

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended **March 31, 2020**

OR

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

For the transition period from     to

Commission file number: **001-37990**

**LEAP THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

State or other jurisdiction of  
incorporation or organization

**27-4412575**

(I.R.S. Employer  
Identification No.)

**47 Thorndike St, Suite B1-1, Cambridge, MA**

Address of Principal Executive Offices

**02141**

Zip Code

**(617) 714-0360**

Registrant's Telephone Number, Including Area Code

N/A

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

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

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
Common Stock, par value \$0.001 per share	LPTX	Nasdaq Global Market

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of May 12, 2020 there were 35,799,488 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q (this “Quarterly Report”) contains forward-looking statements which reflect our current views with respect to, among other things, our operations and financial performance. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will” or the negative of such terms or any other comparable terminology. Forward-looking statements appear in a number of places throughout this Quarterly Report and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19 related issues; our ability and plan to develop and commercialize DKN-01; status, timing and results of preclinical studies and clinical trials; the potential benefits of DKN-01; the timing of our development programs and seeking regulatory approval of DKN-01; our ability to obtain and maintain regulatory approval; our estimates of expenses and future revenues and profitability; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for DKN-01; the benefits to be derived from our agreement with BeiGene, Ltd. (“BeiGene”) or any other collaborations, license agreements, or other acquisition efforts, including those relating to the development and commercialization of DKN-01; sources of revenues and anticipated revenues, including contributions from our agreement with BeiGene or any other collaborations or license agreements for the development and commercialization of products; our ability to create an effective sales and marketing infrastructure if we elect to market and sell DKN-01 directly; the rate and degree of market acceptance of DKN-01; the timing and amount of reimbursement for DKN-01; the success of other competing therapies that may become available; the manufacturing capacity for DKN-01; our intellectual property position; our ability to maintain and protect our intellectual property rights; our results of operations, financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. You should carefully read this Quarterly Report and the documents that we have filed as exhibits to this Quarterly Report completely.

You should refer to Part II, Item 1A, Risk Factors in this Quarterly Report and Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on March 16, 2020 for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statement that we make in this Quarterly Report speaks only as of the date of such statement, and, except to the extent required by applicable law, we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

DKN-01 and TRX518 are investigational drugs undergoing clinical development and have not been approved by the U.S. Food and Drug Administration (the “FDA”), nor been submitted to the FDA for approval. DKN-01 and TRX518 have not been, and may never be, approved by any regulatory agency or marketed anywhere in the world. Statements contained in this Quarterly Report should not be deemed to be promotional.

## INTRODUCTORY COMMENT

### References to Leap

Throughout this Quarterly Report on Form 10-Q, the “Company,” “Leap,” “Leap Therapeutics,” “we,” “us,” and “our,” except where the context requires otherwise, refer to Leap Therapeutics, Inc. and its consolidated subsidiaries, and “our board of directors” refers to the board of directors of Leap Therapeutics, Inc.

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	<u>(Unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 25,465	\$ 3,891
Research and development incentive receivable	247	185
Prepaid expenses and other current assets	272	165
Total current assets	<u>25,984</u>	<u>4,241</u>
Property and equipment, net	114	124
Right of use assets, net	835	1,026
Deferred tax assets	112	127
Deferred costs	623	831
Deposits	1,074	1,099
Total assets	<u>\$ 28,742</u>	<u>\$ 7,448</u>
<b>Liabilities and Stockholders' Equity (Deficiency)</b>		
Current liabilities:		
Accounts payable	\$ 4,933	\$ 4,571
Accrued expenses	2,387	3,441
Deferred revenue - current portion	1,500	-
Lease liability - current portion	379	474
Total current liabilities	<u>9,199</u>	<u>8,486</u>
Non current liabilities:		
Restricted stock liability	-	159
Deferred revenue, net of current portion	1,125	-
Lease liability, net of current portion	454	552
Total liabilities	<u>10,778</u>	<u>9,197</u>
Stockholders' equity (deficiency):		
Common stock, \$0.001 par value; 100,000,000 shares authorized; 35,799,488 and 24,194,877 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	36	24
Additional paid-in capital	219,642	193,319
Accumulated other comprehensive income	988	76
Accumulated deficit	(202,702)	(195,168)
Total stockholders' equity (deficiency)	<u>17,964</u>	<u>(1,749)</u>
Total liabilities and stockholders' equity (deficiency)	<u>\$ 28,742</u>	<u>\$ 7,448</u>

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
License revenue	\$ 375	\$ -
Operating expenses:		
Research and development	4,603	6,790
General and administrative	2,153	2,005
Total operating expenses	<u>6,756</u>	<u>8,795</u>
Loss from operations	(6,381)	(8,795)
Interest income	68	82
Interest expense	(12)	(7)
Australian research and development incentives	85	75
Foreign currency gains (loss)	(991)	42
Net loss	<u>(7,231)</u>	<u>(8,603)</u>
Dividend attributable to down round feature of warrants	(303)	(359)
Dividend attributable to Series A & B convertible preferred stock	(372)	-
Series A & B convertible preferred stock - beneficial conversion feature	(9,399)	-
Net loss attributable to common stockholders	<u>\$ (17,305)</u>	<u>\$ (8,962)</u>
Net loss per share		
Basic	<u>\$ (0.55)</u>	<u>\$ (0.47)</u>
Diluted	<u>\$ (0.55)</u>	<u>\$ (0.47)</u>
Weighted average common shares outstanding		
Basic	<u>31,632,213</u>	<u>19,237,444</u>
Diluted	<u>31,632,213</u>	<u>19,237,444</u>

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

(Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Net loss	\$ (7,231)	\$ (8,603)
Other comprehensive income (loss):		
Foreign currency translation adjustments	912	(24)
Comprehensive loss	<u>\$ (6,319)</u>	<u>\$ (8,627)</u>

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
For the Three Months Ended March 31, 2020 and 2019

