenics Licensed Know-How, or (ii) in the case of Zai, Zai Licensed Patents or Zai Licensed Know-How (each, an "Future Third Party Agreement"), then such licensee Party (the "In-License Party") shall promptly notify the other Party in writing of the terms and conditions of such Future Third Party Agreement, including a description of such Patents or Know-How, any restrictions on use, obligations required to be undertaken by, or otherwise applicable to, any (sub)license and any Triggered Third Party Payment that would be payable if the other Party elects to obtain a sublicense under such Patents or Know-How; and upon the other Party's reasonable written request, provide a copy of such Future Third Party Agreement, provided that the licensee Party shall have the right to redact confidential, proprietary or sensitive information from such copy.
- (b) Subject to Section 3.8(c), unless the other Party [\*\*\*], and subject to all other applicable terms of the Future Third Party Agreement to the extent that would be applicable to the rights (sub)licensed hereunder to such Party, then (i) in the case of MacroGenics as the In-License Party, the MacroGenics Licensed Patents or MacroGenics Licensed Know-How, or (ii) in the case of Zai as the In-License Party, Zai Licensed Patents or Zai Licensed Know-How, in each case (i)-(ii) shall not include such Patents or Know-How in-licensed pursuant to such Future Third Party Agreement.
- (c) [\*\*\*], with respect to any Patents or Know-How that is (i) licensed to the In-License Party under a Zai Third Party Agreement or MacroGenics Third Party Agreement and (ii) necessary or reasonably useful for the non-In-License Party to perform its obligations under this Agreement or exercise the rights licensed to it under this Agreement with respect to the [\*\*\*] Program, then:
  - (i) any Triggered Third Party Payment that is (A) associated with such Patents or Know-How and (B) payable by the In-License Party after the Opt-In shall be [\*\*\*]; and
  - (ii) such Patents or Know-How shall be [\*\*\*] (in the case of MacroGenics as the In-License Party) or [\*\*\*] (in the case of Zai as the In-License Party).
    - (d) [\*\*\*].

# 4. TARGET NOMINATION; RESEARCH

# 4.1 Target Nomination

(a) MGNX Option Molecule. During the period starting from the Effective Date and for [\*\*\*] thereafter, MacroGenics shall have the right to nominate a Target for the MGNX Option Molecule. To exercise such right, MacroGenics shall notify Zai (or the Gatekeeper, if either Party elects to implement a Gatekeeper pursuant to Section 4.1(c)) in writing of the Target that MacroGenics wishes to be the subject of activities under the Research Plan for the MGNX Option Program. Zai shall notify MacroGenics in writing within [\*\*\*] following the receipt of MacroGenics' notice whether it agrees to the inclusion of the selected Target within the MGNX Option Program, provided that Zai may only withhold its consent to such inclusion on the basis that the designated Target is not Available to Zai. If Zai agrees to the inclusion of the selected Target, such Target shall be deemed the Target selected by MacroGenics for the MGNX Option Molecule as of the date of MacroGenics' receipt of Zai's acceptance notice (the "MGNX Option Target Date").

- (b) Zai Selection Molecule. During the period starting from the Effective Date and for [\*\*\*] thereafter, Zai shall have the right to nominate a Target for the Zai Selection Molecule. To exercise such right, Zai shall notify MacroGenics (or the Gatekeeper, if either Party elects to implement a Gatekeeper pursuant to Section 4.1(c)) in writing of the Target that Zai wishes to be the subject of activities under the Research Plan for the Zai Selection Program. MacroGenics shall notify Zai in writing within [\*\*\*] following the receipt of Zai's notice whether it agrees to the inclusion of the selected Target within the Zai Selection Program, provided that MacroGenics may only withhold its consent to such inclusion on the basis that the designated Target is not Available to MacroGenics. If MacroGenics agrees to the inclusion of the selected Target, such Target shall be deemed the Target selected by Zai for the Zai Selection Molecule as of the date of Zai's receipt of MacroGenics' acceptance notice (the "Zai Selection Target Date").
- (c) Target Availability. Upon either Party's reasonable request, the Parties shall mutually agree upon an independent, nationally recognized law firm to act as a gatekeeper (the "Gatekeeper") solely for purposes of facilitating Target nomination and verifying whether or not a Target is Available, as further described in this Section 4.1(c), and the Parties shall [\*\*\*] the Gatekeeper in connection therewith. At the nominating Party's request, the non-nominating Party shall provide the nominating Party (or, at non-nominating Party's discretion, the Gatekeeper) with [\*\*\*]; provided that, the non-nominating Party shall not be obligated to provide to the nominating Party any confidential information of a Third Party, or to breach the terms of any agreement with a Third Party in providing such information. The Parties shall agree upon and enter into a customary three-way agreement with the Gatekeeper, whereby (i) the nominating Party will provide the Gatekeeper with the proposed Target, (ii) the non-nominating Party will provide the Gatekeeper with a list of Targets that are not Available, and (iii) upon review of both lists, the Gatekeeper will inform the nominating Party (and only the nominating Party) of whether the proposed Target is Available; provided that the nominating Party's proposed Target shall be the Confidential Information of nominating Party, and the non-nominating Party's list of Targets shall be the Confidential Information of the non-nominating Party. In the event of any dispute with respect to the Availability of a Target under this Section 4.1, whether or not a Gatekeeper is implemented to facilitate the Target nomination process, either Party may submit such dispute for resolution pursuant to Article 15.

#### 4.2 Research

- (a) **Research Plan**. During the Research Term, the Parties will jointly conduct early Development activities pursuant to a Research Plan for each of the Programs. Within (i) [\*\*\*] following the Effective Date with respect to the [\*\*\*] Program, (ii) [\*\*\*] following the Effective Date with respect to the [\*\*\*], and (iii) [\*\*\*] following the MGNX Option Target Date with respect to the MGNX Option Program, and (iv) [\*\*\*] following the Zai Selection Target Date with respect to the Parties shall mutually agree to a research and early development plan and budget ("**Research Plan**") for the applicable Program, which shall set forth the deliverables, timelines, responsibilities of each Party, criteria for selecting development candidates, and budgeted FTEs and out-of-pocket costs for Development activities. Each Research Plan shall set forth the Development activities to be conducted by the Parties for the applicable Program which extend through [\*\*\*](including completion of [\*\*\*], [\*\*\*], and [\*\*\*]) during the Research Term. The JSC shall review each Research Plan no less than [\*\*\*] during the Research Term, and make updates as appropriate. During the Research Term, each Party shall use Commercially Reasonable Efforts to conduct the activities allocated to such Party in each Research Plan, and the JRDC shall oversee and facilitate the conduct of such activities.
- (b) **Records; Updates**. Each Party shall maintain complete, current and accurate records of (i) all activities conducted pursuant to the Research Plan and (ii) other pre-IND activities that are mutually agreed upon by the Parties and conducted after the Effective Date (collectively the "**Research Plan Activities**"), and all data and other information resulting from such Research Plan Activities. Such records shall fully and properly reflect all work performed and results achieved in the performance of such Research Plan Activities in good scientific manner appropriate for regulatory and patent purposes. During each JRDC meeting, each Party shall provide the JRDC with an update on the progress of Research Plan Activities and any information and data generated from such Research Plan Activities since the prior JRDC meeting.

#### (c) Research Costs

- (i) [\*\*\*] **Program**. With respect to the [\*\*\*] MacroGenics and Zai [\*\*\*] with Research Plan Activities for the [\*\*\*] Product in the [\*\*\*] Program [\*\*\*] Molecule or [\*\*\*] Product under the Research Plan ("[\*\*\*] **Research Costs**").
- (ii) [\*\*\*] **Program**. With respect to the [\*\*\*] Program, [\*\*\*] Research Plan Activities for the applicable Product in the applicable Program.
  - (iii) [\*\*\*] Program. With respect to the [\*\*\*] Program, [\*\*\*]Research Plan Activities [\*\*\*] Program.
- (d) **Subcontractors**. Each Party shall have the right to engage Third Party contractors to perform any portion of its obligations under the Research Plans without the other Party's consent; provided that any subcontractor engaged by a Party pursuant to this Section 4.2(d) shall be required to agree in writing to be bound by terms regarding maintaining the confidentiality of proprietary information that are no less stringent than those contained in this Agreement and regarding ownership of intellectual property that are consistent with those contained in this Agreement. Use of subcontractors for the foregoing purposes by any Party shall not relieve it of any of its obligations pursuant to this Agreement.

# 5. DEVELOPMENT; REGULATORY

# 5.1 **Collaboration Programs**

#### (a) Development Plans.

(i) [\*\*\*] **Program Before Opt-In and MGNX Option Program**. [\*\*\*], the Parties will jointly conduct Development activities pursuant to a Global Development Plan and a Territory-Specific Development Plan for such Collaboration Program; provided that, with respect to the [\*\*\*] Program, the Parties will so conduct the Development activities unless and until Zai elects to exercise its Opt-In pursuant to Section 5.1(e). Subject to Section 5.1(a)(ii), no later than [\*\*\*] prior to the date the Parties reasonably [\*\*\*], the Parties shall mutually prepare a Global Development Plan and a Territory-Specific Development Plan for such Collaboration Program for the JSC's review and approval. Each Global Development Plan and Territory-Specific Development Plan shall set forth in reasonable detail the major Development and regulatory activities to be conducted by or on behalf of each Party (or its Affiliates or Sublicensees) and the estimated timelines for achieving such activities to obtain Regulatory Approval in each country or Region in the applicable Collaboration Territory. Pursuant to each Global Development Plan and Territory-Specific Development Plan for a Collaboration Program Zai shall be primarily responsible for conducting Clinical Trials in the applicable Collaboration Territory, and MacroGenics shall be primarily responsible for conducting Clinical Trials outside the applicable Collaboration Territory. The JSC shall review each Global Development Plan and Territory-Specific Development Plan no less than [\*\*\*] and make updates as appropriate, and the JRDC shall oversee and facilitate cooperation and information transfer between the Parties in conducting the activities set forth in the Global Development Plan and Territory-Specific Development Plan.

(ii) [\*\*\*] **Program After Opt-In.** If Zai exercises the [\*\*\*] Profit Share Option pursuant to Section 5.1(e) the Parties shall mutually prepare a Co-Development Plan within [\*\*\*] of Zai's exercise of the [\*\*\*] Profit Share Option for the JRDC's review and approval; provided that, if there is a Global Development Plan or Territory Specific Development Plan in effect at such time, the Co-Development Plan shall replace such Global Development Plan or Territory Specific Development Plan. The Co-Development Plan shall set forth in reasonable detail (1) the major Development and regulatory activities to be conducted by or on behalf of each Party (or its Affiliates or Sublicensees), (2) the estimated timelines for achieving such activities to obtain Regulatory Approval in each country or Region in the world, and (3) the respective budgets for the Development of the applicable [\*\*\*] Product (A) under the Research Plan, if ongoing, (B) in the [\*\*\*] Opt-In Territory, and (C) in the ROW. Pursuant to the Co-Development Plan and unless otherwise specified therein, Zai shall be primarily responsible for finishing all Clinical Trials in the [\*\*\*] Opt-In Territory that will be initiated after the Opt-In, and MacroGenics shall be primarily responsible for finishing all Clinical Trials it is conducting outside the [\*\*\*] Territory at the time of the Opt-In and conducting Clinical Trials in the ROW that will be initiated after the Opt-In. The JSC shall review the Co-Development Plan no less than [\*\*\*] and make updates as appropriate, and the JRDC shall oversee and facilitate cooperation and information transfer between the Parties in conducting the activities set forth in the Co-Development Plan.

### (b) Diligence; Standards

(i) **Zai's Responsibilities for** [\*\*\*] **Program Before Opt-In and MGNX Option Program.** Zai shall use Commercially Reasonable Efforts to conduct the Development activities allocated to Zai under the Global Development Plans and Territory-Specific Development Plans for (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Option Program, and to achieve the Development goals as described in each Global Development Plan and Territory-Specific Development Plan. Without limiting the generality of the foregoing, with respect to each such Collaboration Program, Zai shall use Commercially Reasonable Efforts to either (y) [\*\*\*] or (z) include the [\*\*\*]. Further, Zai shall provide reasonable assistance to MacroGenics with submissions to and interactions with the FDA and other Regulatory Authorities outside of the applicable Collaboration Territory, at MacroGenics' request and expense; provided that, with respect to the provision of data, information and materials, such obligation to assist shall not require Zai to generate any data not within its possession or control.

- (ii) MacroGenics' Responsibilities for [\*\*\*] Program Before Opt-In and MGNX Program. MacroGenics shall use Commercially Reasonable Efforts to conduct the Development activities allocated to MacroGenics under the Global Development Plans and Territory-Specific Development Plans for (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Program, and to achieve the Development goals as described in the Global Development Plan and Territory-Specific Development Plan. Further, MacroGenics shall provide reasonable assistance to Zai with submissions to and interactions with the NMPA and other Regulatory Authorities in the applicable Collaboration Territory, at Zai's request and expense; provided that, with respect to the provision of data, information and materials, such obligation to assist shall not require MacroGenics to generate any data not within its possession or control.
- (iii) **Parties' Responsibilities for** [\*\*\*] **Program After Opt-In**. After Opt-In, each Party shall use Commercially Reasonable Efforts to conduct the Development activities allocated to it under the Co-Development Plan for the [\*\*\*] Program, and to achieve the Development goals as described in the Co-Development Plan. Each Party shall provide reasonable assistance to the other Party with submissions to and interactions with the Regulatory Authorities that the other Party is responsible for under the Co-Development Plan, at the other Party's request; provided that (a) any cost incurred by such other Party in connection therewith [\*\*\*], and (b) with respect to the provision of data, information and materials, such obligation to assist shall not require such other Party to generate any data not within its possession or control.
- (iv) **Standards**. Each Party shall conduct all Development Plan Activities in compliance with: (A) the terms and conditions of this Agreement; (B) as may be updated from time to time, the Global Development Plans, Territory Specific Development Plans and Co-Development Plan; (C) all applicable GLP, GCP and applicable cGMP requirements, including those specified by the ICH; and (D) all Applicable Laws and Regulations.

### (c) Records; Data; Information Sharing

(i) **Records; Updates**. Each Party shall maintain complete, current and accurate records of all activities conducted pursuant to each Global Development Plan, each Territory- Specific Development Plan and the Co-Development Plan (collectively the "**Development Plan Activities**"), and all data and other information resulting from such Development Plan Activities. Such records shall fully and properly reflect all work performed and results achieved in the performance of such Development Plan Activities in good scientific manner appropriate for regulatory and patent purposes. During each JRDC meeting, each Party shall provide the JRDC with an update on the progress of Development Plan Activities and any information and data generated from such Development Plan Activities since the prior JRDC meeting.

# (ii) Ownership of Data.

- (1) [\*\*\*]. Subject to Section[\*\*\*], [\*\*\*] shall be (A) the sole owner of [\*\*\*] generated or arising [\*\*\*](x) the [\*\*\*] in the Field [\*\*\*], (y) the [\*\*\*] in the Field [\*\*\*] in the Field [\*\*\*]; (B) the [\*\*\*] mentioned in Section [\*\*\*] above; and (C) to the extent permitted under the Applicable Laws and Regulations, the [\*\*\*], as appliable, [\*\*\*], outside the [\*\*\*] and in the [\*\*\*]as set forth in clause (A) above.
- (2) [\*\*\*]. Subject to Section [\*\*\*], [\*\*\*] shall be (A) the sole owner of [\*\*\*]generated or arising [\*\*\*](x) the [\*\*\*]in the Field [\*\*\*], (y) the [\*\*\*] in the Field [\*\*\*] in the Field [\*\*\*]; (B) the [\*\*\*] mentioned in Section [\*\*\*] above; and (C) to the extent permitted under the Applicable Laws and Regulations, the [\*\*\*] in, as applicable, the [\*\*\*], the [\*\*\*] and the [\*\*\*] as set forth in clause (A) above.
- (3) [\*\*\*]. [\*\*\*] shall be (A) the sole owner of [\*\*\*] generated in the conduct of any [\*\*\*] that is [\*\*\*] for (x) any [\*\*\*] and at least [\*\*\*], (y) any [\*\*\*] and at least [\*\*\*], or (z) any [\*\*\*] in at least [\*\*\*] and at least [\*\*\*]; and (B) the [\*\*\*] mentioned in clause (A) above.

(4) **Assignment Obligation and License**. Each Party hereby assigns, transfers and conveys (and to the extent a present assignment is prohibited by Applicable Laws and Regulations, shall assign) to the other Party its, its Affiliates' and its Sublicensees' right, title and interest in and to the data generated or arising after the Research Term from the Collaboration Programs in such a way as to effectuate the terms set forth in this Section 5.1(c)(ii). For clarity, all such Data solely owned by a Party shall be deemed to be such Party's Licensed Know-How, under which such Party shall grant to the other Party a license pursuant to Section 3.1 or Section 3.2.

### (iii) Information Sharing.

- (1) **General**. In addition to each Party's rights and obligations set forth in Section 5.1(c)(i) and Section 5.1(c)(ii), each Party shall use Commercially Reasonable Efforts to provide to the other Party summaries of data generated from its conduct of Development Plan Activities. Upon a Party's reasonable request, and at such Party's cost and expense, the other Party shall, to the extent permitted by the Applicable Laws and Regulations, provide more detailed information and data (including Clinical Data) that is reasonably available to such other Party and in support of such summary data provided by such other Party.
- (2) [\*\*\*] **Program Before Opt-In and MGNX Program.** With respect to (A) the [\*\*\*] Program before the Opt-In and (B) the MGNX Option Program, Zai shall, to the extent permitted by the Applicable Laws and Regulations, have the right to use any information or data so provided by MacroGenics to Develop and obtain Regulatory Approval for the applicable Collaboration Molecules and Collaboration Products in the Field in the applicable Collaboration Territory under the applicable Territory Specific Development Plan, and MacroGenics shall, to the extent permitted by the Applicable Laws and Regulations, have the right to use any information or data so provided by Zai to Develop and obtain Regulatory Approval for the applicable Collaboration Molecules and Collaboration Products in the Field outside the applicable Collaboration Territory under the applicable Global Development Plan.
- (3) [\*\*\*] **Program After Opt-In.** With respect to the [\*\*\*] Program after the Opt-In, each Party shall, to the extent permitted by the Applicable Laws and Regulations, have the right to use any information or data so provided by the other Party to carry out the Development and regulatory activities with respect to the [\*\*\*] Molecules and [\*\*\*] Products solely in accordance with the Co-Development Plan under the [\*\*\*] Opt-In Territory and the ROW.