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balances at December 31, 2018</b>	14,703,159	15	\$ 162,393	\$ 302	\$ (153,535)	\$ 9,175
Issuance of common stock in connection with February 2019 Public Offering, net of issuance costs of \$1,102	7,557,142	7	12,114	-	-	12,121
Reclassification of 2017 warrants from liability to equity	-	-	11,822	-	(8,374)	3,448
Dividend attributable to the down round feature of 2017 Warrants	-	-	359	-	(359)	-
Foreign currency translation adjustment	-	-	-	(24)	-	(24)
Stock-based compensation	-	-	947	-	-	947
Net loss	-	-	-	-	(8,603)	(8,603)
<b>Balances at March 31, 2019</b>	<u>22,260,301</u>	<u>22</u>	<u>\$ 187,635</u>	<u>\$ 278</u>	<u>\$ (170,871)</u>	<u>\$ 17,064</u>

	Series A Convertible Preferred Stock,		Series B Convertible Preferred Stock,		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balances at December 31, 2019</b>	-	\$ -	-	\$ -	24,194,877	24	\$ 193,319	\$ 76	\$ (195,168)	\$ (1,749)
Issuance of Series A & B Convertible Preferred Stock, net of underwriting discounts	1,421,801	14,062	1,137,442	11,260	-	-	-	-	-	-
Series A & B Convertible Preferred Stock discount - beneficial conversion feature	-	(5,226)	-	(4,173)	-	-	9,399	-	-	9,399
Series A & B Convertible Preferred Stock accrued dividends	-	207	-	165	-	-	(372)	-	-	(372)
Conversion of Series A & B Convertible Preferred Stock dividends to prefunded warrants and common stock	-	(207)	-	(165)	-	-	372	-	-	372
Conversion of Series A Convertible Preferred Stock to prefunded warrants	(1,421,801)	(8,836)	-	-	-	-	8,836	-	-	8,836
Conversion of Series B Convertible Preferred Stock to common stock	-	-	(1,137,442)	(7,087)	11,531,133	12	7,076	-	-	7,088
Issuance of common stock upon exercise of stock options	-	-	-	-	7,778	-	11	-	-	11
Issuance of common stock upon exercise of warrants	-	-	-	-	65,700	-	128	-	-	128
Dividend attributable to the down round feature of 2017 Warrants	-	-	-	-	-	-	303	-	(303)	-
Foreign currency translation adjustment	-	-	-	-	-	-	-	912	-	912
Stock-based compensation	-	-	-	-	-	-	570	-	-	570
Net loss	-	-	-	-	-	-	-	-	(7,231)	(7,231)
<b>Balances at March 31, 2020</b>	<u>-</u>	<u>\$ -</u>	<u>-</u>	<u>\$ -</u>	<u>35,799,488</u>	<u>36</u>	<u>\$ 219,642</u>	<u>\$ 988</u>	<u>\$ (202,702)</u>	<u>\$ 17,964</u>

See notes to condensed consolidated financial statements.

LEAP THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,231)	\$ (8,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	10	12
Amortization of contract asset	34	-
Amortization on right-of-use asset	191	177
Stock-based compensation expense	570	947
Foreign currency loss	991	-
Change in fair value of restricted stock liability	(159)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	362	43
Research and development incentive receivable	(86)	(75)
Contract acquisition costs	(270)	-
Accounts payable and accrued expenses	(770)	780
Deferred revenue	2,625	-
Lease liability	(193)	(149)
Net cash used in operating activities	<u>(3,926)</u>	<u>(6,868)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of Series A convertible preferred stock	14,986	-
Proceeds from the issuance of Series B convertible preferred stock	12,000	-
Proceeds from issuance of common stock	-	12,331
Proceeds from the exercise of common stock warrants	128	-
Proceeds from the exercise of stock options	11	-
Payment of deferred offering costs	(1,520)	(9)
Net cash provided by financing activities	<u>25,605</u>	<u>12,322</u>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<u>(105)</u>	<u>(29)</u>
<b>Net increase in cash and cash equivalents</b>	<u>21,574</u>	<u>5,425</u>
Cash and cash equivalents at beginning of period	3,891	16,284
Cash and cash equivalents at end of period	<u>\$ 25,465</u>	<u>\$ 21,709</u>
<b>Supplemental disclosure of non-cash financing activities:</b>		
Reclassification of 2017 Warrants from liability to equity	\$ -	\$ 3,448
Dividend attributable to down round feature of warrants	\$ 303	\$ 359
Offering costs included in accounts payable and accrued expenses	\$ 144	\$ 213
Right-of-use asset recorded upon adoption of ASU 2016-02	\$ -	\$ 1,755
Lease liability recorded upon adoption of ASU 2016-02	\$ -	\$ 1,720
Accrued rent reclassified upon adoption of ASU 2016-02	\$ -	\$ 35
Conversion of Series A convertible preferred stock to prefunded warrants	\$ 8,836	\$ -
Conversion of Series B convertible preferred stock to common stock	\$ 7,087	\$ -
Beneficial conversion feature from Series A convertible preferred stock	\$ 5,226	\$ -
Beneficial conversion feature from Series B convertible preferred stock	\$ 4,173	\$ -

See notes to condensed consolidated financial statements.

**Leap Therapeutics, Inc.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(In thousands, except share and per share amounts)**

**(Unaudited)**

**1. Nature of Business, Basis of Presentation and Liquidity**

*Nature of Business*

Leap Therapeutics, Inc. was incorporated in the state of Delaware on January 3, 2011. During 2015, HealthCare Pharmaceuticals Pty Ltd. (“HCP Australia”) was formed and is a wholly owned subsidiary of the Company.

The Company is a biopharmaceutical company acquiring and developing novel therapeutics at the leading edge of cancer biology. The Company’s approach is designed to target compelling tumor-promoting and immuno-oncology pathways to generate durable clinical benefit and enhanced outcomes for patients. The Company’s programs are monoclonal antibodies that target key cellular pathways that enable cancer to grow and spread and specific mechanisms that activate the body’s immune system to identify and attack cancer.

*Basis of Presentation*

The accompanying condensed consolidated financial statements as of March 31, 2020 and for the three months ended March 31, 2020 and 2019 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the notes thereto for the year ended December 31, 2019 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 16, 2020.

The condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments which are necessary for the fair presentation of the Company’s financial position as of March 31, 2020, statements of operations and statements of comprehensive loss for the three months ended March 31, 2020 and 2019 and statements of cash flows for the three months ended March 31, 2020 and 2019. Such adjustments are of a normal and recurring nature. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

*Liquidity*

Since inception, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the Food and Drug Administration (the “FDA”), has not generated any product sales revenues and has not yet achieved profitable operations, nor has it ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company’s future operations are dependent on the success of the Company’s efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company’s products.

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of March 31, 2020, the Company had cash and cash equivalents of \$25,465. Additionally, the Company had an accumulated deficit of \$202,702 at March 31, 2020, and during the three months ended March 31, 2020, the Company incurred a net loss of \$7,231. The Company expects to continue to generate operating losses for the foreseeable future.

The Company believes that its cash and cash equivalents of \$25,465 as of March 31, 2020, will be sufficient to fund its operating expenses for at least the next 12 months from issuance of these financial statements. In November 2019, the Company suspended enrollment of its TRX518 clinical trials and deprioritized further development.

In addition, the Company will seek additional funding through public or private equity financings and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies, such as the agreement with BeiGene. If the Company does not obtain additional funding or development program cost-sharing, or exceeds its current spending forecasts or fails to receive the research and development tax incentive payment, the Company has the ability and would be forced to: delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and/or delay company and pipeline expansion, any of which would adversely affect its business prospects. The inability to obtain funding, as and when needed, would have a negative impact on the Company's financial condition and ability to pursue its business strategies.

## 2. Summary of Significant Accounting Policies

### *Principles of Consolidation*

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated upon consolidation.

### *Use of Estimates*

The presentation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### *Research and development incentive income and receivable*

The Company recognizes other income from Australian research and development incentives when there is reasonable assurance that the income will be received, the relevant expenditure has been incurred, and the consideration can be reliably measured. The research and development incentive is one of the key elements of the Australian Government's support for Australia's innovation system and is supported by legislative law primarily in the form of the Australian Income Tax Assessment Act 1997, as long as eligibility criteria are met.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive regime described above. At each period end, management estimates the refundable tax offset available to the Company based on available information at the time. This estimate is also reviewed by external tax advisors on an annual basis.

Under the program, a percentage of eligible research and development expenses incurred by the Company through its subsidiary in Australia are reimbursed. The percentage was 43.5% for the year ended December 31, 2019 and for the three months ended March 31, 2020.

The research and development incentive receivable represents an amount due in connection with the above program. The Company has recorded a research and development incentive receivable of \$247 and \$185 as of March 31, 2020 and December 31, 2019, respectively, in the condensed consolidated balance sheets and other income from Australian research and development incentives of \$85 and \$75 for the three months ended March 31, 2020 and 2019, respectively.

The following table shows the change in the research and development incentive receivable from December 31, 2018 to March 31, 2020 (in thousands):

Balance at December 31, 2018	\$ 836
Australian research and development incentive income, net	132
Cash received for 2018 eligible expenses	(757)
Foreign currency translation	(26)
Balance at December 31, 2019	185
Australian research and development incentive income, net	85
Foreign currency translation	(23)
Balance at March 31, 2020	<u>\$ 247</u>

### *Foreign Currency Translation*

The financial statements of the Company's Australian subsidiary are measured using the local currency as the functional currency. Assets and liabilities of this subsidiary are translated into U.S. dollars at an exchange rate as of the consolidated balance sheet date. Equity is translated at historical exchange rates. Revenues and expenses are translated into U.S. dollars at average rates of exchange in effect during the period. The resulting cumulative translation adjustments have been recorded as a separate component of stockholders' equity. Realized foreign currency transaction gains and losses are included in the results of operations.

### *Deferred Costs*

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficiency) as a reduction of additional paid-in capital generated as a result of the offering.

The Company also capitalizes certain contract acquisition costs. During the three months ended March 31, 2020, the Company incurred contract acquisition costs which were capitalized under ASC 340-40 as incremental costs of obtaining the contract with BeiGene. This cost is amortized on a straight-line basis over the performance period of the research and development services.

As of March 31, 2020 and December 31, 2019 there was \$623 and \$831, respectively, of deferred costs.

### *Deposits*

As of March 31, 2020 and December 31, 2019, \$1,074 and \$1,099, respectively, of deposits made by the Company with certain service providers that are to be applied to future payments due under the service agreements or returned to the Company if not utilized, were recorded in the condensed consolidated balance sheets.

### *Warrants*

On January 1, 2019, the Company adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common stockholders in basic EPS.

The Company concluded that the common stock warrants (the "2017 Warrants") issued in connection with the private placement of common stock completed in November 2017 (the "November 2017 Private Placement"), qualify for equity classification. The adoption guidance of ASU 2017-11 provides for a modified retrospective adoption. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified \$3,448 from warrant liability to equity.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the 2017 Warrants when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic EPS calculation. In connection with the public offering, completed in February 2019 (the "2019 Public Offering"), when the 2017 Warrants were repriced from \$6.085 to \$1.75 as a result of a down round, the Company recorded a dividend of \$359 during the three months ended March 31, 2019. In connection with the January 2020 Private Placement, when the 2017 Warrants were repriced from \$1.75 to \$1.055 as a result of a down round, the Company recorded a dividend of \$303 during the three months ended March 31, 2020.

### *Fair Value of Financial Instruments*

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. There were no transfers within the hierarchy during the three months ended March 31, 2020 or the year ended December 31, 2019.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

	Total	Level 1	Level 2	Level 3
<b>March 31, 2020</b>				
<b>Assets:</b>				
Cash equivalents	\$ 25,465	\$ 25,465	\$ -	\$ -
Total assets	<u>\$ 25,465</u>	<u>\$ 25,465</u>	<u>\$ -</u>	<u>\$ -</u>
<b>December 31, 2019</b>				
<b>Assets:</b>				
Cash equivalents	\$ 3,891	\$ 3,891	\$ -	\$ -
Total assets	<u>\$ 3,891</u>	<u>\$ 3,891</u>	<u>\$ -</u>	<u>\$ -</u>

Cash equivalents of \$25,465 and \$3,891 as of March 31, 2020 and December 31, 2019, respectively, consisted of overnight investments and money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

The carrying value of the research and development incentive receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these assets and liabilities.