# (d) Development Costs for [\*\*\*] Program Before Opt-In and MGNX Program

- (i) **Within the** [\*\*\*] **Territory and MGNX Option Territory**. With respect to (A) [\*\*\*], and (B) the [\*\*\*] shall be responsible [\*\*\*] Development Costs incurred by [\*\*\*] in connection with the conduct of any Development Plan Activities that are [\*\*\*].
- (ii) **Outside the** [\*\*\*] **Territory and MGNX Option Territory**. With respect to (A) [\*\*\*], and (B) the [\*\*\*], [\*\*\*]shall be responsible [\*\*\*] Development Costs incurred by [\*\*\*] in connection with the conduct of any Development Plan Activities that are [\*\*\*].
- (iii) **Global Development Costs**. With respect to (A) the [\*\*\*], and (B) [\*\*\*], [\*\*\*]Development Costs incurred by [\*\*\*] in connection with the conduct of any Development Plan Activities that (A) are [\*\*\*], and (B) [\*\*\*] (e.g. [\*\*\*]), as follows: (x) [\*\*\*] such Development Costs, and (y) [\*\*\*]such Development Costs.

# (e) [\*\*\*] Profit Share Option.

- (i) Subject to the terms and conditions of this Agreement (including Section 5.1(e)(ii)), MacroGenics hereby grants Zai an option ("[\*\*\*] **Profit Share Option**") to:
- (1) share in the profit and losses with respect to the [\*\*\*] Product on a worldwide basis, as set forth in more detail in Exhibit D; and

(2) [\*\*\*].

(ii) Zai may exercise the [\*\*\*] Profit Share Option only during the period [\*\*\*]by providing a written notice to MacroGenics and paying MacroGenics the Profit Share Option Payment within [\*\*\*] after providing such notice.

# (f) Subcontractors for Collaboration Programs.

(i) [\*\*\*] **Program Before Opt-In and MGNX Program**. With respect to (i) the [\*\*\*] Program before the Opt-In and (ii) the MGNX Program, each Party shall have the right to engage Third Party contractors to perform any portion of its obligations under this Agreement (each such subcontractor, a "**Permitted Subcontractor**"); provided, however, that [\*\*\*] to be unreasonably withheld, conditioned or delayed.

- (ii) [\*\*\*] **Program After Opt-In.** With respect to the [\*\*\*] Program after the Opt-In, each Party shall have the right to engage Third Party contractors to perform any portion of its obligations under this Agreement; provided, however, that (A) any such Third Party contractor for which such Party is engaging to conduct services [\*\*\*], and (B) [\*\*\*], in each case (A)-(B) [\*\*\*] to be unreasonably withheld, conditioned or delayed (any such subcontractor, as permitted under this Section 5.1(f)(ii), also a "**Permitted Subcontractor**").
- (iii) **Subcontract Requirements.** Any Permitted Subcontractor engaged by a Party pursuant to Section 5.1(f)(i) or Section 5.1(f)(ii) shall be required to agree in writing to be bound by terms regarding maintaining the confidentiality of proprietary information that are no less stringent than those contained in this Agreement and regarding ownership of intellectual property that are consistent with those contained in this Agreement. Use of Permitted Subcontractors by any Party shall not relieve it of any of its obligations pursuant to this Agreement.

# 5.2 License-Only Programs

- (a) **Overview; Diligence.** Following expiration of the applicable Research Term with respect to a License-Only Program, as between the Parties, Zai shall be solely responsible for the Development of License-Only Molecules and License-Only Products for such License-Only Program in the Field in the License-Only Territory and be the sole owner of all data (including Clinical Data) generated or arising from any License-Only Program after the Research Term. Zai shall use Commercially Reasonable Efforts to Develop License-Only Molecules and License-Only Products in the Field in the License-Only Territory.
- (b) **Standards**. Zai shall conduct all Development activities under this Section 5.2 in compliance with: (i) the terms and conditions of this Agreement; (ii) all applicable GLP, GCP and applicable cGMP requirements, including those specified by the ICH; and (iii) all Applicable Laws and Regulations.
- (c) **Records; Updates**. Zai shall maintain complete, current and accurate records of all Development activities conducted pursuant to this Section 5.2, and all data and other information resulting from such Development activities. Such records shall fully and properly reflect all work performed and results achieved in the performance of such Development activities in good scientific manner appropriate for regulatory and patent purposes.
- (d) **Subcontractors**. Zai shall have the right to engage Third Party contractors to perform any portion of its obligations with respect to the License-Only Program, other than those under the Research Plans, without MacroGenics' consent.

# 6. REGULATORY

### 6.1 Collaboration Program

- (a) [\*\*\*] Program Before Opt-In and MGNX Option Program within the Collaboration Territory
- (i) **Regulatory Submissions**. With respect to (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Option Program, as between the Parties, subject to this Section 6.1(a)(i), Zai shall be solely responsible for, at [\*\*\*], preparing, translating (to the extent required by the applicable Regulatory Authority in the applicable Collaboration Territory) and filing all Regulatory Submissions, and obtaining and maintaining Regulatory Approvals, for the Collaboration Products in the applicable Collaboration Territory, in compliance with all Applicable Laws and Regulations. MacroGenics shall have the right, but not the obligation, to review and comment on all Regulatory Submissions for any Collaboration Product to any Regulatory Authority in the applicable Collaboration Territory, and Zai shall reasonably consider any such comments in such Regulatory Submissions prior to filing thereof and shall promptly provide copies of any Regulatory Submissions (including all updates thereof) to MacroGenics. MacroGenics shall cooperate with Zai in all material respects and be actively involved in Zai's efforts with respect to such Regulatory Submissions, including without limitation providing to Zai any revisions to the investigator's brochure and CMC information required for Regulatory Submissions to Regulatory Authorities in the applicable Collaboration Territory.

- (ii) Interactions with Regulatory Authorities. With respect to (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Option Program, as between the Parties, subject to this Section 6.1(a)(ii), Zai shall be responsible for, at [\*\*\*], responding to inquiries and correspondence from the applicable Regulatory Authorities with respect to Collaboration Products in the applicable Collaboration Territory. MacroGenics (or its designee) shall have a right to be present at (but not participate in, unless otherwise requested by Zai or the applicable Regulatory Authority) meetings with the Regulatory Authorities if (1) it is reasonably likely that there would be discussions on the agenda about the Collaboration Product beyond the scope of Zai's Development of the Collaboration Product in the applicable Collaboration Territory (e.g., CMC matters, Clinical Data generated by MacroGenics), (2) MacroGenics' (or its designee's) attendance is permitted under the Applicable Laws and Regulations and by the Regulatory Authorities, and (3) MacroGenics' (or its designee's) attendance would not delay any such meetings. Following each substantive communication (whether by phone or in person) with a Regulatory Authority with respect to a Collaboration Product, Zai shall prepare a record of such meeting in accordance with its standard business practices (e.g., written minutes) and provide to MacroGenics a copy of such record.
- (b) [\*\*\*] **Program Before Opt-In and MGNX Program outside the Territory**. With respect to (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Option Program, as between the Parties, MacroGenics shall be solely responsible for, at [\*\*\*], (i) preparing, translating and filing all Regulatory Submissions, and obtaining and maintaining Regulatory Approvals, for the Collaboration Products outside the applicable Collaboration Territory, in compliance with all Applicable Laws and Regulations, and (ii) responding to inquiries and correspondence from the applicable Regulatory Authorities with respect to Collaboration Products outside the applicable Collaboration Territory. MacroGenics or its designee shall own and hold all Regulatory Approvals for Collaboration Products outside the applicable Collaboration Territory. Zai shall cooperate with MacroGenics in all material respects and be actively involved in MacroGenics' efforts with respect to such Regulatory Submissions, including without limitation providing to MacroGenics any revisions to the investigator's brochure and pharmacovigilance information required for Regulatory Submissions to Regulatory Authorities in the applicable jurisdiction outside the Collaboration Territory.
- (c) [\*\*\*] **Program After Opt-In**. With respect to the [\*\*\*] Program after the Opt-In, subject to the Co-Development Plan, Zai shall be responsible for the regulatory activities in the [\*\*\*] Opt-in Territory and MacroGenics shall be responsible for the regulatory activities in the ROW (each such Party responsible for regulatory activities, the "**Responsible Party**"). Subject to the Co-Development Plan, (1) the Responsible Party shall comply with Sections 6.1(a)(i) and 6.1(a)(ii), *mutatis mutandis*, with respect to the conduct of regulatory activities in the country or Region allocated to it; and (2) the other Party shall have the same rights and obligations set forth in Sections 6.1(a)(i) and 6.1(a)(ii), *mutatis mutandis*, with respect to such country or Region; provided that, in each case of (1) and (2), any cost incurred by any Party in connection therewith will [\*\*\*].

(d) Market Authorization Applications and Regulatory Approvals in Greater China. With respect to (i) the [\*\*\*] Program (whether before or After the Opt-In) and (ii) the MGNX Program, unless otherwise required by Applicable Laws and Regulations, [\*\*\*] shall file all MAAs for Collaboration Products as imported products in Greater China, in [\*\*\*] name. For clarity, such Regulatory Approvals shall be deemed [\*\*\*] for so long as such Regulatory Approvals are in [\*\*\*] name, under which [\*\*\*] shall grant to [\*\*\*] a license pursuant to Section [\*\*\*]. For so long as such Regulatory Approvals are in [\*\*\*] hereby designates [\*\*\*] as [\*\*\*] regulatory agent and exclusive general distributor for each Collaboration Product in Greater China. In the event later permitted by Applicable Laws or Regulations, and upon [\*\*\*] reasonable request, [\*\*\*] shall promptly assist and cooperate with [\*\*\*] and transfer and assign all MAAs or Regulatory Approvals for each Collaboration Product in Greater China to [\*\*\*] to be the holder and sole owner of the Regulatory Approval for each Collaboration Product in Greater China within the scope of the license granted to [\*\*\*] under Section [\*\*\*].

# (e) Pharmacovigilance

- (i) **Pharmacovigilance and Safety Data**. MacroGenics shall establish and maintain, at [\*\*\*], a global drug safety database for the Collaboration Products. Zai shall have the right to access from such global drug safety database all Safety Data necessary for Zai to comply with all Applicable Laws and Regulations in the applicable Collaboration Territory. Zai may establish and maintain, at [\*\*\*], a local drug safety database for the Collaboration Products in the applicable Collaboration Territory. Each Party will be responsible, at its sole cost and expense, for: (A) collecting all pharmacovigilance and other Safety Data for the Collaboration Products in its respective territory as required by Applicable Laws and Regulations; and (B) reporting any such pharmacovigilance and other Safety Data, including Adverse Events in its respective territory, for the Collaboration Products to the applicable Regulatory Authorities in its respective territory, as appropriate to be in compliance with all Applicable Laws and Regulations, including reporting Safety Data to the other Party in XML files (or CIOMS format) (in English) for entry into the global safety database; provided that any cost incurred by any Party in connection therewith with respect to the [\*\*\*] Program [\*\*\*]. Each Party expressly acknowledges that the other Party may provide information it receives pursuant to this Section 6.1(e)(i) to appropriate Regulatory Authorities within its respective territory by itself or through any of its Affiliates or Sublicensees engaged in Development and Commercialization activities of the Collaboration Products in its respective territory.
- (ii) **Pharmacovigilance Agreement**. Within [\*\*\*] following the Effective Date, or such other period as the Parties may agree (but in any case before the first IND filing of the first Product in the applicable Collaboration Territory), the Parties shall enter into a mutually acceptable pharmacovigilance agreement setting forth the Parties' respective obligations in detail regarding pharmacovigilance and the exchange of Safety Data for the Collaboration Programs during the period before the First Commercial Sale of a first Collaboration Product in the applicable Collaboration Territory. Further, no less than [\*\*\*] before the estimated date of the first Regulatory Approval of a first Collaboration Product in the applicable Collaboration Territory, the Parties shall amend such pharmacovigilance agreement to set forth the Parties' respective obligations in the detail regarding pharmacovigilance and the exchange of Safety Data during the period after the First Commercial Sale of a first Collaboration Product in the applicable Collaboration Territory. In the event Zai elects to Opt-In with respect to the [\*\*\*] Program, the Parties will determine the need to amend the pharmacovigilance agreement in view of the Parties' responsibilities set forth in the Co-Development Plan and Co-Commercialization Plan.

#### (f) Recalls.

- (i) **General**. If a Party is required by a Regulatory Authority of competent jurisdiction a recall, withdrawal, or correction (including the dissemination of relevant information) of any Collaboration Product ("**Recall**"), or if a Recall is deemed advisable by a Party in its sole discretion, then such Party shall so notify the other Party no later than [\*\*\*] hours in advance of the earlier of (i) initiation of Recall, or (ii) the submission of plans for such Recall to a Regulatory Authority. Promptly after being notified of a Recall, each Party shall provide the other Party with such assistance in connection with such Recall as may be reasonably requested by such other Party.
- (ii) [\*\*\*] **Program Before Opt-In and MGNX Program**. With respect to (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Program, Zai shall handle exclusively the organization and implementation of any Recalls of any Collaboration Product in the applicable Collaboration Territory, at [\*\*\*], and MacroGenics shall handle exclusively the organization and implementation of any Recalls of any Collaboration Product outside the Collaboration Territory, at [\*\*\*].
- (iii) [\*\*\*] **Program After Opt-In.** With respect to the [\*\*\*] Program after the Opt-In, Zai shall handle exclusively the organization and implementation of any Recalls of any [\*\*\*] Product in the [\*\*\*] Opt-In Territory, and MacroGenics shall handle exclusively the organization and implementation of any Recalls of any [\*\*\*] Product in the ROW; provided that any cost incurred by any Party in connection therewith will [\*\*\*].
- 6.2 **License-Only Programs**. As between the Parties, Zai shall [\*\*\*], (a) preparing, translating and filing all Regulatory Submissions, and obtaining and maintaining Regulatory Approvals, for the License-Only Products in the License-Only Territory, in compliance with all Applicable Laws and Regulations, (b) responding to inquiries and correspondence from the applicable Regulatory Authorities with respect to License-Only Products in the License-Only Territory, and (c) handling exclusively the organization and implementation of any Recalls of any License-Only Products [\*\*\*]. Zai or its designee shall own and hold all Regulatory Approvals for License-Only Products.

### 7. COMMERCIALIZATION

### 7.1 Collaboration Programs

(a) [\*\*\*] **Program Before Opt-In and MGNX Program Within the Territory.** With respect to (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Program, as between the Parties, subject to this Section 7.1, Zai shall be solely responsible for the Commercialization of Collaboration Products in the applicable Collaboration Territory, at [\*\*\*], including developing and executing a plan for commercial launch, obtaining all required approvals from Regulatory Authorities for Commercialization (including reimbursement activities), marketing and promotion, booking sales and distribution and performance of related services, providing customer support, including handling medical queries, and performing other related functions. Following Regulatory Approval of a Collaboration Product in the Field in any country or Region in the applicable Collaboration Territory, (i) Zai shall use Commercially Reasonable Efforts to Commercialize such Collaboration Product in the Field in such country or Region, and (ii) at each JCC meeting, Zai shall provide the JCC with an update with respect to its Commercialization activities for such Collaboration Product in the Field in such country or Region, and consider in good faith any comments thereto provided by the JCC. As between the Parties, Zai shall book all sales of Collaboration Products in any country or Region in the applicable Collaboration Territory, and shall have the sole right to determine all pricing of Collaboration Products in such country or Region.

- (b) [\*\*\*] **Program Before Opt-In and MGNX Program Outside the Territory**. With respect to (1) the [\*\*\*] Program before the Opt-In and (2) the MGNX Program, as between the Parties, subject to this Section 7.1, MacroGenics shall be solely responsible for the Commercialization of Collaboration Products in the Field outside the applicable Collaboration Territory.
- (c) [\*\*\*] **Program After Opt-In.** If Zai elects to Opt-In with respect to the [\*\*\*] Program pursuant to Section 5.1(e), no later than [\*\*\*] prior to the anticipated First Commercial Sale of the first [\*\*\*] Product worldwide, the Parties shall mutually prepare a Co-Commercialization Plan for the JCC's review and approval. The Co-Commercialization Plan shall set forth in reasonable detail the major Commercialization activities to be conducted by or on behalf of each Party (or its Affiliates or Sublicensees), (2) the estimated timelines for achieving such activities in each country or Region in the world, and (3) the respective budgets for the Commercialization of the applicable [\*\*\*] Product in (A) the [\*\*\*] Opt-in Territory, and (B) the ROW. The JSC shall review the Co-Commercialization Plan on a regular basis and make updates as appropriate. The Parties hereby agree that, after the Opt-In, as between the Parties, [\*\*\*] shall book all sales of [\*\*\*] Products in [\*\*\*] and [\*\*\*] shall book all sales of [\*\*\*] Products in [\*\*\*]. Each Party shall use Commercially Reasonable Efforts to conduct the Commercialization activities allocated to it under the Co-Commercialization Plan for the [\*\*\*] Program. At each JCC meeting, each Party shall provide the JCC with an update with respect to its Commercialization activities for the [\*\*\*] Product in the Field worldwide, and consider in good faith any comments thereto provided by the JCC.