#### Leases

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02, *Leases*, or ASU 2016-02, to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted ASU 2016-02 on January 1, 2019, or the effective date, and used the effective date as its date of initial application.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including observable debt yields from comparable companies and the volatility in the debt market for securities with similar terms, in determining that 8% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

In accordance with the guidance in ASU 2016-02, components of a lease should be split into three categories: lease components (e.g. land, building, etc.), non-lease components (e.g. common area maintenance, maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the contract consideration to the lease component only. The lease component results in an operating right-of-use asset being recorded on the consolidated balance sheets and amortized such that lease expense is recorded on a straight line basis over the term of the lease.

#### Revenue Recognition

The Company records revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue From Contracts with Customers*. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

*License revenue.* The Company's performance obligations under its license agreements may include providing intellectual property licenses, performing technology transfer, performing research and development consulting services and notifying the customer of any enhancements to licensed technology or new technology that it discovers, among others. The Company determined that its performance obligations under its license agreements as evaluated at contract inception were not distinct and represented a single performance obligation. For these agreements, revenue is recognized using a proportional performance model, representing the transfer of goods or services as activities are performed over the term of the agreement. Upfront payments are also amortized to revenue on a straight-line basis over the performance period. Upfront payment contract liabilities resulting from the Company's license agreements do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company. When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts are recognized upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license revenues. Sales-based milestones and royalties under the Company's license agreements will be recognized as royalty revenue in the period the related sale occurred. The Company generally invoices its licensees upon the completion of the effort or achievement of a milestone, based on the terms of each agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

*Research and Development Services.* The promises under the Company's license agreements may include research and development services to be performed by the Company on behalf of the customer. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts. Reimbursements from and payments to the customer that are the result of a collaborative relationship with a partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development expense.

*Customer Options.* If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

*Milestone Payments.* At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

*Royalties.* For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

#### *Collaborative Arrangements*

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenues as such amounts are incurred by the collaboration partner. Where amounts owed to a collaboration partner exceed the Company's collaboration revenues in each quarterly period, such amounts are classified as research and development expense. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

See footnote 3 for a complete discussion of the revenue recognition for the Company's license agreement.

### *Net Loss per Share*

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants.

### *Warrant Liability*

In connection with entering into the November 2017 Private Placement, the Company issued the 2017 Warrants with each share of common stock sold in the November 2017 Private Placement. The Company classified the 2017 Warrants as a liability on its consolidated balance sheet prior to January 1, 2019, because each warrant represented a freestanding financial instrument that is not indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the November 2017 Private Placement agreement and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as gains (losses) in the condensed consolidated statements of operations through the year ended December 31, 2018.

### *Subsequent Events*

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

### *Recent Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the FASB, and are early adopted by the Company or adopted as of the specified effective date.

In November 2018, the FASB issued "ASU 2018-18, Clarifying the Interaction between Topic 808 and Topic 606." The objective of the standard is to clarify the interaction between ASC Topic 808--Collaborative Arrangements and ASC Topic 606--Revenue from Contracts with Customers. Currently, ASC Topic 808 does not provide comprehensive recognition or measurement guidance for collaborative arrangements, and the accounting for those arrangements is often based on an analogy to other accounting literature or an accounting policy election. Similarly, aspects of ASC Topic 606 have resulted in uncertainty in practice about the effect of the revenue standard on the accounting for collaborative arrangements. The standard became effective for us beginning on January 1, 2020 and the adoption of this ASU did not have a material impact on our financial condition, results of operations, cash flows, and financial statement disclosures.

## **3. BeiGene Exclusive Option and License Agreement**

### *Terms of Agreement*

On January 3, 2020, the Company entered into an exclusive option and license agreement (the "BeiGene Agreement") with BeiGene, Ltd. ("BeiGene") for the clinical development and commercialization of DKN-01, in Asia (excluding Japan), Australia, and New Zealand. The Company retains exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the rest of the world.

Pursuant to the BeiGene Agreement, the Company received an upfront cash payment of \$3,000 from BeiGene in exchange for granting BeiGene an option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The Company is eligible to receive up to \$132,000 in future option exercise and milestone payments, based upon the achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on any product sales of DKN-01 in the licensed territory.

The Company is responsible for conducting development activities prior to the exercise of the option. After the option is exercised, BeiGene is solely responsible for development and commercialization activities of DKN-01 in the territory. The BeiGene Agreement continues in effect until the earlier of: (i) 120 days after the end of the option period, if BeiGene has not exercised the option by such date; and (ii) on a country-by country and Licensed Product-by-Licensed Product (as defined in the BeiGene Agreement) basis, the expiration of the Royalty Term (as defined in the BeiGene Agreement) applicable to such licensed product in such country. At any time, BeiGene may terminate the agreement by providing at least 60 days written notice of termination to the Company. Upon termination of the License Agreement, all rights granted by the Company to BeiGene terminate.

## Revenue Recognition

The Company evaluated the BeiGene Agreement to determine whether it is a collaborative arrangement for purposes of ASC 808. The Company concluded that because both parties were active participants and were exposed to the risks and rewards of the BeiGene Agreement, that such activities are under the scope of ASC 808. The Company concluded that BeiGene was a customer with regard to the combined license and research & development activities and as such the contract should be evaluated under ASC 606.

In determining the appropriate amount of revenue to be recognized under ASC 606 as the Company fulfills its obligations under the Agreement, the Company performed the following steps: (i) identified the promised goods or services in the contract; (ii) determined whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measured the transaction price, including any constraints on variable consideration; (iv) allocated the transaction price to the performance obligations; and (v) recognizes revenue when (or as) the Company satisfies each performance obligation.

The Company identified the following material promises under the BeiGene Agreement: (1) option to an exclusive license to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand, (2) participation in a joint development committee, (3) technology transfer services and (4) pre-option research and development services. The Company determined that the option to an exclusive license in the territory did not represent a material right. Additionally, the Company determined that the participation in the joint development committee, research and development services and technology transfer services were not distinct from each other, as each has limited value without the other. As such, for the purposes of ASC 606, the Company determined that these four material promises, described above, should be combined into a single performance obligation.