# (d) Global Branding; Promotional Materials.

- (i) [\*\*\*] **Program Before Opt-In and MGNX Option Program.** With respect to each [\*\*\*] Product before the Opt-In and MGNX Option Product, Zai shall reasonably cooperate with MacroGenics and its designees to establish a global branding strategy worldwide ("**Global Branding Strategy**"). Zai shall Commercialize each such Collaboration Product in the applicable Collaboration Territory under a worldwide brand (the "**Global Product Brand**") specified by MacroGenics consistent with the Global Branding Strategy, except to the extent such Global Product Brand is not practicable in the applicable Collaboration Territory or not permitted by any applicable Regulatory Authority in such Collaboration Territory, in which case MacroGenics and Zai shall agree on an alternate product brand specific to such Collaboration Territory or MacroGenics may make adjustments to the Global Branding Strategy, as MacroGenics deems appropriate.
- (ii) [\*\*\*] **Program After Opt-In.** In the event that Zai elects to Opt-In with respect to the [\*\*\*] Program pursuant to Section 5.1(e), each Party shall Commercialize each [\*\*\*] Product in accordance with a Global Branding Strategy jointly established by the Parties after the Opt-In and under the Global Product Brand jointly specified by the Parties after the Opt-In, except to the extent such Global Product Brand is not practicable or not permitted by in any country or Region in the world, in which case the Party responsible for Commercialization of [\*\*\*] Products in such country shall decide on an alternate product brand specific to such country or Region.

(iii) Zai's Responsibilities. Except for any Trademarks that are intended to identify MacroGenics' as the manufacturer or owner of a Collaboration Product, and subject to Section 7.1(d)(i) and Section 7.1(d)(ii), Zai shall be responsible for the following aspects of Commercialization of the Collaboration Products: (i) the design and supply of printable artworks and labels in promotional materials for Collaboration Products for the applicable Collaboration Territory (and other countries allocated to Zai under the Co-Commercialization Plan with respect to the [\*\*\*] Program after the Opt-In), (ii) determining the product names of the Collaboration Products in a local language and how the Collaboration Products shall be presented and described in any promotional materials to the medical community in the applicable Collaboration Territory (and other countries allocated to Zai under the Co-Commercialization Plan with respect to the [\*\*\*] Program after the Opt-In), (iii) the placement of the name and logos of Zai in any such promotional materials and (iv) branding the Collaboration Products in the applicable Collaboration Territory (and other countries allocated to Zai under the Co-Commercialization Plan with respect to the [\*\*\*] Program after the Opt-In) using any trademarks it determines appropriate, which branding may vary by country or Region, in each case (i)-(iii) as permitted by Applicable Laws and Regulation and consistent with the applicable Global Branding Strategy. Except with respect to the MacroGenics Licensed Trademarks, Zai will own all rights in all other trademarks it creates for the [\*\*\*] Products and MGNX Option Products for use in the applicable Collaboration Territory, where and how it determines appropriate.

### (e) No Diversion

- (i) Each Party hereby covenants and agrees that it shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold Collaboration Products, including via the Internet or mail order, to any Third Party, address or Internet Protocol address in the other Party's territory.
- (ii) If any of the Collaboration Products are diverted into the other Party's territory (the "Unauthorized Territory") for use (excluding use by or on behalf of any Party, its Affiliates and Sublicensees for activities permitted under this Agreement) or sale therein ("Unauthorized Activity"), the following shall apply: (1) if such Collaboration Products were diverted by an identifiable customer, distributor, employee, consultant or agent of the source Party (each an "Unauthorized Person") then, upon the request of the other Party, the source Party shall not sell such Collaboration Products to, or allow the sale of such Collaboration Products by, such Unauthorized Person (including by requiring the discontinuation of sales of such Collaboration Product or enforcement of contractual obligations against such Unauthorized Person) for the remaining Term and shall use Commercially Reasonable Efforts to buy back all such Collaboration Products from such Unauthorized Person within [\*\*\*] of such request from the other Party; or (2) the source Party shall use Commercially Reasonable Efforts to investigate the location of such diverted Collaboration Products and buy them back; but, if and to the extent that, the source Party elects not to, or is unable to, buy back the applicable diverted Collaboration Products, then the other Party may, in its sole discretion, buy back the applicable diverted Collaboration Products, then the other Party for all reasonable costs incurred by such other Party in connection with the buy-back or lost sales of any such diverted Collaboration Products. Notwithstanding the foregoing, any cost incurred by any Party in connection with (1) or (2) above with respect to the [\*\*\*] Program after the Opt-In [\*\*\*].
- 7.2 **License-Only Programs**. As between the Parties, Zai shall be solely responsible for the Commercialization of License-Only Products in the Field in the License-Only Territory. Following the Regulatory Approval of a License-Only Product in the Field in any country or Region in the License-Only Territory, Zai shall use Commercially Reasonable Efforts to Commercialize such License-Only Product in the Field in such country or Region. Zai will own all rights in all other trademarks it creates for the License-Only Products for use in the License-Only Territory, and register and maintain such trademarks in the License-Only Territory, where and how it determines appropriate

#### 7.3 Compliance.

- (a) **General**. Each Party shall comply with the terms of this Agreement and all Applicable Laws and Regulations relating to activities performed or to be performed by such Party (or its Affiliates, contractor(s) or Sublicensee(s)) under or in relation to the Commercialization of Products pursuant to this Agreement.
- (b) **Zai's Covenants, Representations and Warranties**. Without limiting the generality of Section 7.3(a), Zai agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants, and Subcontractors (together with Zai, the "**Zai Representatives**") that for the performance of its obligations hereunder:
  - (i) The Zai Representatives shall not directly or indirectly pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything else of value, to: (1) any Government Official in order to influence official action; (2) any Person (whether or not a Government Official) (a) to influence such Person to act in breach of a duty of good faith, impartiality or trust ("Acting Improperly"), (b) to reward such Person for Acting Improperly, or (c) where such Person would be Acting Improperly by receiving the money or other thing of value; (3) any other Person while knowing or having reason to know that all or any portion of the money or other thing of value shall be paid, offered, promised or given to, or shall otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or (4) any Person to reward that Person for Acting Improperly or to induce that Person to Act Improperly.
  - (ii) The Zai Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.
  - (iii) Zai and the other Zai Representatives shall comply with the Anti- Corruption Laws and shall not take any action that shall, or would reasonably be expected to, cause either Party (or its Affiliates) to be in violation of any such laws. In furtherance of the foregoing, Zai acknowledges and confirms the following:
  - (1) Zai has reviewed its internal programs in relation to the Anti- Corruption Laws and the ability of the Zai representatives to adhere to such laws in performance of its obligations hereunder in advance of the signing of this Agreement and warrants that it and the other Zai Representatives can and shall continue to comply with such Anti-Corruption Laws in performance of its obligations hereunder and further represents and warrants that should either Party identify in writing to the other Party any measures that should be reasonably taken to improve Zai Representatives' compliance with such Anti-Corruption Laws for the performance of its obligations hereunder (the "Zai Improvement Plan"), Zai shall use Commercially Reasonable Efforts to implement such Zai Improvement Plan within an agreed reasonable timeframe (which shall in any event not be in excess of [\*\*\*]) from the date the Zai Improvement Plan is delivered to the receiving Party. In the absence of the full implementation by Zai of such Zai Improvement Plan within the aforesaid [\*\*\*] period, MacroGenics shall be entitled to terminate this Agreement, upon written notice to Zai with immediate effect, to be relieved of any obligations, and to seek compensation from Zai;
  - (2) To the best of Zai's and its Affiliates' knowledge after reasonable diligence, no Zai Representative that shall participate or support Zai's performance of its obligations hereunder has, directly or indirectly, (x) paid, offered or promised to pay, or authorized the payment of any money; (y) given, offered or promised to give, or authorized the giving of anything else of value; or (z) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((x), (y) and (z)), in violation of the Anti-Corruption Laws during the [\*\*\*] preceding the date of this Agreement.

- (3) To the best of Zai 's and its Affiliates' knowledge, none of its intellectual property rights, technology, contracts, materials, or licenses or other assets that are the subject of this Agreement, other than those provided by or on behalf of MacroGenics, were procured in violation of any Anti-Corruption Laws.
- (iv) Zai, on behalf of itself and the Zai Representatives, represents and warrants to MacroGenics that all information provided by Zai and the Zai Representatives to MacroGenics in any anti-bribery and corruption due diligence checklist, similar due diligence process performed by MacroGenics or its Affiliates or inquiry by MacroGenics related to Zai 's or the Zai Representatives compliance with Anti-Corruption Laws is true, complete and correct in all material respects at the date it was provided and that any material changes in circumstances relevant to the answers provided in such exercise shall be promptly disclosed to MacroGenics.
- (v) Zai shall promptly provide MacroGenics with written notice of the following events: (i) upon becoming aware of any actual, alleged, or potential breach or violation by Zai or any Zai Representative of any representation, warranty or undertaking set forth in this Section 0; or (ii) upon receiving a formal notification that it is the target of a formal investigation by a government authority for any violation of any Anti-Corruption Law or upon receipt of information from any of the Zai Representatives that any of them is the target of a formal investigation by a government authority for a violation of any Anti-Corruption Law.
- (vi) For the Term and for [\*\*\*] following the expiration or earlier termination of the Agreement, Zai shall for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly this Section 0 permit MacroGenics, its Affiliates, any auditors of any of them and any government authority to have reasonable access to any premises of Zai or other Zai Representatives used in connection with this Agreement, together with a right to reasonably access personnel and records that relate to this Agreement ("Zai Audit"). Zai shall provide or procure that the Zai Representatives shall provide all co-operation as reasonably requested by MacroGenics for the purposes of the Zai Audit, with the understanding that MacroGenics shall be responsible for all costs and fees of any Zai Audit and MacroGenics shall procure that any auditor enters into a confidentiality agreement consistent with the confidentiality provisions elsewhere in this Agreement in all material respects.
- (vii) If (A) MacroGenics becomes aware of, whether or not through a Zai Audit, that Zai (or any other Zai Representative) is in breach or violation of any representation, warranty or undertaking in Section 0 or of the Anti-Corruption Laws; or (B) MacroGenics receives notification that a suspected or actual violation of an Anti-Corruption Law has occurred by Zai or any other Zai Representative, in each case of (A)-(B), MacroGenics shall have the right, in addition to any other rights or remedies under this Agreement or to which MacroGenics may be entitled in law or equity, to take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by MacroGenics or any of its Affiliates of the Anti-Corruption Laws, including by requiring that Zai agrees to and uses Commercially Reasonable Efforts to implement any curative actions requested by MacroGenics. In the event that Zai refuses to agree to all of the curative actions requested by MacroGenics (and provided that MacroGenics has (x) provided Zai with an explanation in reasonable detail as to why MacroGenics considers such actions necessary, (y) given Zai a reasonable opportunity to review and comment upon the proposed actions and to provide its view as to the necessity or usefulness of these to address the event concerned, and (z) considered such comments in good faith), MacroGenics shall be entitled to terminate this Agreement in its entirety with immediate effect. Any termination of this Agreement pursuant to this Section 0 shall be treated as a termination for breach by Zai of this Agreement and the consequences of termination shall apply and additionally: (1) subject to the accrued rights of the Parties prior to termination, MacroGenics shall have no liability to Zai for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (2) any amounts that would otherwise be payable to Zai pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under Applicable Laws and Regulations.

- (viii) Zai shall be responsible for any breach of any representation, warranty or undertaking in this Section 0 or of the Anti-Corruption Laws by any Zai Representative.
- (ix) MacroGenics may disclose the terms of this Agreement or any action taken under this Section 0 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of Zai and the payment terms, to any government authority if MacroGenics determines, upon advice of counsel, that such disclosure is necessary.
- (c) **MacroGenics's Covenants, Representations and Warranties**. Without limiting the generality of Section 7.3(a), MacroGenics agrees, on behalf of itself, its officers, directors and employees and on behalf of its Affiliates, agents, representatives, consultants, and Subcontractors (together with MacroGenics, the "**MacroGenics Representatives**") that for the performance of its obligations hereunder:
  - (i) The MacroGenics Representatives shall not directly or indirectly pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything else of value, to: (1) any Government Official in order to influence official action; (2) any Person (whether or not a Government Official) (a) to influence such Person to act in breach of a duty of good faith, impartiality or trust, (b) to reward such Person for Acting Improperly, or (c) where such Person would be Acting Improperly by receiving the money or other thing of value; (3) any other Person while knowing or having reason to know that all or any portion of the money or other thing of value shall be paid, offered, promised or given to, or shall otherwise benefit, a Government Official in order to influence official action for or against either Party in connection with the matters that are the subject of this Agreement; or (4) any Person to reward that Person for Acting Improperly or to induce that Person to Act Improperly.
  - (ii) The MacroGenics Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything else of value in violation of the Anti- Corruption Laws.
  - (iii) MacroGenics and the other MacroGenics Representatives shall comply with the Anti-Corruption Laws and shall not take any action that shall, or would reasonably be expected to, cause either Party (or its Affiliates) to be in violation of any such laws. In furtherance of the foregoing, MacroGenics acknowledges and confirms the following:
  - (1) MacroGenics has reviewed its internal programs in relation to the Anti-Corruption Laws and the ability of the MacroGenics representatives to adhere to such laws in performance of its obligations hereunder in advance of the signing of this Agreement and warrants that it and the other MacroGenics Representatives can and shall continue to comply with such Anti- Corruption Laws in performance of its obligations hereunder and further represents and warrants that should either Party identify in writing to the other Party any measures that should be reasonably taken to improve MacroGenics Representatives' compliance with such Anti-Corruption Laws for the performance of its obligations hereunder (the "MacroGenics Improvement Plan"), MacroGenics shall use Commercially Reasonable Efforts to implement such MacroGenics Improvement Plan within an agreed reasonable timeframe (which shall in any event not be in excess of [\*\*\*]) from the date the MacroGenics Improvement Plan within the aforesaid [\*\*\*] period, Zai shall be entitled to terminate this Agreement, upon written notice to MacroGenics with immediate effect, to be relieved of any obligations, and to seek compensation from MacroGenics;

- (2) To the best of MacroGenics's and its Affiliates' knowledge after reasonable diligence, no MacroGenics Representative that shall participate or support MacroGenics's performance of its obligations hereunder has, directly or indirectly, (x) paid, offered or promised to pay, or authorized the payment of any money; (y) given, offered or promised to give, or authorized the giving of anything else of value; or (z) solicited, received or agreed to accept any payment of money or anything else of value, in each case ((x), (y) and (z)), in violation of the Anti-Corruption Laws during the [\*\*\*] preceding the date of this Agreement.
- (3) To the best of MacroGenics 's and its Affiliates' knowledge, none of its intellectual property rights, technology, contracts, materials, or licenses or other assets that are the subject of this Agreement, other than those provided by or on behalf of Zai, were procured in violation of any Anti-Corruption Laws.
- (iv) MacroGenics, on behalf of itself and the MacroGenics Representatives, represents and warrants to Zai that all information provided by MacroGenics and the MacroGenics Representatives to Zai in any anti-bribery and corruption due diligence checklist, similar due diligence process performed by Zai or its Affiliates or inquiry by Zai related to MacroGenics 's or the MacroGenics Representatives compliance with Anti-Corruption Laws is true, complete and correct in all material respects at the date it was provided and that any material changes in circumstances relevant to the answers provided in such exercise shall be promptly disclosed to Zai.
- (v) MacroGenics shall promptly provide Zai with written notice of the following events: (i) upon becoming aware of any actual, alleged, or potential breach or violation by MacroGenics or any MacroGenics Representative of any representation, warranty or undertaking set forth in this Section 0; or (ii) upon receiving a formal notification that it is the target of a formal investigation by a government authority for any violation of any Anti-Corruption Law or upon receipt of information from any of the MacroGenics Representatives that any of them is the target of a formal investigation by a government authority for a violation of any Anti-Corruption Law.
- (vi) For the Term and for [\*\*\*] following the expiration or earlier termination of the Agreement, MacroGenics shall for the purpose of auditing and monitoring the performance of its compliance with this Agreement and particularly this Section 0 permit Zai, its Affiliates, any auditors of any of them and any government authority to have reasonable access to any premises of MacroGenics or other MacroGenics Representatives used in connection with this Agreement, together with a right to reasonably access personnel and records that relate to this Agreement ("MacroGenics Audit"). MacroGenics shall provide or procure that the MacroGenics Representatives shall provide all co-operation as reasonably requested by Zai for the purposes of the MacroGenics Audit, with the understanding that Zai shall be responsible for all costs and fees of any MacroGenics Audit and Zai shall procure that any auditor enters into a confidentiality agreement consistent with the confidentiality provisions elsewhere in this Agreement in all material respects.

- (vii) If (A) Zai becomes aware of, whether or not through a MacroGenics Audit, that MacroGenics (or any other MacroGenics Representative) is in breach or violation of any representation, warranty or undertaking in Section 0 or of the Anti-Corruption Laws; or (B) Zai receives notification that a suspected or actual violation of an Anti-Corruption Law has occurred by MacroGenics or any other MacroGenics Representative, in each case of (A)-(B), Zai shall have the right, in addition to any other rights or remedies under this Agreement or to which Zai may be entitled in law or equity, to take such steps as are reasonably necessary in order to avoid a potential violation or continuing violation by Zai or any of its Affiliates of the Anti-Corruption Laws, including by requiring that MacroGenics agrees to and uses Commercially Reasonable Efforts to implement any curative actions requested by Zai. In the event that MacroGenics refuses to agree to all of the curative actions requested by Zai (and provided that Zai has (x) provided MacroGenics with an explanation in reasonable detail as to why Zai considers such actions necessary, (y) given MacroGenics a reasonable opportunity to review and comment upon the proposed actions and to provide its view as to the necessity or usefulness of these to address the event concerned, and (z) considered such comments in good faith), Zai shall be entitled to terminate this Agreement in its entirety with immediate effect. Any termination of this Agreement pursuant to this Section 0 shall be treated as a termination for breach by MacroGenics of this Agreement and the consequences of termination shall apply and additionally: (1) subject to the accrued rights of the Parties prior to termination, Zai shall have no liability to MacroGenics for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination; and (2) any amounts that would otherwise be payable to MacroGenics pursuant to this Agreement in its entirety, as applicable, including any then outstanding and unpaid claims for payment shall be null and void to the extent permissible under Applicable Laws and Regulations.
- (viii) MacroGenics shall be responsible for any breach of any representation, warranty or undertaking in this Section 0 or of the Anti-Corruption Laws by any MacroGenics Representative.
- (ix) Zai may disclose the terms of this Agreement or any action taken under this Section 0 to prevent a potential violation or continuing violation of applicable Anti-Corruption Laws, including the identity of MacroGenics and the payment terms, to any government authority if Zai determines, upon advice of counsel, that such disclosure is necessary.