The Company determined the transaction price is equal to the up-front fee of \$3,000. The transaction price was fully allocated to the single performance obligation and is recognized as revenue on a straight-line basis over the performance period of the research and development services. During the three months ended March 31, 2020, the Company recognized \$375 of license revenue related to the up-front fee received from BeiGene. The Company did not have any such license revenue during the three months ended March 31, 2019.

## Cost of contract acquisition

The Company incurred contract acquisition costs of \$270 which were capitalized under ASC 340-40 as incremental costs of obtaining the contract with BeiGene. This cost is amortized on a straight-line basis over the performance period of the research and development services. The total amount of amortization expense in the period is \$34 and the closing balance recorded in deferred costs as of March 31, 2020 was \$236.

## Royalties

As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the three months ended March 31, 2020.

The following table presents a summary of the activity in the Company's contract liabilities, related to the upfront cash payment received of \$3,000, during the three months ended March 31, 2020 (in thousands):

	Balance at January 1, 2020	Additions	Deductions	Balance at March 31, 2020
Contract liabilities				
Deferred revenue - current	\$ -	\$ 1,875	\$ (375)	\$ 1,500
Deferred revenue - non current	-	1,125	-	1,125
Total contract liabilities	<u>\$ -</u>	<u>\$ 3,000</u>	<u>\$ (375)</u>	<u>\$ 2,625</u>

## 4. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2020	December 31, 2019
Clinical trials	\$ 1,421	\$ 1,828
Professional fees	270	609
Payroll and related expenses	696	1,004
Accrued expenses	<u>\$ 2,387</u>	<u>\$ 3,441</u>

## 5. Leases

In February 2016, the FASB issued ASU 2016-02, Leases, or ASU 2016-02. ASU 2016-02 requires a lessee to recognize on its balance sheet (for both finance and operating leases) a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The Company adopted ASU 2016-02 on January 1, 2019, on the effective date, and used the effective date as its date of initial application. As such, the Company did not adjust prior period amounts. The Company also elected to adopt the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under ASU 2016-02 for leases that commenced prior to the effective date.

The Company has operating leases for real estate in the United States and does not have any finance leases. The Company's leases may contain options to renew and extend lease terms and options to terminate leases early. Reflected in the right-of-use asset and lease liability on the Company's consolidated balance sheets are the periods provided by renewal and extension options that the Company is reasonably certain to exercise, as well as the periods provided by termination options that the Company is reasonably certain to not exercise.

The Company has existing leases that include variable lease and non-lease components that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. Such payments primarily include common area maintenance charges and increases in rent

payments that are driven by factors such as future changes in an index (e.g., the Consumer Price Index).

In calculating the present value of future lease payments, the Company utilized its incremental borrowing rate based on the remaining lease term at the date of adoption. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. This will potentially result in the initial and subsequent measurement of the balances of the right-of-use asset and lease liability for leases being greater than if the policy election was not applied. The Company has existing net leases in which the non-lease components (e.g. common area maintenance, maintenance, consumables, etc.) are paid separately from rent based on actual costs incurred and therefore are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. On January 1, 2019, the Company recorded a right-of-use asset of \$1,755 and a lease liability of \$1,720 on its consolidated balance sheets and reclassified a rent liability against the right-of-use asset of \$35. As of March 31, 2020, a right-of-use asset of \$835 and lease liability of \$833 are reflected on the consolidated balance sheets. The Company recorded rent expense of \$198 and \$209, respectively, during the three months ended March 31, 2020 and 2019.

Future lease payments under non-cancelable operating leases as of March 31, 2020 are detailed as follows:

<b><u>Future Operating Lease Payments</u></b>	
2020	\$ 321
2021	434
2022	146
<b>Total Lease Payments</b>	<b>901</b>
Less: imputed interest	(68)
<b>Total operating lease liabilities</b>	<b><u>\$ 833</u></b>

## 6. Warrants

As of March 31, 2020, outstanding warrants to purchase common stock, all of which are classified as equity warrants, consisted of the following:

March 31, 2020			
Date Exercisable	Number of Shares Issuable	Exercise Price	Classification
1/23/2017	54,516	\$ 0.01	Equity
11/14/2017	2,758,094	\$ 1.055	Equity
2/5/2019	7,491,442	\$ 1.95	Equity
3/5/2020	14,413,902	\$ 0.001	Equity
3/5/2020	25,945,035	\$ 2.11	Equity
	<u>50,662,989</u>		

### 2017 Warrants

The 2017 Warrants contain full ratchet anti-dilution protection provisions. Prior to January 1, 2019, the Company classified the 2017 Warrants as a liability on its consolidated balance sheet because each warrant represented a freestanding financial instrument that, due to the potential variable nature of the exercise price, is not considered to be indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the November 2017 Private Placement and has been subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as gains (losses) in the Company's consolidated statement of operations.

On January 1, 2019, the Company adopted ASU 2017-11 and concluded that the 2017 Warrants now qualify for equity classification. The Company applied the guidance retrospectively to the 2017 Warrants by means of a cumulative-effect adjustment to its statement of financial position as of the beginning of the interim and annual period beginning January 1, 2019. The Company performed a final remeasurement of the warrant liability as of January 1, 2019 and reclassified \$3,448 to additional paid in capital.

The Company will recognize on a prospective basis the value of the effect of the down round feature in the warrant when it is triggered (i.e., when the exercise price is adjusted downward). This value is measured as the difference between (1) the financial instrument's fair value (without the down round feature) using the pre-trigger exercise price and (2) the financial instrument's fair value (with the down round feature) using the reduced exercise price. The value of the effect of the down round feature will be treated as a dividend and a reduction to income available to common stockholders in the basic EPS calculation. In connection with the 2019 Public Offering, when the 2017 Warrants were repriced from \$6.085 to \$1.75, the Company recorded a dividend of \$359 during the three months ended March 31, 2019. In connection with the January 2020 Private Placement, when the 2017 Warrants were repriced from \$1.75 to \$1.055, the Company recorded a dividend of \$303 during the three months ended March 31, 2020.

### 2019 Warrants

On February 5, 2019, in connection with the 2019 Public Offering, the Company issued immediately exercisable warrants (the "2019 Warrants") to purchase 7,557,142 shares of common stock to investors. The 2019 Warrants have an exercise price of \$1.95 per share and expire on February 5, 2026. The 2019 Warrants qualify for equity classification.