#### 8. MANUFACTURE AND SUPPLY

#### 8.1 Supply of [\*\*\*] Products Before Opt-In and MGNX Products

- (a) MacroGenics Responsibility. With respect to the [\*\*\*] Products before the Opt-In and the MGNX Products, subject to other provisions in this Agreement (including Section 4.2(c)(i) and Section 8.3), MacroGenics shall be solely responsible for the Manufacture, either by itself or through one or more Third Parties selected by MacroGenics at its sole discretion, of (i) all such Collaboration Molecules and Collaboration Products required for the Clinical Trials described in each Global Development Plan or Territory-Specific Development Plan, at MacroGenics' Fully-Burdened Manufacturing Cost, and (ii) all commercial supplies of Collaboration Products required by Zai for the Commercialization of Collaboration Products in the applicable Collaboration Territory, at MacroGenics' Fully-Burdened Manufacturing Cost.
- (b) **Supply Agreements**. No later than [\*\*\*] before the first anticipated IND filing for a Collaboration Molecule or Collaboration Product in the applicable Collaboration Territory, the Parties shall enter into negotiations for a supply agreement governing the clinical supply to Zai for its requirements of such Collaboration Molecule and Collaboration Product required for Development hereunder in the applicable Collaboration Territory. Within [\*\*\*] (but no later than [\*\*\*]) prior to the projected date of First Commercial Sale of a Product in any country or Region in the applicable Collaboration Territory, the Parties shall negotiate and enter into a supply agreement governing the commercial supply of such Collaboration Product to Zai for its requirements of such Collaboration Product for Commercialization in the applicable Collaboration Territory. Each supply agreement shall provide customary terms and conditions, such as acceptance and rejection procedures, forecast and order procedures, release documentations and audit rights by Zai and for MacroGenics and Zai to discuss and agree upon a Third Party supplier for Products in the event of certain material supply failures, as determined in accordance with criteria to be mutually agreed by the Parties thereunder.

- (c) **Manufacturing Specifications**. All clinical and commercial supplies of Collaboration Molecules and Collaboration Product supplied by MacroGenics shall be manufactured in accordance with the specifications (i) determined by MacroGenics, (ii) subject to Section 8.1(d), consistent with those specifications required by the applicable Regulatory Authority in the Territory provided by Zai to MacroGenics in writing, and (iii) in compliance with all regulatory requirements and all Applicable Laws and Regulations, as further set forth in the supply agreements and related quality agreements.
- (d) Change of Manufacturing Process. MacroGenics shall reasonably inform Zai of developments in matters of process development and Manufacture of the Collaboration Products, and shall consult with Zai with respect to the development and Manufacture processes of the Collaboration Products adopted by MacroGenics to the to obtain Regulatory Approval(s) of the same in the Collaboration Territory, all as described in further detail in the supply agreements and quality agreements. In addition, MacroGenics shall implement changes required by Regulatory Authority in the Collaboration Territory to the extent commercially practicable, provided that Zai shall bear any and all incremental costs resulting from any changes to the manufacturing specifications required by the applicable Regulatory Authority in the Collaboration Territory but not by any of the Regulatory Authorities outside the Collaboration Territory, and the supply agreements and quality agreements shall provide the mechanism for such implementation. In the event it is not commercially practicable for MacroGenics or its supplier to implement a change required by a Regulatory Authority in the Collaboration Territory, the Parties shall explore the potential engagement of any other Third Party supplier or [\*\*\*]. Each Party shall promptly notify the other Party of any information that may impact approvability or regulatory status (before or after approval) of Collaboration Products of which it is aware and reasonably believes may impact the regulatory status before or after Regulatory Approval of a Product in the Collaboration Territory.
  - 8.2 **Supply of** [\*\*\*] **Products After Opt-In**. With respect to each [\*\*\*] Product after the Opt-In, the Parties will [\*\*\*].
  - 8.3 [\*\*\*]Collaboration Products.
- (a) [\*\*\*]. In the event that [\*\*\*] Collaboration Molecule or Collaboration Product other than because of (1) [\*\*\*] or (2) [\*\*\*], or (ii) following the [\*\*\*], then in each case of (i) or (ii) Zai may, upon written notice to MacroGenics [\*\*\*] request MacroGenics to initiate, or cause its applicable Affiliate or designated Third Party to [\*\*\*].

- (b) [\*\*\*]. [\*\*\*]the Parties will [\*\*\*]. MacroGenics will use Commercially Reasonable Efforts to [\*\*\*]. Among other things, [\*\*\*]will provide that MacroGenics will, or will cause its applicable Affiliate or designated Third Party to, [\*\*\*] Collaboration Molecule and Collaboration Product [\*\*\*] such Collaboration Molecule and Collaboration Product [\*\*\*] Zai, its Affiliates or Sublicensees as [\*\*\*]
- (c) If Zai, its Affiliate [\*\*\*], MacroGenics shall have the right [\*\*\*]. MacroGenics may exercise such right by providing written notice to Zai of its intent to do so, and promptly following Zai's receipt thereof, the Parties shall [\*\*\*].
- 8.4 **Supply of cGMP Materials for the First Phase I Clinical Trial of MGNX Option Product**. Notwithstanding anything to the contrary in this Agreement, [\*\*\*] the Manufacture and supply of the cGMP materials for the first Phase I Clinical Trial of the MGNX Option Product at its own cost and expense.
- 8.5 **Supply of License-Only Products**. Zai shall be solely responsible for the manufacture of clinical and commercial supply of License-Only Molecules and License-Only Products, at its sole cost and expense. Zai shall ensure that all clinical and commercial supplies of License-Only Molecules and License-Only Products are manufactured in accordance with the specifications in compliance with all regulatory requirements and all Applicable Laws and Regulations in the applicable country or Region in the License-Only Territory.

#### 9. PAYMENTS

- 9.1 **Upfront Payment**. Within [\*\*\*] after the Effective Date, Zai shall pay to MacroGenics Twenty-Five Million US Dollars (US\$25,000,000) (the "**Upfront Payment**"), which shall be non-creditable, non-refundable against any other payments due under this Agreement.
- 9.2 **Equity Investments**. As partial consideration for the rights granted to Zai hereunder, the Parties are entering into separate stock issuance and related agreements concurrently with the execution of this Agreement whereby Zai will purchase Thirty Million Seventeen US Dollars and Ten Cents (US\$30,000,017.10) of MGNX stock at Thirty-One US Dollars and Thirty Cents (\$31.30) per share.
- 9.3 **Development and Regulatory Milestone Payments**. On a Program-by-Program basis, Zai shall pay to MacroGenics the non-creditable, non-refundable milestone payments listed set forth in the table below within [\*\*\*] after the first achievement of the applicable milestone events by the first Product in such Program, whether by or on behalf of Zai, its Affiliate or any Sublicensee. For clarity, each of the following milestone payments shall be payable only once per Program, regardless of the number of times such milestone is achieved.

Milestone Event	Milestone Payment		
For each of the Collaboration Programs		-	
[***]		[***])	
[***]		[***])	
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
For each of the License-Only Programs			
[***]		[***]	
[***]		[***]	
	[***]	[***]	[***]

provided that, after Zai exercises the [\*\*\*] Profit Share Option, [\*\*\*].

The milestone events above are intended to be successive with respect to each Product and each Program, such that if a particular milestone event set forth in the table above for a Product for an Indication is not achieved prior to the achievement of the next milestone event set forth in the table above for such Product in such Indication (and with respect to the BLA submission acceptance and Regulatory Approval milestones, in the corresponding country or Region) (such non-achieved milestone event, a "Skipped Milestone"), then such Skipped Milestone shall be deemed to have been achieved upon the achievement of such next milestone event to occur, and the milestone payment for such Skipped Milestone shall be due and payable by Zai to MacroGenics at the time the milestone payment is due and payable for such next milestone event. For example, if a Registration Trial for a Collaboration Product for an Indication has not been Initiated in the applicable Collaboration Territory prior to the acceptance of a BLA submission for such Collaboration Product for such Indication in China, then the milestone payment for both milestone events shall be due and payable by Zai to MacroGenics at the time the milestone payment for the BLA acceptance milestone event is due and payable under this Section 9.3.

9.4 **Commercial Milestone Payments for License-Only Products**. With respect to each License-Only Program, Zai shall pay to MacroGenics the non-creditable, non-refundable milestone payments set forth in the table below within [\*\*\*] after the first achievement of aggregate annual Net Sales for all License-Only Products for a License-Only Program in a Calendar Year of the applicable sales milestone event. For clarity, the milestone payments in this Section 9.4 shall be additive such that if multiple milestone events specified below are achieved in the same Calendar Year, then the milestone payments for all such milestone events shall be payable with respect to such Calendar Year. For clarity, each of the following milestone payments shall be payable only once for each License-Only Program regardless of the number of times such milestone is achieved.

Commercial Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]
[***])	[***]
[***])	[***]

# 9.5 Royalties on Net Sales of Products Other Than [\*\*\*] Products After Opt-In

(a) **Royalty Rate**. On a Product-by-Product basis, other than any [\*\*\*] Product in the event that Zai elects to Opt-In pursuant to Section 5.1(e), subject to the terms and conditions of this Section 9.5, for each Calendar Quarter during the Royalty Term, Zai shall pay to MacroGenics non-creditable, non-refundable royalties on Net Sales of such Product (excluding any [\*\*\*] Product in the event that Zai elects to Opt-In pursuant to Section 5.1(e)) in the Territory during such Calendar Quarter, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales of such Product in the Territory, as follows:

Annual Net Sales of each Product in the Territory	
For each of the [***] Products prior to the Opt-In	
For that portion of annual Net Sales of a Product less than or equal to [***]Dollars (\$[***])	[***]
For that portion of annual Net Sales of a Product greater than [***]Dollars (\$[***]) but less than or equal to [***]Dollars (\$[***])	[***]
For that portion of annual Net Sales of a Product greater than [***]Dollars (\$[***])	[***]
For each of the MGNX Option Products, [***] and Zai Selection Products	
For that portion of annual Net Sales of a Product less than or equal to [***]Dollars (\$[***])	[***]
For that portion of annual Net Sales of a Product greater than [***]Dollars (\$[***]) but less than or equal to [***]Dollars (\$[***])	[***]
For that portion of annual Net Sales of a Product greater than [***]Dollars (\$[***]) but less than or equal to [***]Dollars (\$[***])	[***]
For that portion of annual Net Sales of a Product greater than [***]Dollars (\$[***])	[***]

#### (b) Royalty Reduction

- (i) **Biosimilar Product Market Effect.** Subject to Section 9.5(c), with respect to a Product in a country or Region in the Territory, (1) if, in any Calendar Quarter, one or more Biosimilar Products for such Product are on the market in such country or Region and the sales of such Biosimilar Products in such country or Region constitute [\*\*\*]percent ([\*\*\*]%) or more of the total sales [\*\*\*]in such country or Region, the royalty payment for such Product in such country or Region for such Calendar Quarter shall be reduced to [\*\*\*][\*\*\*]% of the amount otherwise payable with respect to such Product in the absence of such Biosimilar Product(s); or (2) if, in any Calendar Quarter, one or more Biosimilar Products for such Product are on the market in such country or Region and the sales [\*\*\*]in such country or Region constitute [\*\*\*]percent ([\*\*\*]%) or more of the total sales [\*\*\*] in such country or Region, the royalty payments for such Product in such country or Region for such Calendar Quarter shall be reduced to [\*\*\*]percent ([\*\*\*]%) of the amount otherwise payable with respect to such Product in the absence of such Biosimilar Product(s).
- (ii) **Valid Claim Expiration**. Subject to Section 9.5(c), if, in any Calendar Quarter, a Product in a country or Region in the Territory is not Covered by a Valid Claim within any MacroGenics Licensed Patent under which Zai is granted an effective license pursuant to this Agreement, then the royalty payments for Net Sales for such Product in such country or Region shall be reduced by [\*\*\*]percent ([\*\*\*]%) in such Calendar Quarter.
- (iii) **Third Party Payments**. Subject to Section 9.5(c), if Zai obtains a license to any [\*\*\*] rights owned by a Third Party that is necessary for Zai to (1) Develop or Commercialize a Collaboration Product in a country or Region in the applicable Collaboration Territory, (2) Manufacture a Collaboration Product in a country or Region in the applicable Collaboration Territory after the date of the [\*\*\*], or (3) Develop, Manufacture or Commercialize a License-Only Product in a country or Region in the applicable License-Only Territory, then the royalties payable by Zai to MacroGenics with respect to Net Sales of the applicable Product in such country or Region in any Calendar Quarter shall be reduced, on a Product-by-Product and country-by-country or Region-by-Region basis, by [\*\*\*]percent ([\*\*\*]%) of the [\*\*\*]paid by Zai to such Third Party with respect to such Product in such country or Region in such Calendar Quarter.
- (c) **Royalty Floor**. In no event shall the royalty reductions available to Zai under Section 9.5(b), collectively or individually, reduce the royalties payable to MacroGenics for a given Calendar Quarter to less than [\*\*\*] percent ([\*\*\*]%) of the amount otherwise payable under Section 9.5 with respect to an applicable Product; provided that [\*\*\*].
- 9.6 **Triggered Third Party Payments for Products Other Than** [\*\*\*] **Products After Opt-In.** In the event that a Party will be obligated to reimburse the other Party for any Triggered Third Party Payments, the obligated Party shall reimburse the other Party at least [\*\*\*] prior to the applicable payment date for such Triggered Third Party Payment specified under the applicable Future Third Party Agreement. Such Party's obligation under this Section 9.6 with respect to the payment of Triggered Third Party Payments under a given Future Third Party Agreement for which such Party elects to obtain a sublicense pursuant to Section 3.8 shall terminate upon termination of the In-License Party's obligation to pay such Triggered Third Party Payments under the terms of such Future Third Party Agreement.

9.7 **Profit Sharing for** [\*\*\*] **Program After Opt-In.** After the Opt-In, the Parties shall share the profit and loss for the [\*\*\*] Program equally in accordance with the terms set forth in Exhibit D.

# 10. Payments; Reports; Records; Audits

- 10.1 **Net Sales Quarterly Reports for Products Other Than** [\*\*\*] **Products After Opt-In.** During the Term, for each Calendar Quarter following the First Commercial Sale of a Product, other than [\*\*\*] Product after the Opt-In, in the Territory, Zai shall furnish to MacroGenics:
- (a) a quarterly written report for the Calendar Quarter showing, on a country-by-country and Region-by-Region basis, the Net Sales of all Products subject to royalty payments sold by Zai and its Related Parties in the Territory during the reporting period and the royalties payable under this Agreement; and
- (b) a quarterly report for the Calendar Quarter showing, on a country-by-country and Region-by-Region basis, the Triggered Third Party Payments, Zai's royalties payable to Third Parties on Net Sales made during such Calendar Quarter and any royalty adjustments taken by Zai pursuant to Section 9.5(b), with such detail as shall reasonably allow MacroGenics to determine the basis for such quarterly costs.

# 10.2 Submission and Payment Schedule for Products Other Than [\*\*\*] Products After Opt-In.

- (a) Reports under this Article 10 shall be due on the [\*\*\*] Calendar Day following the close of each Calendar Quarter.
- (b) Royalties (including those within the Triggered Third Party Payments) shown to have accrued by each report shall, unless otherwise specified under this Agreement, be due and payable [\*\*\*] after the date such report is due.
- 10.3 **Payment Exchange Rate**. All payments to be made by one Party to the other Party under this Agreement shall be made in US Dollars by bank wire transfer in immediately available funds to a bank account in the United States designated in writing by such other Party. For invoices that a Party shall forward to the other Party, such first Party shall use an exchange rate as published by the *Wall Street Journal* as of the close of business on the last business day of the preceding month, or such other source as the Parties may agree in writing. Each Party shall take all possible steps to ensure all payments are made to the other Party under this Agreement, including by paying from non-Territory sources.
- 10.4 **Taxes**. In the event any withholding, value added, or other tax is required to be withheld and deducted from payments by Zai pursuant to this Agreement under Applicable Laws and Regulations, notwithstanding anything to the contrary herein, Zai will make such deduction and withholding and will pay the remainder to MacroGenics, and any amounts so withheld and deducted will be remitted by Zai to the appropriate governmental authority(ies) for the account of MacroGenics and Zai will provide MacroGenics reasonable evidence of the remittance within [\*\*\*] thereof. If [\*\*\*], then [\*\*\*].

#### 10.5 Records.

- (a) **Research, Development, Manufacturing and Commercialization Activities.** Each Party shall maintain appropriate records of: (i) all research, Development, Manufacturing and Commercialization events and activities conducted by it or on its behalf related to a Product, and all costs in connection therewith, as applicable; and (ii) all information generated by it or on its behalf in connection with Development of Licensed Molecules and Products under this Agreement, in each case in accordance with such Party's usual documentation and record retention practices. Such records shall be in sufficient detail to properly reflect, in good scientific manner, all significant work done and results of studies and trials undertaken, and further shall be at a level of detail appropriate for patent and regulatory purposes. Upon the reasonable request of a Party, the other Party shall make such records available to the requesting Party. Each Party shall cause its Related Parties and Permitted Subcontractors to comply with this Section 10.5(a).
- (b) **Zai Financial Records**. Without limiting the foregoing under Section 10.5(a), Zai shall keep complete and accurate records in sufficient detail to allow MacroGenics to determine the basis for any amounts payable to or by Zai under this Agreement. At the reasonable request of MacroGenics, Zai shall make such records available to MacroGenics.
- (c) **MacroGenics Financial Records**. Without limiting the foregoing under Section 10.5(a), MacroGenics shall keep complete and accurate records in sufficient detail to allow Zai to determine the basis for any amounts payable to or by MacroGenics under this Agreement. At the reasonable written request of Zai, MacroGenics shall make such records available to Zai.
- 10.6 **Late Payments.** In the event that any payment due under this Agreement is not sent to the payee Party when due in accordance with the applicable provisions of this Article 10 [\*\*\*], the payment shall accrue interest from the date due at the prime rate as reported by Citibank N.A., plus [\*\*\*]percent ([\*\*\*]%); provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the payee Party from exercising any other rights it may have as a consequence of the lateness of any payment.
- 10.7 **Audit Rights**. Upon the written request of a Party ("**Requesting Party**") with reasonable advance notice and not more than [\*\*\*] in each Calendar Year, the other Party shall permit an independent certified public accounting firm of internationally recognized standing selected by Requesting Party and reasonably acceptable to the other Party, at its own expense, to have access during normal business hours to such records as may be reasonably necessary to verify the that the correct amounts have been paid to such Party under or in connection with this Agreement during any Calendar Year ending not more than [\*\*\*] prior to the date of such request. The accounting firm shall disclose to the Requesting Party only whether the reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Requesting Party in connection with this audit right. This right to audit shall remain in effect throughout the life of this Agreement and for a period of [\*\*\*] after the termination of this Agreement. If such accounting firm identifies a discrepancy, the other Party shall pay Requesting Party the amount of the discrepancy within [\*\*\*] of the date Requesting Party delivers to the other Party such accounting firm's written report so concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by Requesting Party unless the underpayment by the other Party exceeded [\*\*\*] percent ([\*\*\*]%) of the amount owed for such Calendar Year, in which case the other Party shall pay to Requesting Party the reasonable fees charged by such accounting firm.

10.8 **Confidentiality**. Each Party shall treat all information of the other Party subject to review under this Article 10 in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party and any applicable Related Parties, obligating it or them to retain all such information in confidence pursuant to such confidentiality agreement.

#### 11. CONFIDENTIALITY; PUBLICATION

#### 11.1 Nondisclosure Obligation

- (a) **Definition and Restrictions**. All Confidential Information disclosed by one Party to the other Party at any time, including before the Effective Date or after the expiration or termination of this Agreement, shall be maintained in confidence by the receiving Party and shall not be disclosed by the receiving Party to any Third Party or used by the receiving Party for any purpose except as set forth herein without the prior written consent of the disclosing Party, during the Term and for a period of [\*\*\*] thereafter; provided that, with respect to Confidential Information that is confidential information of a Third Party to which a Party has an obligation of confidentiality or non-use under an agreement with such Third Party, the confidentiality and non-use obligations in this Agreement shall (A) further include such additional confidentiality and non-use obligations as such Party is required to undertake with respect to such confidential information pursuant to such Third Party agreement, and (B) continue beyond such [\*\*\*] period for so long as such Party is required to maintain such confidential information as confidential pursuant to such Third Party agreement (including any MacroGenics Third Party Agreement and Zai Third Party Agreement). The following shall not be deemed Confidential Information of the disclosing Party for purposes of the restrictions set forth in this Section 11.1(a):
  - (i) Information that is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
  - (ii) Information that is or becomes part of the public domain through no wrongful act or fault on the part of the receiving Party;
  - (iii) Information that is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; and
  - (iv) Information that is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.
- (b) **Combinations**. Any combination of features or disclosures shall not be deemed to fall within the exclusions set forth in Section 11.1(a) merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.
- (c) **Permitted Disclosures**. Notwithstanding the restrictions set forth in Section 11.1(a), the receiving Party may disclose Confidential Information of the other Party to:
  - (i) governmental or other regulatory agencies in order to obtain Patents or to gain or maintain approval to conduct clinical trials or to market Products, but such disclosure may be only to the extent reasonably necessary to obtain Patents or authorizations; or

- (ii) as the receiving Party deems necessary to be disclosed, to its Affiliates, agents, consultants, or other Third Parties for the Development, Manufacture or Commercialization of Product(s), or in connection with a potential or actual licensing transaction or contractual obligation related to such Product(s) or potential or actual loan, financing or investment or acquisition, merger, consolidation or similar transaction (or for such entities to determine their interest in performing such activities or to determine their rights and obligations as a result of completing such transactions) or in order to perform its obligations or exercise its rights under this Agreement, in each case on the condition that any Third Parties, other than Regulatory Authorities, to whom such disclosures are made agree to be bound by confidentiality and non-use obligations substantially similar to those contained in this Agreement; provided that the term of confidentiality and non-use applicable to such Third Parties shall be no less than [\*\*\*] (but of shorter duration if customary given the nature of such Person (i.e., investors, lenders and banking institutions) from the date of disclosure to them, provided further, that with respect to Confidential Information of a Party that constitutes (a) a trade secret, such confidentiality and non-use obligations shall apply for so long as such information constitutes a trade secret under Applicable Laws and Regulations, or (b) confidential information of a Third Party, such confidentiality and non-use obligations shall apply for so long as such Party is required to keep such information confidential under such Third Party agreement (including any MacroGenics Third Party Agreement and Zai Third Party Agreement), but only if such Party informs the other Party in writing of such additional obligations and identifies to the other Party at the time of disclosure the information subject to such additional obligations.
- (d) **Disclosure Required by Judicial or Administrative Process.** If a Party is required by judicial or administrative process to disclose Confidential Information of the other Party that is subject to the non-disclosure provisions of this Section 11.1, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 11.1, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including obtaining an order of confidentiality, to ensure the continued confidential treatment of such Confidential Information, including, by using not less than the same level of efforts to secure such confidential treatment of such information as it would to protect its own Confidential Information of like nature from disclosure.
- (e) **Obligations Upon Termination.** Upon the termination or expiration of this Agreement, or upon the earlier request of either Party, the receiving Party shall return to the disclosing Party, all of the disclosing Party's Confidential Information, including all copies thereof, provided that the receiving Party may retain one copy for archival purposes, and provided further, that a receiving Party shall not be required to destroy electronic files containing such Confidential Information of the disclosing Party that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information, and any such retained copies shall continue to be subject to the confidentiality and non-use obligations in accordance with this Agreement.

#### 11.2 **Publication**

(a) **Publication of Results**. Zai and MacroGenics each acknowledge the other Party's interest in publishing the results of its activities under the Programs in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. The JSC shall establish procedures for review of publications related to the Collaboration Programs and License-Only Programs, ensuring that, except for disclosures permitted pursuant to Section 11.1, either Party and its employees wishing to make a publication related to work performed under this Agreement (including under a License-Only Program) shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least [\*\*\*] prior to submission for publication or for presentation. Notwithstanding the foregoing, (i) no Party may publish any results of the Parties' activities conducted under any Research Plan without the other Party's prior written consent; (ii) subject to the review procedures established by the JSC, Zai may publish any results related to any License-Only Program without MacroGenics' consent; (iii) MacroGenics shall not publish any results of the Parties' activities related to any License-Only Program without Zai's prior written consent; and (ii) no Party may publish any results of the Parties' activities related to any Collaboration Program without the other Party's prior written consent.

#### (b) Review of Publications and Presentations

- (i) The reviewing Party shall have the right (A) to propose modifications to the publication or presentation for patent reasons, trade secret reasons, or for purposes of removing the Confidential Information of the reviewing Party, or (B) to request a reasonable delay in publication or submission for presentation in order to protect trade secret or patentable information.
- (ii) If the reviewing Party requests the removal of the reviewing Party's Confidential Information or a delay, the publishing Party shall remove such Confidential Information and if requested by the reviewing Party delay submission for publication or submission for presentation for a period of [\*\*\*] to enable patent applications protecting each Party's rights in such Confidential Information to be filed in accordance with Article 14 below.
- (iii) Upon expiration of such [\*\*\*] and satisfaction of any other conditions imposed by the JSC, the publishing Party shall be free to proceed with the publication or submission for presentation.
- (iv) Upon request of the Party seeking publication, the reviewing Party shall consider expediting the time frames set forth in this Section 11.2.
- (v) If the reviewing Party requests modifications to the publication or submission for presentation, the publishing Party shall edit such publication to prevent disclosure of the Confidential Information of the reviewing Party.

# 11.3 Publicity; Use of Names

(a) **Press Releases**. The Parties shall issue the press release included in this Agreement as Exhibit E announcing the execution of this Agreement. A Party may issue any subsequent press release relating to this Agreement or activities conducted hereunder upon prior written approval of the other Party, such approval not to be unreasonably withheld or delayed; provided, however, that no approval of the other Party shall be required if a subsequent press release or securities filing solely discloses the information that (1) a milestone under this Agreement has been achieved or any payments associated therewith have been received; (2) the filing or approval of a BLA generally has occurred (provided, however, that specific dates of filing shall not be disclosed); (3) initiation of any clinical trial; and (4) commercial launch of a Product or any information that has previously been approved and disclosed as permitted by this Section 11.3(a). In the case of items (1) to (4) of the preceding sentence, the disclosing Party shall provide the other Party a copy of such proposed disclosures at least [\*\*\*] prior to the proposed release and consider in good faith any comments the other Party may make, where practicable, and in light of any reporting obligations of such disclosing Party under Applicable Laws and Regulations, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any other relevant stock exchange or governmental agency.

- (b) **No Other Use of Company Names**. Neither Party shall use the name, trademark, trade name or logo of the other Party or its employees in any publicity or news release relating to this Agreement or its subject matter without the prior express written permission of the other Party.
- (c) Approved Press Releases. In addition and notwithstanding anything to the contrary herein, (a) if the relevant text of a proposed press release has already previously been reviewed and approved for disclosure by the other Party then such text may be disclosed or republished in such proposed press release provided that the Party issuing such press release provides notice to the other Party of such press release at least [\*\*\*] prior to the issuance of such press release, where practicable, and (b) if the relevant text of a proposed public announcement such as a corporate presentation or comments to analysts or investors has already previously been reviewed and approved for disclosure by the other Party (whether in the form of an approved press release or prior approved presentation materials, Q&A script or the like) then such text may be included in such proposed public announcement (but not a press release) without resubmission and review by the other Party.

# (d) Existence of Agreement

(i) **No Disclosure**. Neither Party shall disclose the existence or terms of this Agreement pursuant to a press release or otherwise except as provided in this Section 11.3(d).

# (ii) Permitted Disclosures

- (A) Notwithstanding the terms of this Article 11, either Party shall be permitted to disclose the existence and terms of this Agreement and the conduct of the Programs under this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with Applicable Laws and Regulations, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any other relevant stock exchange or governmental agency. The disclosing Party shall take reasonable and lawful actions to avoid or minimize the degree of such disclosure.
- (B) Either Party may also disclose the existence and terms of this Agreement to its attorneys, accountants and advisors, and to potential acquirors, in connection with a potential acquisition or other change of control transaction and to existing and potential investors or lenders of such Party, as a part of their due diligence investigations, or to potential licensees or to potential and current permitted assignees in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement and to use such confidential information solely for the purpose of the contemplated transaction.
- (C) Each Party may also disclose the existence and terms of this Agreement pursuant to transactions related to the research, Development, Manufacture or Commercialization or exploitation of a Licensed Molecule or any Product, in each case under an agreement to keep the terms of this Agreement confidential under terms of confidentiality and non-use substantially similar to the terms contained in this Agreement and to use such confidential information solely for the purpose of the contemplated transaction.

## 12. REPRESENTATIONS AND WARRANTIES

- 12.1 **Representations and Warranties of MacroGenics**. MacroGenics represents and warrants to Zai that, as of the Effective Date, and covenants, that:
- (a) it is duly organized and validly existing under the Applicable Laws and Regulations of the jurisdiction of its incorporation and has the full right, power and authority to enter into this Agreement, to perform the Programs, and to grant the licenses contemplated under Article 3;
- (b) this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and fulfillment of its obligations and performance of its activities hereunder do not conflict with, violate, or breach or constitute a default under any contractual obligation or court or administrative order by which MacroGenics is bound, nor violate any material Application Laws and Regulations;
- (c) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by MacroGenics as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;
- (d) it is not aware of any action, suit or inquiry or investigation instituted by any Person which could question or threaten the validity of this Agreement;
- (e) in the conduct of any activities under this Agreement, it shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws and Regulations, including all export control, anti-corruption and anti-bribery laws and regulations, and shall not cause Zai's Indemnitees to be in violation of any Applicable Laws and Regulations or otherwise cause any reputational harm to Zai;
- (f) it Controls the right, title and interest in and to the MacroGenics Platform, MacroGenics Licensed Patents, MacroGenics Licensed Know-How and MacroGenics Licensed Trademarks, and has the right to grant to Zai the licenses that it purports to grant hereunder;
- (g) it has not granted, and shall not grant during the Term, any Third Party rights and has not taken, and shall not take during the Term, any other action which would be inconsistent or interfere with Zai's rights hereunder, including Zai's [\*\*\*] Profit Share Option;
- (h) the MacroGenics Platform, MacroGenics Licensed Patents, MacroGenics Licensed Know-How and MacroGenics Licensed Trademarks are not subject to any other Third Party agreements or existing royalty or other payment obligations to any Third Party;
- (i) it is the sole and exclusive owner of the entire right, title and interest in the MacroGenics Licensed Patents. All MacroGenics Licensed Patents owned by MacroGenics as of the Effective Date are listed in Exhibit A. All MacroGenics Licensed Patents are (i) subsisting and in good standing and (ii) being diligently prosecuted in the respective patent offices in accordance with Applicable Laws and Regulations, and have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment. To its knowledge after due investigation, the issued Patents in the MacroGenics Licensed Patents are valid and enforceable;
- (j) to its knowledge, no Third Party is infringing or misappropriating any MacroGenics Platform, MacroGenics Licensed Technology or MacroGenics Licensed Trademarks;

- (k) there is no action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing by any Third Party that challenges or threatens the validity, enforceability or MacroGenics' Control of any of the MacroGenics Licensed Patents or MacroGenics Licensed Trademarks. In the event that MacroGenics receives notice of any such action or proceeding, it shall notify Zai promptly in writing;
- (l) there is no action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing by any Third Party (and it is not aware of any grounds therefor) that alleges the use of the MacroGenics Platform, MacroGenics Licensed Technology or MacroGenics Licensed Trademarks or the development, manufacture, commercialization, and use of the Products would infringe intellectual property rights or misappropriate any Know-How of any Third Party (and it has not received any notice alleging such an infringement). In the event that MacroGenics receives notice of any such action or proceeding, it shall notify Zai promptly in writing;
- (m) to MacroGenics knowledge, no material breach of confidentiality has been committed by any Person with respect to the MacroGenics Licensed Know-How that is maintained as a trade secret and MacroGenics has used reasonable measures to protect the confidentiality thereof;
- (n) it has obtained or shall obtain written agreements from each of its employees, consultants and contractors who perform any activities pursuant to this Agreement, which agreements shall obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement; and
- (o) neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (i) debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (ii) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (iii) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (iv) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. MacroGenics further covenants that if, during the Term, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, MacroGenics will promptly notify Zai. The foregoing sentence will survive termination or expiration of this Agreement.
  - 12.2 **Representations and Warranties of Zai**. Zai represents and warrants to MacroGenics that, as of the Effective Date:
- (a) it is duly organized and validly existing under the Applicable Laws and Regulations of the jurisdiction of its incorporation and has the full right, power and authority to enter into this Agreement, to perform the Programs, and to grant the licenses contemplated under Article 3;
- (b) this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and fulfillment of its obligations and performance of its activities hereunder do not conflict with, violate, or breach or constitute a default under any contractual obligation or court or administrative order by which Zai is bound, nor violate any material Application Laws and Regulations;
- (c) all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by Zai as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained;

(d)	the Zai Platform, Zai Licensed Patents and Zai Licensed Know-How are not subject to any other Third Party agreements or
existing royalty or othe	payment obligations to any Third Party;

- (e) it is not aware of any action, suit or inquiry or investigation instituted by any Person which questions or threatens the validity of this Agreement;
- (f) in the conduct of any activities under this Agreement, it shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws and Regulations, including all export control, anti-corruption and anti-bribery laws and regulations, and shall not cause MacroGenics' Indemnitees to be in violation of any Applicable Laws and Regulations or otherwise cause any reputational harm to MacroGenics
- (g) it Controls the right, title and interest in and to the Zai Platform, Zai Licensed Patents and Zai Licensed Know-How, and has the right to grant to MacroGenics the licenses that it purports to grant hereunder;
- (h) it has not granted, and shall not grant during the Term, any Third Party rights and has not taken, and shall not take during the Term, any other action which would be inconsistent or interfere with MacroGenics rights hereunder;
  - (i) to its knowledge, no Third Party is infringing or misappropriating any Zai Platform or Zai Licensed Technology;
- (j) there is no action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing by any Third Party (and it is not aware of any grounds therefor) that alleges the use of the Zai Platform or Zai Licensed Technology would infringe intellectual property rights or misappropriate any Know-How of any Third Party (and it has not received any notice alleging such an infringement). In the event that Zai receives notice of any such action or proceeding, it shall notify MacroGenics promptly in writing;
- (k) it has obtained or shall obtain written agreements from each of its employees, consultants and contractors who perform any activities pursuant to this Agreement, which agreements shall obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement; and
- (1) neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (i) debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (ii) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (iii) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (iv) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Zai further covenants that if, during the Term, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, Zai will promptly notify MacroGenics. The foregoing sentence will survive termination or expiration of this Agreement.
- 12.3 **Covenant**. Each Party hereby covenants to the other Party that it will not, and will not permit its Affiliates, (Sub)licensees or anyone acting on its or their behalf to, grant or otherwise convey to any Third Party any rights that would interfere or be inconsistent with such other Party's rights hereunder.