During the three months ended March 31, 2020, 65,700 warrants were exercised for cash resulting in gross proceeds to the Company of \$128.

### 2020 Warrants

On January 3, 2020, the Company entered into a Securities Purchase Agreement with investors, providing for a private placement transaction exempt from the Securities Act of 1933, as amended, pursuant to which the Company issued and sold 1,421,801 shares of its Series A Preferred Stock, at a purchase price of \$10.54 per share, and 1,137,442 shares of its Series B Preferred Stock at a purchase price of \$10.55 per share, and one (1) share of the Company's Special Voting Stock entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of \$0.001 (the "2020 Pre-funded Warrants") and the conversion of the Series B Preferred Stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares of common stock at an exercise price of \$2.11 per share (the "Coverage Warrants"). The 2020 Pre-funded Warrants and the Coverage Warrants expire on March 5, 2027 and qualify for equity classification.

## 7. Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the preferred stockholders. Through March 31, 2020, no dividends have been declared.

### *Public Offering of Common Stock — February 2019*

On February 5, 2019, the Company completed the 2019 Public Offering whereby the Company issued 7,557,142 shares of its common stock at a price of \$1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of \$1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the 2019 Public Offering were approximately \$12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

### *Issuance of Common Stock under Distribution Agreement*

On September 7, 2018, the Company filed a Prospectus Supplement to register the offer and sale of shares of common stock having an aggregate offering price of up to \$30,000 pursuant to the terms of a distribution agreement, or the Distribution Agreement, with Raymond James & Associates, Inc. During the year ended December 31, 2019, the Company issued 1,033,147 shares under the Distribution Agreement, for net proceeds of \$1,923. During the three months ended March 31, 2020, the Company did not issue any shares under the Distribution Agreement.

### *Lincoln Park Purchase Agreements*

On July 10, 2019, the Company entered into a Commitment Purchase Agreement and a Registration Rights Agreement with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park up to \$20,000 in shares of its common stock, subject to certain limitations and conditions set forth in the Commitment Purchase Agreement. As consideration for Lincoln Park's commitment to purchase shares of common stock pursuant to the Commitment Purchase Agreement, the Company issued to Lincoln Park 330,000 shares of common stock. The Company did not receive any cash proceeds from the issuance of such shares. During the three months ended March 31, 2020, the Company did not issue any shares under the Commitment Purchase Agreement.

On July 11, 2019, the Company entered into a Registered Offering Purchase Agreement and together with the Commitment Purchase Agreement, under which the Company agreed to sell to Lincoln Park, and Lincoln Park agreed to purchase 571,429 shares of common stock, at a price of \$1.75 per share for an aggregate purchase price of \$1,000, pursuant to the Company's effective shelf Registration Statement on Form S-3, including the prospectus supplement thereto dated July 11, 2019.

### *January 2020 Private Placement*

On January 3, 2020, the Company issued and sold 1,421,801 shares of its Series A Preferred Stock at a purchase price of \$10.54 per share, and 1,137,442 shares of its Series B Preferred Stock at a purchase price of \$10.55 per share, and one (1) share of its Special Voting Stock, entitling the purchaser of Series A Preferred Stock to elect one member of the Company's board of directors, for aggregate net proceeds to the Company of approximately \$25,322.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock at an exercise price of \$0.001 per share and the conversion of the Series B Preferred Stock into 11,531,133 shares of its common stock, par value \$0.001 per share. Each investor also received the Coverage Warrants to purchase an equal number of shares at an exercise price of \$2.11 per share.

In connection with the January 2020 Private Placement, Series A Preferred Stock holders and Series B Preferred Stock holders were entitled to cash dividends at fixed cumulative percentage of 8% per annum plus any dividends declared on outstanding common stock on an as-converted basis, effective on the issuance date of the Series A Preferred Stock and Series B Preferred Stock. The cash dividends were converted to shares of common stock upon the conversion of the Series A Preferred Stock to pre-funded warrants and Series B Preferred Stock to common stock. During the three months ended March 31, 2020, the Company recorded \$372 of Series A Preferred Stock and Series B Preferred Stock dividends, which qualify as cumulative dividends, and in the calculation of EPS are subtracted from net income in arriving at income attributable to common stockholders.

The Company determined that the embedded conversion features of the Series A Preferred Stock and Series B Preferred Stock to receive the Coverage Warrants both met the definition a beneficial conversion feature and should be accounted for separately as a derivative. The recognition of the beneficial conversion feature occurred upon the conversion of the Series A Preferred Stock into pre-funded warrants and Series B Preferred Stock into common stock and the issuance of the Coverage Warrants. The Company measured the beneficial conversion features' intrinsic values on January 3, 2020 and determined that the beneficial conversion features were valued at \$5,226 for Series A and \$4,173 for Series B, respectively. Upon conversion, the discount originated by the beneficial conversion option, at its intrinsic value for Series A Preferred Stock and Series B Preferred Stock, was immediately recognized as a dividend. The dividend is reflected as an adjustment to basic and diluted net loss per share attributable to common stockholders.

## 8. Equity Incentive Plans

### Equity Incentive Plans

In September 2012, the Company adopted the 2012 Equity Incentive Plan, as amended (the “Plan”), which provides designated employees of the Company and its affiliates, certain consultants and advisors who perform services for the Company and its affiliates, and nonemployee members of the board of directors of the Company and its affiliates with the opportunity to receive grants of incentive stock options, nonqualified stock options and stock awards.

On January 20, 2017, the Company’s stockholders approved the 2016 Equity Incentive Plan (the “2016 Plan”). Beginning on January 1, 2018, the number of shares of common stock authorized for issuance pursuant to the 2016 Plan was increased each January 1 by an amount equal to four percent (4%) of the Company’s outstanding common stock as of the end of the immediately preceding calendar year or such other amount as determined by the compensation committee of the Company’s board of directors. In 2019, the board of directors and the stockholders approved and authorized an additional 3,000,000 shares of Common Stock to be added to the shares authorized for issuance under the 2016 Plan.

As of March 31, 2020, there were 1,760,288 shares available for grant under the Company’s equity incentive plans.