12.4 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN BY OR ON BEHALF OF A PARTY. ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

# 13. INDEMNIFICATION

- 13.1 **By Zai.** Zai agrees to indemnify and hold harmless MacroGenics, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**MacroGenics Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Losses**") first arising after the Effective Date to the extent arising from (a) activities by Zai or any of its Related Parties, or any Zai Representatives with respect to the research, Development, use, Manufacture, Commercialization, import, distribution, or sale of Licensed Molecules or Products or the exercise of their rights or performance of their obligations related thereto, (b) the use by Zai or any of its Related Parties, or Permitted Subcontractors of the MacroGenics Licensed Patents or MacroGenics Licensed Know-How pursuant to this Agreement, (c) the negligence, illegal conduct or willful misconduct of Zai, or (d) Zai's breach of this Agreement; provided, however, that Zai's obligations pursuant to this Section 13.1 will not apply to the extent such Losses result from Losses for which MacroGenics has an obligation to indemnify Zai pursuant to Section 13.2.
- 13.2 **By MacroGenics**. MacroGenics agrees to indemnify and hold harmless Zai, its Affiliates, and their directors, officers, employees and agents (individually and collectively, the "**Zai Indemnitee(s)**") from and against all Losses to the extent arising from (a) activities by MacroGenics or any of its Related Parties or Permitted Subcontractors or MacroGenics Representatives with respect to the research, Development, use, Manufacture, Commercialization or sale of Licensed Molecules or Products or the exercise of their rights or performance of their obligations related thereto, (b) the negligence, illegal conduct or willful misconduct of MacroGenics, (c) the use by MacroGenics or any of its Related Parties or Permitted Subcontractors of the Zai Licensed Patents or Zai Licensed Know-How pursuant to this Agreement, or (d) MacroGenics' breach of this Agreement; provided, however, that MacroGenics' obligations pursuant to this Section 13.2 will not apply to the extent such Losses result from Losses for which Zai has an obligation to indemnify MacroGenics pursuant to Section 13.1.
- 13.3 **Defense**. If any such claims or actions are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnitee, provided that the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such claim or action, subject to the terms of this Section 13.
- 13.4 **Settlement**. The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (a) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, provided such settlement would not subject the Indemnitee to an injunction or otherwise adversely impact any of the Indemnitee's rights under this Agreement or constitute an admission of guilt or wrongdoing by the Indemnitee, or (b) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld. The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

- 13.5 **Notice**. The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Section 13.1 or Section 13.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.
- 13.6 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR FOR LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.6 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 13, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11.

#### 14. INTELLECTUAL PROPERTY

## 14.1 Ownership of Intellectual Property

- (a) **Ownership of current MacroGenics IP**. As between MacroGenics and Zai, MacroGenics shall remain the sole and exclusive owner of all MacroGenics Licensed Patents, MacroGenics Licensed Trademarks and MacroGenics Licensed Know-How that exist as of the Effective Date
- (b) **Ownership of current Zai IP**. As between Zai and MacroGenics, Zai shall remain the sole and exclusive owner of all Zai Licensed Patents and Zai Licensed Know-How that exists as of the Effective Date.
- (c) MacroGenics Improvement IP. MacroGenics shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting the Research Plan for any Licensed Molecule or Product or in the course of either Party conducting Development, Manufacturing or Commercialization of a Collaboration Molecule or Collaboration Product, in each case that is solely and specifically related to the MacroGenics Platform, together with all intellectual property rights therein ("MacroGenics Improvement IP"). Zai 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 MacroGenics all of its and their right, title and interest in and to MacroGenics Improvement IP. Upon MacroGenics's written request, Zai 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 Laws and Regulations, or as MacroGenics may reasonably request to effectuate and confirm the vesting of all right, title and interest in and to the MacroGenics Improvement IP in MacroGenics.
- (d) **Zai Improvement IP**. Zai shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting the Research Plan for a Program for any Licensed Molecule or Product or in the course of either Party conducting Development, Manufacturing or Commercialization of a Collaboration Compound or Collaboration Product, in each case that is solely and specifically related to the Zai Platform, together with all intellectual property rights therein ("**Zai Improvement IP**"). MacroGenics 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 Zai all of its and their right, title and interest in and to Zai Improvement IP. Upon Zai's written request, MacroGenics 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 Laws and Regulations, or as Zai may reasonably request to effectuate and confirm the vesting of all right, title and interest in and to the Zai Improvement IP.

- (e) Zai License-Only IP. Subject to Section 14.1(c) and Section 14.1(f), Zai shall own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting Development, Manufacturing or Commercialization of any License-Only Molecule or License-Only Product and any other activities within the License-Only Programs, together with all intellectual property rights therein ("Zai License-Only IP"); provided that, notwithstanding the foregoing, [\*\*\*]. Subject to this Section 14.1(e), MacroGenics 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 Zai all of its and their right, title and interest in and to Zai License-Only IP. Upon Zai's written request, MacroGenics 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 Laws and Regulations, or as Zai may reasonably request to effectuate and confirm the vesting of all right, title and interest in and to the Zai License-Only in Zai.
- (f) **Research IP**. Subject to the terms of this Agreement, and other than MacroGenics Improvement IP and Zai Improvement IP, MacroGenics and Zai shall jointly own all data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting Research Plan Activities ("**Research IP**"), with each Party owning an undivided half interest and the right to exploit without the duty of accounting or seeking consent from the other Party to the extent to be permitted under Applicable Laws and Regulations.
- (g) **Ownership of All Other IP.** Subject to the terms of this Agreement and other than MacroGenics Improvement IP, Zai Improvement IP, Zai License-Only IP and Research IP, ownership of data, results and inventions, whether patentable or not, conceived or reduced to practice in the course of conducting Development, Manufacture or Commercialization of a Licensed Molecule or Product shall be based upon inventorship, as determined in accordance with U.S. patent law.
- (h) **Jointly Owned IP**. Each Party shall promptly disclose any Joint Owned IP developed by or on behalf of it to the other Party. Each Party 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 the other Party an undivided half interest of its and their right, title and interest in and to Jointly Owned IP. Upon either Party's written request, the other Party 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 Laws and Regulations, or as the requesting Party may reasonably request to effectuate and confirm the vesting of such right, title and interest in and to the Jointly Owned IP.

# 14.2 Patent and Trademark Filing, Prosecution and Maintenance

(a) **Overall Strategy**. The JSC shall establish an overall strategy for the filing, prosecution and maintenance of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks, Jointly Owned Patents and Zai Licensed Patents in the Territory.

#### (b) Prosecution

- (i) **Solely Owned Patents General**. Subject to Section 14.2(b)(ii) and Section 14.2(b)(iii), the responsibility for Patent Prosecution and Trademark Prosecution related to a Patent or Trademark that is within the MacroGenics Licensed Patents, MacroGenics Licensed Trademarks and the Zai Licensed Patents that is owned solely by a Party shall be the responsibility of such Party. Zai has the sole right to prepare, file, prosecute, maintain or abandon any Patent that is within the Zai License-Only IP.
- (ii) MacroGenics Product-Specific Patents for License-Only Products. Zai shall have the first right (but not the obligation), at its election and cost and expense, to file, prosecute and maintain, in the name of MacroGenics, (A) MacroGenics Product-Specific Patents, and (B) MacroGenics Licensed Trademarks for a License-Only Product. In the event that Zai elects not to undertake the Patent Prosecution for such MacroGenics Product-Specific Patents, Zai shall notify MacroGenics at least [\*\*\*] before any such patent rights would become abandoned or otherwise forfeited, and MacroGenics shall have the right (but not the obligation), at its sole cost and expense, to undertake the Patent Prosecution of such MacroGenics Product-Specific Patents. Thereafter, any MacroGenics Product-Specific Patents that are the subject of such opt-out notice by Zai shall cease to be MacroGenics Licensed Patents for all purposes under this Agreement, including for purposes of the license granted by MacroGenics to Zai under Section 3.1. The right to assume Patent Prosecution of a MacroGenics Product-Specific Patent shall not apply in the event such a patent application would become abandoned or otherwise forfeited as a result of the prosecuting Party (x) discontinuing Patent Prosecution of such patent application but also filing a continuation application claiming the same invention or (y) settling an opposition to obtain a license to a competing patent.
- (iii) Zai Product-Specific Patents for Collaboration Products. MacroGenics shall have the first right (but not the obligation), at its election and cost and expense, to file, prosecute and maintain, in the name of Zai, Zai Product-Specific Patents within the scope of the exclusive license granted by Zai to MacroGenics pursuant to Section 3.2. In the event that MacroGenics elects not to undertake the Patent Prosecution for such Zai Product-Specific Patents, MacroGenics shall notify Zai at least [\*\*\*] before any such patent rights would become abandoned or otherwise forfeited, and Zai shall have the right (but not the obligation), at its sole cost and expense, to undertake the Patent Prosecution of such Zai Product-Specific Patents. Thereafter, any Zai Product-Specific Patents that are the subject of such opt-out notice by MacroGenics shall cease to be Zai Licensed Patents for all purposes under this Agreement, including for purposes of the license granted by Zai to MacroGenics under Section 3.2. The right to assume Patent Prosecution of a Zai Product-Specific Patent shall not apply in the event such a patent application would become abandoned or otherwise forfeited as a result of the prosecuting Party (A) discontinuing Patent Prosecution of such patent application but also filing a continuation application claiming the same invention or (B) settling an opposition to obtain a license to a competing patent.
- (iv) **Jointly Owned Patents**. Subject to Section 14.2(b)(ii) and Section 14.2(b)(iii), MacroGenics shall be responsible for undertaking the Patent Prosecution with respect to Patents jointly owned by the Parties (the "**Jointly Owned Patents**"), (i) with respect to Jointly Owned Patents generated or developed under a Collaboration Program, [\*\*\*], and (ii) with respect to Jointly Owned Patents generated or developed under a License-Only Program, at Zai's sole cost and expense. With respect to Jointly Owned Patents, in the event that MacroGenics elects not to undertake the Patent Prosecution for the Jointly Owned Patents, MacroGenics shall notify Zai at least [\*\*\*] before any such patent rights would become abandoned or otherwise forfeited, and Zai shall have the right (but not the obligation), to undertake the Patent Prosecution of such Jointly Owned Patents and become the prosecuting Party therefor. The right to assume Patent Prosecution of a Jointly Owned Patent shall not apply in the event such a patent application would become abandoned or otherwise forfeited as a result of the prosecuting Party (A) discontinuing Patent Prosecution of such patent application but also filing a continuation application claiming the same invention or (B) settling an opposition to obtain a license to a competing patent.

- (v) **Prosecuting Party Responsibilities**. The prosecuting Party shall keep the JSC and the other Party informed of the status of all matters affecting Patent Prosecution and Trademark Prosecution of MacroGenics Product-Specific Patents, MacroGenics Licensed Trademarks, Jointly Owned Patents, and the Zai Product-Specific Patents, including providing a copy of all patent applications filed hereunder and any material correspondence from or with any governmental authorities (including the applicable patent office) to the IP Coordinator and the other Party in sufficient time to allow for review and comment by the non-prosecuting Party, and timely consulting with the non-prosecuting Party and its patent counsel on the strategy and content of submissions to such governmental authorities in advance of any submissions. Timely advice and suggestions of the non-prosecuting Party and its patent counsel in connection with such filing.
- (vi) **IP Coordinators; Disputes**. Each Party shall designate one (1) qualified and experienced intellectual property professional to serve as that Party's primary contact and coordinator regarding Patent Prosecution and Trademark Prosecution within this Agreement (each, an "**IP Coordinator**"). Each Party may replace its IP Coordinator with an alternative representative at any time with prior written notice to the other Party. The IP Coordinators shall be responsible for facilitating information exchange and discussion between the Parties regarding Patent Prosecution and Trademark Prosecution under this Agreement. Each Party will be responsible for all of its own costs with respect to its IP Coordinator. Any dispute regarding Patent Prosecution and Trademark Prosecution of MacroGenics Licensed Patents, MacroGenics Licensed Trademarks, Zai Product-Specific Patent or Jointly Owned Patents that cannot be resolved by intellectual property counsel of the Parties shall be resolved by the IP Coordinators, and the IP Coordinator of the applicable prosecuting Party shall have final say with respect to any such disputes.
- (vii) **Third Party Agreements**. Each Party's rights and obligations under this Section 14.2 with respect to MacroGenics Licensed Patents and Zai Licensed Patents are secondary to and shall be subject to any Third Party rights and obligations under the applicable MacroGenics Third Party Agreements and Zai Third Party Agreements.
- (c) **Patent and Trademark Invalidations**. The JSC shall decide whether and how to undertake activities intended to invalidate pending or issued Third Party Patents in the Territory that Cover the composition, use or manufacture of Licensed Molecules or Products.
- (d) **Costs of Patent and Trademark Prosecution**. Subject to Section 14.2(b)(iv), all out-of-pocket costs for Patent Prosecution and Trademark Prosecution of any Patent or Trademark shall be solely incurred by and the sole responsibility of the prosecuting Party, except that (a) if MacroGenics is conducting the Patent Prosecution of the Zai Product-Specific Patents pursuant to Section 14.2(b)(iii), Zai shall be responsible for the out-of-pocket costs for Patent Prosecution of such Zai Product-Specific Patents in the Collaboration Territory, and (b) if Zai assumes the responsibility to conduct the Patent Prosecution of such Zai Product-Specific Patents pursuant to Section 14.2(b)(iii), the costs of such activities conducted by or on behalf of Zai shall be borne solely by Zai. Notwithstanding the foregoing, all such costs incurred by the Parties with respect to the [\*\*\*] Program after the Opt-In shall be [\*\*\*].

- (e) **Patent and Trademark Prosecution Cooperation**. With respect to all Patent Prosecution and Trademark Prosecution related to pending or issued Patents and Trademarks included in Jointly Owned Patents, MacroGenics Licensed Patents, MacroGenics Licensed Trademarks, MacroGenics Product-Specific Patents, or Zai Product-Specific Patents, each Party shall:
  - (i) execute all further instruments to document their respective ownership consistent with this Agreement as reasonably requested by the other Party;
  - (ii) make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the appropriate Party hereunder to undertake its Patent Prosecution and Trademark Prosecution responsibilities;
    - (iii) cooperate, if necessary and appropriate, with the other Party in gaining Patent and Trademark term extensions; and
  - (iv) endeavor in good faith to coordinate its efforts under this Agreement with the other Party to minimize or avoid interference with the Patent Prosecution and Trademark Prosecution of the other Party's Patents and Trademarks.

#### 14.3 Enforcement

(a) **Notice**. Each Party shall promptly provide, but in no event later than [\*\*\*], the other with written notice reasonably detailing any known or alleged infringement of any Patent or Trademark owned by the other Party and subject to a license under this Agreement. The notifying Party will provide the other Party with all evidence available to it supporting its belief of such infringement.

## (b) Enforcement of Intellectual Property Rights

- (i) Except as expressly set forth in this Section 14.3, the sole owner (as between the Parties) of a Patent, Trademark, Know-How or Confidential Information shall have the exclusive right to institute and direct legal proceedings against any Third Party believed to be infringing such Patent or Trademark or misappropriating or otherwise violating such Know-How or Confidential Information.
- (ii) Zai shall have the initial right (but not the obligation) to institute and direct legal proceedings in the applicable Territory against any Third Party believed to be infringing (A) Collaboration Product-specific claims within other MacroGenics Licensed Patents (in each case within the scope of the exclusive license granted by MacroGenics to Zai under this Agreement) or Jointly Owned Patents, with respect to the [\*\*\*] Program before the Opt-In or MGNX Option Program in the applicable Collaboration Territory, (B) Collaboration Product-specific claims within other MacroGenics Licensed Patents (in each case within the scope of the exclusive license granted by MacroGenics to Zai under this Agreement) or Jointly Owned Patents, with respect to the [\*\*\*] Program after the Opt-In in the [\*\*\*] Opt-In Territory, or (C) (1) MacroGenics Product-Specific Patents and (2) License-Only Product-specific claims within MacroGenics Licensed Patents or Jointly Owned Patents, in the License-Only Territory. Zai agrees to discuss the foregoing in good faith with MacroGenics. If Zai (x) does not initiate any action against such violation of any such Patent or claim, including by commencement of a lawsuit against the accused person if necessary or obtain settlement thereof (in accordance with this Agreement), within [\*\*\*] after receiving notice of such infringement of such Patent or claim, or (y) if such action is initiated within such period, ceases to pursue or withdraws from such action, then in each case ((x) and (y)) MacroGenics shall be entitled (but shall not be obligated) to take all actions reasonably necessary to abate such violation in the applicable Territory, including commencement of a lawsuit against the accused Third Party if necessary.

- (iii) MacroGenics shall have the first right (but not the obligation) to institute and direct legal proceedings against any Third Party believed to be infringing (1) Zai Product-Specific Patents, Collaboration Product-specific claims within other Zai Licensed Patents (each within the scope of the exclusive license granted by Zai to MacroGenics under this Agreement) or Jointly Owned Patents, with respect to the [\*\*\*] Program before the Opt-In or MGNX Option Program outside the applicable Collaboration Territory, or (2) Zai Product-Specific Patents, Collaboration Product-specific claims within other Zai Licensed Patents (each within the scope of the exclusive license granted by Zai to MacroGenics under this Agreement), or Jointly Owned Patents, with respect to the [\*\*\*] Program after the Opt-In in the ROW. MacroGenics agrees to discuss the foregoing in good faith with Zai. If MacroGenics (x) does not initiate any action against such violation of any such Patent or claim, including by commencement of a lawsuit against the accused person if necessary or obtain settlement thereof (in accordance with this Agreement), within [\*\*\*] after receiving notice of such infringement of such Patent or claim, or (y) if such action is initiated within such period, ceases to pursue or withdraws from such action, then in each case ((x) and (y)) Zai shall be entitled (but shall not be obligated) to take all actions reasonably necessary to abate such violation outside the applicable Territory, including commencement of a lawsuit against the accused Third Party if necessary.
- (iv) All amounts recovered from enforcement of any such rights by either Party in accordance with Section 14.3(b)(ii) or 14.3(b)(iii) relating to the intellectual property licensed under this Agreement shall be first used to reimburse each Party's costs and expenses incurred in connection with such action, and any remainder of such recovery, other than amounts recovered as lost profits, shall be (A) retained by Zai if Zai is the Party instituting the action, provided that any remainder retained by Zai shall be treated as Net Sales and shall be subject to Zai's royalty payment obligations at the applicable rate specified in Section 9.5 to the extent such action is related to any Product that is subject to royalty payments pursuant to Section 9.5; (B) shared between MacroGenics and Zai equally if MacroGenics is the Party instituting the action during the Term in the Territory where MacroGenics has the first right to enforce, or retained by MacroGenics if MacroGenics is the Party instituting the action during the Term in the Territory where MacroGenics exercised its backup right to enforce; and (C) MacroGenics if MacroGenics is the Party instituting the action with respect to a Zai Product-Specific Patent outside the applicable Territory or Collaboration Product-specific claims within Zai Licensed Patents outside the applicable Territory (x) during the Term or (y) after the Term and MacroGenics has exercised its option under Section 16.8(a)(iv) or Section 16.8(b)(ii), provided that any remainder retained by MacroGenics shall be treated in the same as Net Sales were treated during the Term and shall be subject to MacroGenics royalty payment obligations or Third Party Triggered Payments, to the extent applicable, at the applicable rate specified in Section 16.8(a)(iv) or Section 16.8(b)(ii). Notwithstanding the foregoing, any costs and expenses incurred by the Parties or amounts recovered from enforcement with respect to the [\*\*\*] Program after the Opt-In pursuant to this Section 14.3(b)(iv) [\*\*\*].
- (c) **Cooperation in Enforcement Proceedings.** For any action by a Party pursuant to subsection (b) above, in the event that such Party is unable to initiate or prosecute such action solely in its own name, the other Party shall join such action voluntarily and shall execute all documents necessary for such Party to initiate, prosecute and maintain such action. If either Zai or MacroGenics initiates an enforcement action pursuant to Section 14.3(b), then the other Party shall cooperate to the extent reasonably necessary and at the first Party's sole expense (except for the expenses of the non-controlling Party's counsel, if any). Upon the reasonable request of the Party instituting any such action, such other Party shall join the suit and can be represented in any such legal proceedings using counsel of its own choice. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof.