A summary of stock option activity under the Equity Plans is as follows:

	<b>Options</b>	<b>Weighted Average Exercise Price Per Share</b>	<b>Weighted Average Remaining Life in Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2019	4,024,566	\$ 7.48	7.98	\$ 2
Granted	1,265,000	\$ 2.34		
Exercised	(7,778)	\$ 1.39		
Forfeited	(190,579)	\$ 6.87		
Outstanding at March 31, 2020	<u>5,091,209</u>	\$ 6.23	8.16	\$ 299
Options exercisable at March 31, 2020	2,567,661	\$ 9.79	6.98	\$ 61
Options vested and expected to vest at March 31, 2020	5,091,209	\$ 6.23	8.16	\$ 299

The grant date fair value of the options granted during the year ended December 31, 2019 and the three months ended March 31, 2020, was estimated at the date of grant using the Black-Scholes option valuation model. The expected life was estimated using the “simplified” method as defined by the SEC’s Staff Accounting Bulletin 107, Share-Based Payment. The expected volatility was based on the historical volatility of comparable public companies from a representative peer group selected based on industry and market capitalization data. The risk-free interest rate was based on the continuous rates provided by the U.S. Treasury with a term approximating the expected life of the option. The expected dividend yield was 0% because the Company does not expect to pay any dividends for the foreseeable future. The Company elected the straight-line attribution method in recognizing the grant date fair value of options issued over the requisite service periods of the awards, which are generally the vesting periods.

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors during the year ended December 31, 2019 and the three months ended March 31, 2020 were as follows, presented on a weighted average basis:

	<b>Three Months Ended March 31, 2019</b>	<b>Year Ended December 31, 2018</b>
Expected volatility	66.94%	66.94%
Weighted average risk-free interest rate	0.00%	0.00%
Expected dividend yield	0.89%	2.07%
Expected term (in years)	6.81	6.77

Stock options generally vest over a three or four year period, as determined by the compensation committee of the board of directors at the time of grant. The options expire ten years from the grant date. As of March 31, 2020, there was approximately \$4,090 of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average period of approximately 2.33 years.

The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees in the condensed consolidated statements of operations and comprehensive loss as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Research and development	\$ 189	\$ 176
General and administrative	368	771
<b>Total</b>	<b>\$ 557</b>	<b>\$ 947</b>

#### *Restricted Stock Units*

During the year ended December 31, 2019, the Company issued 181,000 restricted stock units (“RSUs”) to employees under the 2016 Plan. Upon vesting of the RSUs, the Company has the option to settle the award by either issuing shares of the Company’s common stock or paying an amount of cash equal to the fair value of the Company’s common stock on the settlement date. In October 2019 and January 2020, the Company cash settled 90,500 and 90,500 RSUs, respectively.

During the three months ended March 31, 2020, the Company granted 660,606 RSUs to an executive officer that will cliff vest and will be settled after three years of continuous service, or upon a change of control of the Company, whichever is earlier, pursuant to the 2016 Plan. During the three months ended March 31, 2020, the Company recognized \$13 of stock based compensation expense related to RSUs. The Company did not recognize any stock based compensation expense related to RSUs during the three months ended March 31, 2019.

The following table presents a summary of outstanding RSUs under the 2016 Plan as of March 31, 2020:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Outstanding at December 31, 2019	90,500	\$ 1.74
Awarded	660,606	\$ 1.42
Settled in cash	(90,500)	\$ 1.74
Outstanding at March 31, 2020	<u>660,606</u>	<u>\$ 1.42</u>

As of March 31, 2020, there were 660,606 shares outstanding covered by RSUs that are expected to vest. The weighted average grant date fair value of these shares of restricted stock was \$1.42 per share and the aggregate grant date fair value of these shares of restricted stock was approximately \$932. As of March 31, 2020, there was approximately \$919 of unrecognized compensation costs, net of estimated forfeitures, related to RSUs granted to employees, which are expected to be recognized as expense over a remaining weighted average period of 2.96 years.

#### **9. Net Loss Per Share**

Basic and diluted net loss per share for the three months ended March 31, 2020 and 2019 was calculated as follows (in thousands except share and per share amounts):

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Numerator:</b>		
Net loss	\$ (7,231)	\$ (8,603)
Dividend attributable to down round feature of warrants	(303)	(359)
Dividend attributable to Series A & B convertible preferred stock	(372)	-
Series A & B convertible preferred stock - beneficial conversion feature	(9,399)	-
Net loss attributable to common stockholders for basic and diluted loss per share	<u>\$ (17,305)</u>	<u>\$ (8,962)</u>
<b>Denominator:</b>		
Weighted average number of common shares outstanding - basic and diluted	31,632,213	19,237,444
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.47)</u>

Included within weighted average common shares outstanding are common shares issuable upon the exercise of the pre-funded warrants as the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders.

The Company’s potentially dilutive securities include RSUs, stock options and warrants. These securities were excluded from the computations of diluted net loss per share for the three months ended March 31, 2020 and 2019, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Restricted stock units to purchase common stock	660,606	-
Options to purchase common stock	5,091,209	2,905,334
Warrants to purchase common stock	36,249,087	10,369,752
	<u>42,000,902</u>	<u>13,275,086</u>

## 10. Commitments and Contingencies

**Manufacturing Agreements**—The Company is party to manufacturing agreements with vendors to manufacture DKN-01, its lead product candidate, for use in clinical trials. As of March 31, 2020, there were no noncancelable commitments under these agreements.

**License and Service Agreement**—On January 3, 2011, the Company entered into a license agreement with Eli Lilly and Company (“Lilly”) to grant a license to the Company for certain intellectual property rights relating to pharmaceutically active compounds that may be useful in the treatment of bone healing, cancer and, potentially, other medical conditions. The Company previously issued 9,000,000 shares of Series A Preferred Stock to Lilly in consideration for the grant of the license. As defined in the license agreement, the Company would be required to pay royalties to Lilly based upon a percentage in the low single digits of net sales of developed products, if and when achieved. However, there can be no assurance that clinical or commercialization success of developed products will occur, and no royalties have been paid or accrued through March 31, 2020.