(d) **Status; Settlement**. The Parties shall keep each other informed of the status of and of their respective activities regarding any enforcement action pursuant to Section 14.3(b). Neither Party shall settle any litigation or legal proceeding (i) in the Territory to enforce MacroGenics Licensed Patents against a Third Party selling a Product or MacroGenics Licensed Trademarks without the other Party's written authorization or (ii) outside the Territory to enforce Zai Licensed Patents against a Third Party selling a Product without the other Party's written authorization. Zai will not enter into any settlement of any action described in this Section 14.3 that admits to the invalidity, unpatentability, narrowing of scope or unenforceability of the MacroGenics Licensed Patents or the Jointly Owned Patents in any manner, incurs any financial liability on the part of MacroGenics will not enter into any settlement of any action described in this Section 14.3 that admits to the invalidity, unpatentability, narrowing of scope or unenforceability of the Zai Licensed Patents or the Jointly Owned Patents in any manner, incurs any financial liability on the part of Zai or requires an admission of liability, wrongdoing or fault on the part of Zai, in each case without Zai's prior written consent.

## 14.4 **Defense**

- (a) **Notice of Allegations**. Each Party shall notify the other in writing of any allegations it receives from a Third Party that the manufacture, production, use, development, sale, offer for sale, import or distribution of any Product or practice of any MacroGenics Licensed Technology or Zai Licensed Patents or Zai Licensed Know-How licensed by a Party under this Agreement or Jointly Owned Patents infringes the intellectual property rights of such Third Party in the Territory or with respect to the Zai Licensed Patents, Zai Licensed Know-How or Jointly Owned Patents outside the Territory. Such notice shall be provided promptly, but in no event after more than [\*\*\*], following receipt of such allegations.
- (b) **Notice of Suit.** In the event that a Party receives notice that it or any of its Affiliates have been individually or collectively named as a defendant (or defendants) in a legal proceeding by a Third Party alleging infringement of a Third Party's Patents issued (i) in the Territory as a result of the manufacture, production, use, development, sale, offer for sale, import or distribution of Products or any MacroGenics Licensed Technology or Zai Licensed Technology licensed by a Party under this Agreement or Jointly Owned Patents, or (ii) outside the Territory as a result of the practice of any Zai Licensed Technology or Jointly Owned Patents, such Party shall immediately notify the other Party in writing and in no event notify such other Party later than [\*\*\*] after the receipt of such notice. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Each Party shall assert and not waive the joint defense privilege with respect to all communications between the Parties reasonably the subject thereof. In such event, the Parties shall agree how best to mitigate or control the defense of any such legal proceeding; provided however, that if either Party or any of its Affiliates have been individually named as a defendant in a legal proceeding relating to the alleged infringement of a Third Party's issued Patents in the Territory as a result of the manufacture, production, use, development, sale or distribution of Products, the other Party shall be allowed to join in such action, at its own expense.
- (c) **Status; Settlement.** The Parties shall keep each other informed of the status of and of their respective activities regarding any litigation or settlement thereof initiated by a Third Party as contemplated under Section 14.4(a) or Section 14.4(b); provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this Section 14.4(c) may be undertaken by a Party without the consent of the other Party which consent shall not be unreasonably withheld, conditioned or delayed.

## 15. **DISPUTE RESOLUTION**

- 15.1 **Exclusive Dispute Resolution Mechanism**. The Parties agree that the procedures set forth in this Article 15 shall be the exclusive mechanism for resolving any Dispute between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder that is not resolved through good faith negotiation between the Parties. For the avoidance of doubt, this Article 15 shall not apply to any decision with respect to which a Party has final decision-making authority hereunder. Any Dispute, including Disputes that may involve the parent company, subsidiaries, or Affiliates under common control of any Party, shall be resolved in accordance with this Article 15.
- 15.2 **Resolution by Executive Officers**. Except as otherwise provided in this Article 15, in the event of any Dispute, either Party may, by written notice to the other Party, refer the Dispute to the Executive Officer of each Party for attempted resolution by good faith negotiation within [\*\*\*] after such notice is received (unless otherwise agreed by the Parties). Each Party may, in its discretion, seek resolution of any and all Disputes that are not resolved under this Section 15.2 in accordance with Section 15.3.
- 15.3 **Arbitration**. If the Executive Officers of the Parties fail to resolve (a) the Dispute pursuant to Section 15.2 or (b) a Deadlock pursuant to Section 2.2(c), and a Party desires to pursue resolution of such Dispute or Deadlock, such Dispute or Deadlock shall be referred to and finally resolved by arbitration in accordance with the International Chamber of Commerce Rules ("**ICC Rules**") for the time being in force, which rules are deemed incorporated by reference in this clause. The seat of the arbitration shall be in New York, New York, the United States, and the arbitration tribunal shall consist of three arbitrators, of whom each Party shall designate one in accordance with the appointment procedures provided in the ICC Rules and the chairs shall be selected by the tribunal in accordance the ICC Rules. The language of the arbitration shall be English. Notwithstanding the foregoing or anything to the contrary in this Agreement, (a) if any matter is within the scope of the JSC's authority, the provisions of Section 2.2(c) will initially apply with respect to such matter; and (b) if this Agreement expressly provides that such matter is subject to a Party's discretion or a Party's sole or final decision-making authority (including the matters set forth in Sections 2.2(c)(i) and 2.2(c)(ii)), such matter shall not be subject to dispute resolution under this Section 15.3 and shall be finally determined by such Party in accordance with the terms of this Agreement.
- 15.4 **Costs of Dispute Resolution**. Each Party shall be solely responsible for the costs it incurs to resolve a Dispute except for the costs of engaging arbitrators which shall be [\*\*\*].

#### 16. TERMS AND TERMINATION

16.1 **Term.** Unless earlier terminated, this Agreement shall continue in effect, on a Program-by-Program and country-by-country or Region-by-Region basis, until the expiration of the applicable Royalty Term ("**Term**"), except that, with respect to the [\*\*\*] Program after the Opt-In, this Agreement shall continue in effect until the expiration of all payment obligations of each Party under this Agreement. Upon the expiration (but not early termination) of this Agreement with respect to a Program (other than the [\*\*\*] Program after the Opt-In), on a country-by-country or Region-by-Region basis, the licenses granted hereunder by MacroGenics to Zai shall become fully paid-up, royalty-free, irrevocable and perpetual.

16.2 **Termination for Cause**. This Agreement may be terminated in its entirety or on a Program-by-Program basis at any time during the Term upon written notice by either Party (the "**Non-Breaching Party**") if the other Party (the "**Breaching Party**") is in material breach of this Agreement and, in each case, has not cured such breach within [\*\*\*] after notice requesting cure of the breach (other than for non-payment which shall be cured within [\*\*\*]. Notwithstanding the foregoing, in the event there is a good faith dispute as to whether a material breach exists, the dispute shall be resolved pursuant to Section 15.3. During the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. If (a) as a result of the application of such dispute resolution procedures, the Breaching Party is determined to be in material breach of one (1) or more of its obligations under this Agreement, and (b) the Breaching Party fails to complete the actions specified by such adverse ruling to cure such material breach in accordance with any procedures or timeframes established by the tribunal, then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

#### 16.3 **Termination for Convenience**.

- (a) At any time after (i) the second (2nd) anniversary of the Effective Date with respect to the [\*\*\*] Program ([\*\*\*]), or any of the License-Only Programs, or (ii) the fourth (4th) anniversary of the Effective Date with respect to the MGNX Option Program, Zai may terminate this Agreement (A) in its entirety, (B) on a Program-by-Program basis, or (C) solely with respect to the [\*\*\*], in each case (i)-(iii) for any or no reason upon ninety (90) days' written notice to MacroGenics.
- (b) At any time after the second (2<sup>nd</sup>) anniversary of the Effective Date with respect to the [\*\*\*] Program [\*\*\*], Zai may terminate this Agreement with respect to the [\*\*\*] Program for any or no reason upon one hundred and eighty (180) days' written notice to MacroGenics.

## 16.4 Termination for Safety and End of Global Development.

- (a) MacroGenics may terminate this Agreement on a Collaboration Product-by- Collaboration Product basis upon ninety (90) days' written notice if a Major Safety Issue has occurred with respect to a Collaboration Product (other than any [\*\*\*] Product after the Opt-In) before First Commercial Sale of the Product in the Territory and MacroGenics, its Affiliates and other licensees have all discontinued the global Development, Manufacturing and Commercialization activities with respect to such Collaboration Product and announced such discontinuation through a press release or other public announcement; provided that such written notice shall set forth with reasonably details the basis of such Major Safety Issue. [\*\*\*].
- (b) With respect to any [\*\*\*] Product after the Opt-In, either Party may terminate this Agreement pursuant to the procedures set forth in Section 16.4(a); provided that (i) [\*\*\*] and (ii) [\*\*\*].

- 16.5 **Termination for Bankruptcy**. This Agreement may be terminated in its entirety, to the extent permitted by the Applicable Laws and Regulations, by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding, such right to terminate will only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within [\*\*\*] after the filing thereof.
- Regulations of a particular jurisdiction in the Territory, MacroGenics may terminate this Agreement (other than with respect to the [\*\*\*] Program after the Opt-In) upon [\*\*\*]' prior written notice to Zai if Zai, its Affiliates, or Sublicensees, individually or in association with any other person or entity, commences a legal action challenging the validity, enforceability or scope of any MacroGenics Licensed Patent in a court or other governmental agency of competent jurisdiction, including a reexamination or opposition proceeding; provided that if (i) Zai or its Affiliates, or Sublicensees withdraws such legal action within such [\*\*\*]' notice period or (ii) with respect to a such interference, opposition or challenge brought by a Sublicensee, if the applicable Sublicense is terminated within such [\*\*\*]' notice period, then MacroGenics shall not have the right to terminate this Agreement under this Section 16.6.
- 16.7 **Termination for Collaboration Program Cessation**. On a Collaboration Program-by- Collaboration Program basis (other than the [\*\*\*] Program after the Opt-In), [\*\*\*], if [\*\*\*] under a Collaboration Program, in each case, in the Collaboration Territory for [\*\*\*] other than because of (a) any [\*\*\*], (b) any [\*\*\*], (c) any [\*\*\*], or (d) any [\*\*\*]shall have the right to terminate this Agreement with respect to such Collaboration Program (other than the [\*\*\*] Program after the Opt-In) upon [\*\*\*]' prior written notice to Licensee.

# 16.8 Effect of Termination for Collaboration Programs

- (a) If MacroGenics terminates this Agreement with respect to a Collaboration Program (other than the [\*\*\*] Program after the Opt-In) pursuant to [\*\*\*], or if Zai terminates this Agreement with respect to a Collaboration Program (other than the [\*\*\*] Program after the Opt-In) pursuant to [\*\*\*]:
  - (i) Each Party shall pay any amounts due pursuant to, as applicable, Section 5.1(d) (solely for all Development Costs and non-cancellable commitments such Party actually incurred for such Terminated Program prior to such termination) or [\*\*\*] (with respect to all costs, solely for all costs (as applicable) and non-cancellable commitments such Party actually incurred for such Terminated Program prior to such termination) and Zai shall pay any amounts due pursuant to Article 9 prior to the date of termination;
  - (ii) For the avoidance of doubt, the applicable licenses and sublicenses granted to Zai with respect to such Terminated Program under Sections 3.1 shall terminate;
    - (iii) [\*\*\*]shall survive;

- (iv) [\*\*\*]with respect to such Terminated Program under Section [\*\*\*] to include the [\*\*\*] of the effective date of termination of this Agreement. In the event that [\*\*\*] hereunder within such [\*\*\*], then the [\*\*\*] with respect to such Terminated Program pursuant to Section [\*\*\*]shall automatically [\*\*\*] of such notice, and thereafter, [\*\*\*], [\*\*\*], a [\*\*\*]of the applicable Products [\*\*\*]in the Territory during the [\*\*\*], which [\*\*\*] shall further be subject to Section [\*\*\*] (in which case [\*\*\*], provided that, for clarity, that subsection (b) of the defined [\*\*\*] shall be based on the [\*\*\*] (for which [\*\*\*] maintains the [\*\*\*]);
- (v) Zai shall return to MacroGenics or its designee all Products (including all Licensed Molecules) of the Terminated Program within its possession or control and arrange for the Zai Sublicensees to return to MacroGenics or its designee all Products (including all Licensed Molecules) of the Terminated Program within such Zai Sublicensees' possession or control;
- (vi) Zai shall cease to Develop and Commercialize all Licensed Molecules and Products (including all Combination Products) of the Terminated Program, including immediately stopping enrollment of subjects (unless otherwise directed in writing by MacroGenics) into any Clinical Trial being conducted by the Parties and at MacroGenics' sole election either wind-down (including to cease administering Licensed Molecules or Products to Clinical Trial subjects and conducting Clinical Trial procedures on Clinical Trial subjects, to the extent medically advisable) or transition to MacroGenics (or its designee) any Clinical Trial then being conducted by Zai, but in all cases in a timely manner and in accordance with all Applicable Laws and Regulations;
- (vii) for the Products (including Licensed Molecules) of the Terminated Program, to the extent [\*\*\*], Zai will [\*\*\*], for the purpose of the [\*\*\*] of the [\*\*\*], to [\*\*\*] (A) all Regulatory Submissions (such as Regulatory Approvals, INDs, BLAs, NDAs, and drug master files) and clinical trial agreements (to the extent assignable and not cancelled) for such Product(s), to the extent that [\*\*\*]; (B) all data, including clinical data, materials and information of any kind or nature whatsoever, in Zai 's possession or in the possession of its Affiliates or its or their respective agents related to such Product(s); (C) all trademarks related to such Products (if such termination occurs after approval of such trademark by a Regulatory Authority); and (D) all material information, and any other information reasonably requested and required by MacroGenics, relating to the manufacture of such Products;
- (viii) all sublicenses under the license granted pursuant to Section 3.3 shall terminate, unless converted to a direct license upon the mutual agreement between MacroGenics and the applicable sublicensee; and
- (ix) MacroGenics shall revoke (and Zai shall allow revocation of) any powers of attorney for any MacroGenics Licensed Patents that Zai holds as of the time of such termination; and

- (b) If Zai terminates this Agreement with respect to a Collaboration Program (other than the [\*\*\*] Program after the Opt-In) pursuant to [\*\*\*], the following shall apply:
  - (i) Section 16.8(a)(i), Section 16.8(a)(ii), Section 16.8(a)(vi), Section 16.8(a)(viii) and Section 16.8(a)(ix) shall apply, and Section 16.8(a)(v) shall apply subject to MacroGenics' payment to Zai for the Fully Burdened Manufacturing Costs for the Products transferred to MacroGenics thereunder:
  - (ii) [\*\*\*]with respect to such Terminated Program by within [\*\*\*]of the effective date of termination of this Agreement. In the event that [\*\*\*]hereunder within such [\*\*\*], then the [\*\*\*]with respect to the Terminated Program under Section [\*\*\*] shall survive (subject to [\*\*\*]) and [\*\*\*] if [\*\*\*] of and the applicable Products [\*\*\*], which [\*\*\*]shall further be subject to Section (in which case [\*\*\*], provided that, for clarity, that subsection (b) of the defined [\*\*\*] shall be based on the [\*\*\*] (for which [\*\*\*]maintains the [\*\*\*]) and not the [\*\*\*]);
    - (iii) Section 16.8(a)(vii) will apply if [\*\*\*] set forth in Section 16.8(b)(ii).
- (c) If Zai terminates this Agreement with respect to the [\*\*\*] Program after the Opt-In pursuant to [\*\*\*] or if MacroGenics terminates this Agreement with respect to the [\*\*\*] Program after the Opt-In pursuant to [\*\*\*], then MacroGenics may elect one of the following:
  - (i) MacroGenics may elect to also terminate this Agreement with respect to the [\*\*\*] Program, in which case (x) all licenses granted under this Agreement with respect to the [\*\*\*] Program shall terminate, and (y) each Party shall cease to Develop and Commercialize all [\*\*\*] Molecules and [\*\*\*] Products, including immediately stopping enrollment of subjects into any Clinical Trial being conducted by such Party for [\*\*\*] Products, and wind-down (including to cease administering [\*\*\*] Molecules or Products to Clinical Trial subjects and conducting Clinical Trial procedures on Clinical Trial subjects, to the extent medically advisable) then be conducted by such Party, but in all cases in a timely manner and in accordance with all Applicable Laws and Regulations, at such Party's sole cost and expense; or
  - (ii) MacroGenics may [\*\*\*], in which case (A) [\*\*\*], and [\*\*\*] the [\*\*\*] ("[\*\*\*]"), [\*\*\*]; and (B) [\*\*\*] shall[\*\*\*], [\*\*\*]: (x) the [\*\*\*], (y) the [\*\*\*] of the [\*\*\*] Product [\*\*\*], or (z) the [\*\*\*].
- (d) If Zai terminates this Agreement with respect to the [\*\*\*] Program after the Opt-In pursuant to [\*\*\*], then [\*\*\*], except that in the event that Zai [\*\*\*], then the [\*\*\*]mentioned therein shall be [\*\*\*], and thereafter, [\*\*\*], during the period set forth in [\*\*\*].

(e) If this Agreement is terminated with respect to one or more Programs or one or more [\*\*\*] (but not in the case of any termination of this Agreement in its entirety or all Programs), then Section 16.8 shall apply solely with respect to such Terminated Program(s) or such[\*\*\*], as applicable.

# 16.9 Effect of Termination for License-Only Programs

- (a) If MacroGenics terminates this Agreement with respect to a License-Only Program pursuant to [\*\*\*], or if Zai terminates this Agreement with respect to a License-Only Program pursuant to [\*\*\*]:
  - (i) Zai shall pay any amounts due pursuant to Article 9 prior to the date of termination;
  - (ii) For the avoidance of doubt, the applicable licenses and sublicenses granted to Zai with respect to such Terminated Program under Sections 3.1 shall terminate;
  - (iii) Zai [\*\*\*] Affiliates and Third Party (subject to Section [\*\*\*]) [\*\*\*] for the Terminated Program, by providing written notice [\*\*\*]. In the event that [\*\*\*] hereunder [\*\*\*], then the [\*\*\*] in the preceding sentence shall be [\*\*\*], and thereafter, [\*\*\*] will (A) [\*\*\*] by or on behalf of [\*\*\*] after the [\*\*\*], and (B) have the option to purchase any of Zai's inventory of the applicable License-Only Molecule and License-Only Product, at Zai's Fully-Burdened Manufacturing Cost;
  - (iv) Zai shall cease to Develop and Commercialize all Licensed Molecules and Products (including all Combination Products) of the Terminated Program, including immediately stopping enrollment of subjects (unless otherwise directed in writing by MacroGenics) into any Clinical Trial being conducted by the Parties and at MacroGenics' sole election either wind-down (including to cease administering Licensed Molecules or Products to Clinical Trial subjects and conducting Clinical Trial procedures on Clinical Trial subjects, to the extent medically advisable) or transition to MacroGenics (or its designee) any Clinical Trial then be conducted by Zai, but in all cases in a timely manner and in accordance with all Applicable Laws and Regulations;
  - (v) all sublicenses under the license granted pursuant to Section 3.3 shall terminate, unless converted to a direct license upon the mutual agreement between MacroGenics and such sublicensee; and

- (vi) MacroGenics shall revoke (and Zai shall allow revocation of) any powers of attorney for any MacroGenics Licensed Patents that Zai holds as of the time of such termination.
- (b) If Zai terminates this Agreement with respect to a License-Only Program pursuant to [\*\*\*], the provisions in Section [\*\*\*], except that in the event that [\*\*\*] pursuant to Section 16.9(a)(iii), then [\*\*\*]therein shall be [\*\*\*], and thereafter, [\*\*\*] achieved by or on [\*\*\*]and [\*\*\*] the License-Only Products [\*\*\*] that are[\*\*\*].
- (c) If this Agreement is terminated with respect to one or more Programs or one or more [\*\*\*] (but not in the case of any termination of this Agreement in its entirety or all Programs), then Section 16.9 shall apply solely with respect to such Terminated Program(s) or such [\*\*\*], as applicable.
- 16.10 **Survival**. The following provisions shall survive the termination or expiration of this Agreement for any reason: Articles 1, 13, 15 and 17, and Sections 5.1(c)(ii), 7.3(b)(vi), 7.3(c)(vi), 10.3- 10.8 (solely with respect to any amounts due but unpaid), 11.1, 11.3(b), 11.3(d), 12.4, 14.1, 16.1, 16.4, 16.8, 16.9 and 16.10, and, in the event Zai exercises the [\*\*\*] Profit Share Option, Section 4 of Exhibit D-1, and Sections 6 and 7 of Exhibit D-2. In addition, the other applicable provisions of Article 10 and Exhibit D, in the event Zai exercises the [\*\*\*] Profit Share Option, shall survive such expiration or termination of this Agreement in its entirety to the extent required to make final reimbursements, reconciliations or other payments incurred or accrued prior to the date of termination or expiration or termination of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of expiration or termination.

#### 17. MISCELLANEOUS

17.1 **Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party ("**Force Majeure**"). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a Force Majeure Event for the purposes of this Agreement solely to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances. In the event a Party is unable to perform its obligations under a Program due to Force Majeure for a period of [\*\*\*], the Parties will discuss in good faith to seek an equitable remedy for such nonperformance, including the possibility of the termination of this Agreement.

- 17.2 **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, and that upon commencement of a bankruptcy proceeding by or against the licensing Party (such Party, the "Involved Party") under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party (such Party, the "Noninvolved Party") shall be entitled to a complete duplicate of or complete access to (as such Noninvolved Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, provided the Noninvolved Party continues to fulfill its payment or royalty obligations as specified herein in full. Such intellectual property and all embodiments thereof shall be promptly delivered to the Noninvolved Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by the Noninvolved Party, unless the Involved Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Involved Party upon written request therefor by Noninvolved Party. The foregoing is without prejudice to any rights the Noninvolved Party may have arising under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, or other Applicable Laws and Regulations.
- 17.3 **Assignment**. Neither Party may assign this Agreement or any right or obligation under this Agreement without the prior written consent of the other Party, provided that each Party may assign this Agreement and its rights and obligations under this Agreement, without such consent from the other Party, to its Affiliate or any successor in interest in connection with the sale of all or substantially all of its assets or a sale of all or substantially of the business related to a Licensed Molecule or a Product, or a merger, acquisition or other similar transactions. For the avoidance of doubt, the terms and conditions of this Agreement shall be binding on the permitted successors and assignees of each Party and any permitted successor and assignee shall assume all obligations of the assigning Party under this Agreement and shall agree in writing to be bound by the terms and conditions of this Agreement. Any assignment not in accordance with this Section 17.3 shall be null and void.
- 17.4 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.
- 17.5 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to MacroGenics, to: 9704 Medical Center Drive Rockville, MD 20850

Attention: Chief Executive Officer [\*\*\*]

with copy to: 9704 Medical Center Drive (which shall not constitute Rockville, MD 20850

notice) [\*\*\*][\*\*\*]

if to Zai, to: Zai Lab (Hong Kong) Limited

Room 2301, 23/F, Island Place Tower 510 King's Road, North Point

Hong Kong

Attention: Chief Executive Officer

with copy to: [\*\*\*] [\*\*\*] Zai Lab (which shall not constitute Limited

which shall not constitute Limited

notice) 314 Main Street, 4th Floor Cambridge, MA 02142 [\*\*\*]

[\*\*\*]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given upon receipt.

- 17.6 **Applicable Intellectual Property Law**. All questions of inventorship shall be determined in accordance with U.S. patent laws. In respect to all other Patent issues related to the enforceability or validity of a Patent, the laws of the jurisdiction in which the applicable Patent is filed or granted shall govern. Except as otherwise indicated, in all other respects, the right and obligations of the Parties under this Agreement shall be governed by and construed in accordance with the laws of the State of New York, US.
- 17.7 **Entire Agreement; Amendments**. The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof, including the Programs and licenses granted hereunder. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof, including the Programs and the licenses granted hereunder, are superseded by the terms of this Agreement, including the Existing CDA. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto. The "**Existing CDA**" means that certain Mutual Confidentiality Agreement between the Parties effective as of [\*\*\*]. Any confidential information disclosed by the Parties pursuant to the Existing CDA shall be deemed to constitute Confidential Information under this Agreement.
- 17.8 **Headings**. The captions to the several Sections hereof are not a part of the Agreement, but are merely for convenience to assist in locating and reading the several Sections and Sections of this Agreement.
- 17.9 **Independent Contractors**. It is expressly agreed that MacroGenics and Zai shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MacroGenics nor Zai shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.
- 17.10 **Waiver**. The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.
- 17.11 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

- 17.12 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- 17.13 **Counterparts.** The Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 17.14 **Further Assurances**. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.
- 17.15 **Construction**. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". References to "Section" or "Sections" are references to the numbered sections of this Agreement, unless expressly stated otherwise. All dollars are United States Dollars. Unless the context otherwise requires, countries shall include territories. References to any specific law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement law thereto.

(Remainder of page intentionally left blank)

The Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Zai Lab US LLC

MacroGenics, Inc.

By: /s/ Samantha Du
Name: Samantha Du

By: /s/ Scott Koenig
Name: Scott Koenig

Title: CEO

Title: CEO

CONFIDENTIAL

# Exhibit B

# **MacroGenics Licensed Trademarks**

DART® TRIDENT®

# Exhibit D

# [\*\*\*] Profit Share Option

This Exhibit D covers the financial planning, accounting policies and procedures to be followed in determining the Development Cost Share and Profit & Loss Share, and the Parties' other rights and obligations, upon Zai's exercise of the [\*\*\*] Profit Share Option.

# **Exhibit D-1. Development Cost Share**

- 1. <u>Research and Development Costs</u>. Subject to this Paragraph 1 and Paragraph 2 of this <u>Exhibit D-1</u>, upon exercise of the [\*\*\*] Profit Share Option, the Parties shall share all Research and Development Costs incurred on or after the exercise of the [\*\*\*] Profit Share Option in connection with the Development of the [\*\*\*] Product(s), including preclinical, CMC, clinical development, and companion diagnostic development but excluding, for clarity, any Research and Development Costs incurred with respect to a Competing Study or Proprietary Compound Combination Study, as follows:
  - (a) Research and Development Costs shall be borne fifty percent (50%) by MacroGenics and fifty percent (50%) by Zai;
  - (b) [\*\*\*]; and
  - (c) [\*\*\*].
- 2. [\*\*\*].

[\*\*\*].

- 3. [\*\*\*].
  - (a) [\*\*\*].
  - (b) [\*\*\*]
  - (c) [\*\*\*]
  - (d) [\*\*\*]
  - (e) [\*\*\*]
  - (f) [\*\*\*]
  - (g) [\*\*\*]
  - (h) [\*\*\*]
  - (i) [\*\*\*]
  - (i) [\*\*\*].
  - (k) [\*\*\*]

- (l) [\*\*\*].
- (m) [\*\*\*].
- (n) [\*\*\*].
- (0) [\*\*\*].

# Exhibit D-2. Profit & Loss Share

- 1. [\*\*\*].
  - (a) [\*\*\*].
  - (b) [\*\*\*].
  - (c) [\*\*\*]

- (d) [\*\*\*].
- (e) [\*\*\*].
- (f) [\*\*\*].
- 2. [\*\*\*].
  - (a) [\*\*\*].
  - (b) [\*\*\*].
  - (c) [\*\*\*].
- 3. [\*\*\*]

# 4. Net Profits/Losses Sharing.

(a) Upon Zai's exercise of the [***] Profit Share Option, during the Profit & Loss Share Term, [***], the Parties agree to share equally (which
for clarity, shall mean that MacroGenics shall bear (and be entitled to) fifty percent (50%), and Zai will bear (and be entitled to) fifty percent (50%) or
the Net Profits/Losses with respect to [***] Product (" <b>Profit &amp; Loss Share</b> ").

- (b) [\*\*\*].
- (c) [\*\*\*].
- 5. [\*\*\*].
  - (a) [\*\*\*].
  - (b) [\*\*\*].
- 6. [\*\*\*].

- 7. [\*\*\*].
  - (a) [\*\*\*].
  - (b) [\*\*\*].
  - (c) [\*\*\*].
  - (d) [\*\*\*].
  - (e) [\*\*\*].
  - (f) [\*\*\*]

- (g) [\*\*\*]
- (h) [\*\*\*].
- (i) [\*\*\*].
- (j) [\*\*\*]:
  - (i) [\*\*\*];
  - (ii) [\*\*\*]; and
  - (iii) [\*\*\*].
- (k) [\*\*\*].
- (l) [\*\*\*].

- (m) [\*\*\*].
- (n) [\*\*\*].
- (0) [\*\*\*].
- (p) [\*\*\*].
- (q) [\*\*\*].
- (r) [\*\*\*].

- (s) [\*\*\*].
- (t) [\*\*\*].
- (u) [\*\*\*].
- (v) [\*\*\*].
- (w) [\*\*\*].
- (x) [\*\*\*].
- (y) [\*\*\*].
- (z) [\*\*\*].
  - (aa) [\*\*\*].
  - (bb) [\*\*\*].

## Exhibit E

## **Press Release**

# Zai Lab and MacroGenics Enter Into Broad Strategic Collaboration to Develop and Commercialize Preclinical Bispecific Antibodies in Oncology

- Zai Lab granted combination of regional Asian and global rights for up to four CD3-or CD47-based bispecific molecules
- MacroGenics provides rights to Zai Lab for its DART® and TRIDENT® multi-specific platforms and a lead research program targeting solid tumors
- Zai Lab provides rights to MacroGenics for certain intellectual property related to CD47 for select tumor targets

SHANGHAI, SAN FRANCISCO and ROCKVILLE, MD, June 16, 2021 (GLOBE NEWSWIRE) – Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688), an innovative commercial-stage biopharmaceutical company, and MacroGenics (NASDAQ: MGNX), a biopharmaceutical company focused on developing and commercializing innovative monoclonal-antibody-based therapeutics for the treatment of cancer, announced today that the companies have entered into an exclusive collaboration and license agreement involving up to four immuno-oncology molecules.

The first collaboration program covers a lead research molecule that incorporates MacroGenics' DART platform and binds CD3 and an undisclosed target that is expressed in multiple solid tumors. The next-generation CD3 component of the DART bispecific molecule has been designed to minimize cytokine-release syndrome while maintaining anti-tumor cytolytic activity. The second collaboration program will cover a target to be designated by MacroGenics. For both molecules, Zai receives commercial rights in Greater China, Japan, and Korea and MacroGenics receives commercial rights in all other territories. For the lead molecule, Zai Lab receives an option upon reaching a predefined clinical milestone to convert the regional arrangement into a global 50/50 profit share.

Zai Lab also obtains exclusive, global licenses from MacroGenics to develop, manufacture and commercialize two additional molecules. For the four programs, each company will contribute intellectual property to generate either CD3- or CD47-based bispecific antibodies.

"We are very pleased to be expanding our existing relationship with Zai Lab, which already includes regional rights in Greater China for two clinicalstage programs," said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. "Zai has a strong track record of rapidly progressing the development of innovative product candidates in China. This new partnership enables us to jointly discover, develop and deliver potentially best-in-class therapeutics to address patients' unmet medical needs."

"MacroGenics has been a great partner and one of the leading companies in the immuno-oncology field," said Samantha Du, Ph.D., Founder, Chairperson, Chief Executive Officer of Zai Lab. "We are pleased to expand our strategic collaboration, which leverages both companies' unique research capabilities and gives Zai Lab access to MacroGenics' proprietary technologies to expand our innovative oncology portfolio on a global basis."

Under the terms of the agreement, MacroGenics receives initial consideration from Zai Lab of \$55 million, including an upfront payment of \$25 million and an equity investment of \$30 million in MacroGenics' common stock at \$31.30 per share. In addition, MacroGenics is eligible to receive up to \$1.4 billion in potential development, regulatory and commercial milestone payments for the four programs. If products from the collaboration are commercialized, MacroGenics would also receive royalties on annual net sales in Zai Lab's territories.

## About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is an innovative commercial-stage biopharmaceutical company focused on bringing transformative medicines for cancer and infectious and autoimmune diseases to patients in China and around the world. We aim to address significant unmet medical needs in large, fast-growing segments of the pharmaceutical market. Our experienced team has secured partnerships with leading global biopharmaceutical companies to generate a broad pipeline of potentially innovative, marketed products and product candidates. We have also built an in-house team with strong drug discovery and translational research capabilities and are establishing a pipeline of proprietary drug candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to positively impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab\_Global.

## About MacroGenics, Inc.

MacroGenics is a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see the Company's website at www.macrogenics.com. MacroGenics, the MacroGenics logo, DART and TRIDENT are trademarks or registered trademarks of MacroGenics, Inc.

## Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects for Zai Lab, including, without limitation, statements regarding the prospects and plans for developing and commercializing the preclinical bispecific molecules monoclonal antibodies and other statements containing words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on Zai Lab's expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) Zai Lab's ability to successfully commercialize and generate revenue from its approved products; (2) Zai Lab's ability to finance its operations and business initiatives and obtain funding for such activities, (3) Zai Lab's results of clinical and pre-clinical development of its product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of Zai Lab's product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. Zai Lab anticipates that subsequent events and developments will cause Zai Lab's expectations and assumptions to change and undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing Zai Lab's views as of any date subsequent to the date of this press

## **MacroGenics Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, commercial prospects of or product revenues from MARGENZA, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: risks that MARGENZA revenue, expenses and costs may not be as expected, risks relating to MARGENZA's market acceptance, competition, reimbursement and regulatory actions, the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other risks described in the Company's rilings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements as ome point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-l

# For more information, please contact:

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# **MacroGenics Contacts**

Jim Karrels, Senior Vice President, CFO 1-301-251-5172 info@macrogenics.com

## **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;
  - 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):
  - 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: August 9, 2021 /s/ Samantha (Ying) Du

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

## **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;
  - 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;
  - 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):
  - 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: August 9, 2021 /s/ Billy Cho

Billy Cho Chief Financial Officer (Principal Financial and Accounting Officer)

## 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 June 30, 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: August 9, 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.

## 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 June 30, 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: August 9, 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.