**License Agreement**—On May 28, 2015, the Company entered into a license agreement with Lonza Sales AG (“Lonza”), pursuant to which Lonza granted the Company a world-wide, non-exclusive license for certain intellectual property relating to a gene expression system for manufacturing DKN-01. As defined in the license agreement, the Company would be required to pay royalties to Lonza based on a percentage in the low single digits of net sales of DKN-01, if and when achieved. However, there can be no assurance that clinical or commercialization success will occur, and no royalties have been paid or accrued through March 31, 2020.

**Legal Proceedings**—At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to its legal proceedings.

A patent covering the TRX518 antibody and its uses in methods of inducing or enhancing an immune response in a subject was granted in 2013 to the Company by the European Patent Office (EPO). Three notices of opposition to this patent were filed: two by major pharmaceutical companies and a third by an individual, possibly on behalf of a major pharmaceutical company. At the conclusion of the opposition proceedings before the Opposition Division of the EPO, the Opposition Division issued a decision indicating that the Company’s patent was maintained with modified claims that differ from the claims as originally granted. These narrowed claims cover the TRX518 antibody and uses of the TRX518 antibody in methods of inducing or enhancing an immune response in a subject. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain broader claims that more closely reflect the claims as granted in the patent. The EPO Board of Appeal has scheduled a date for the appeal hearing in September 2020.

In 2016, a patent covering the use of the TRX518 antibody in combination with a chemotherapeutic agent for treating cancer was granted to the Company by the EPO. In March 2017, notices of opposition to this patent were filed at the EPO by ten different entities, including several major pharmaceutical companies. Oral proceedings at the EPO took place on December 4 and 5, 2018. At the conclusion of the oral proceedings, the Opposition Division decided that the patent should be revoked in its entirety on the ground that the claims as granted contained added matter. Subsequently, the Opposition Division issued an interlocutory decision restating its conclusion that the claims as granted contained added matter and revoking the patent. The Company has filed an appeal of the decision of the Opposition Division seeking to obtain a reversal of the Opposition Division’s decision on added matter. The EPO Board of Appeal has not yet scheduled the appeal hearing.

**Indemnification Agreements**—In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of March 31, 2020 or December 31, 2019.

## 11. Related Party Transactions

The Company has a license agreement with a stockholder (See Note 10).

On February 5, 2019, the Company completed the 2019 Public Offering pursuant to which the Company issued 7,557,142 shares of its common stock at a price of \$1.75 per share, which included 985,714 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, each share issued with a warrant to purchase one share of common stock. Each warrant has an exercise price of \$1.95 per share with an exercise period expiring seven years from the date of issuance. The aggregate net proceeds received by the Company from the offering were approximately \$12,122, net of underwriting discounts and commissions and estimated offering expenses payable by the Company. HealthCare Ventures IX, L.P. purchased common stock and warrants in the 2019 Public Offering on the same terms and conditions as the other Purchasers. Three of the Company's directors and executive officers are affiliated with HealthCare Ventures IX, L.P. and its affiliates.

### *January 2020 - Private Placement*

In January 2020, the Company issued and sold 1,421,801 shares of its Series A Preferred Stock, at a purchase price of \$10.54 per share, and 1,137,442 shares of its Series B Preferred Stock, at a purchase price of \$10.55 per share, and one (1) share of its Special Voting Stock entitling the purchaser of Series A Preferred Stock to elect one member of its board of directors for aggregate net proceeds to the Company of approximately \$25,322.

On March 5, 2020, the Company's stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock and the conversion of the Series B Preferred Stock into 11,531,133 shares of its common stock. Each investor also received the Coverage Warrants to purchase an equal number of shares at an exercise price of \$2.11 per share. In the January 2020 Private Placement, (i) BeiGene received 4,804,637 shares of common stock and a warrant to purchase an equal number of shares of common stock and (ii) Perceptive Life Sciences Master Fund, Ltd. and its affiliates ("Perceptive") received 6,726,496 shares of common stock and a warrant to purchase an equal number of shares of common stock. As a result of the January 2020 Private Placement, each of BeiGene and Perceptive became a greater than 5% holder of the Company, and, as a result, a "related party" as contemplated by Item 404 of Regulation S-K.

In connection with the January 2020 Private Placement, the Company entered into a registration rights agreement with each of BeiGene and Perceptive pursuant to which the Company agreed, following demand by either BeiGene or Perceptive, to file with the SEC a Registration Statement on Form S-3 covering the resale of the shares of common stock issued or issuable upon exercise of the above-referenced Coverage Warrants by BeiGene or Perceptive as promptly as reasonably practicable following such demand, and in any event within sixty days after such demand.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and the accompanying notes thereto and other disclosures included in this Quarterly Report on Form 10-Q, including the disclosures under Part II, Item 1A "Risk Factors," and our audited condensed consolidated financial statements and the accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission, or the SEC, on March 16, 2020. Our condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and, unless otherwise indicated, amounts are presented in U.S. dollars.

### Company Overview

We are a biopharmaceutical company developing novel therapies designed to treat patients with cancer by inhibiting fundamental tumor-promoting pathways and by harnessing the immune system to attack cancer cells. Our strategy is to identify, acquire, and develop molecules that will rapidly translate into high impact therapeutics that generate durable clinical benefit and enhanced patient outcomes. Our two clinical stage programs are:

- **DKN-01:** A monoclonal antibody that inhibits Dickkopf-related protein 1, or DKK1. DKK1 is a protein that regulates the Wnt signaling pathways and enables tumor cells to proliferate and spread, as well as suppresses the immune system from attacking the tumor. When DKN-01 binds to DKK1, an anti-tumor effect can be generated. DKN-01-based therapies have generated responses and clinical benefit in several patient populations. We are currently studying DKN-01 in multiple ongoing clinical trials in patients with esophagogastric cancer, hepatobiliary cancer, gynecologic cancers, or prostate cancer. In January 2020, we entered into an exclusive option and license agreement (the "BeiGene Agreement") with BeiGene, Ltd., or BeiGene, which granted BeiGene the right to develop and commercialize DKN-01 in Asia (excluding Japan), Australia, and New Zealand.
- **TRX518:** A monoclonal antibody targeting the glucocorticoid-induced tumor necrosis factor-related receptor, or GITR. GITR is a receptor found on the surface of a wide range of immune cells. GITR stimulation activates tumor fighting white blood cells and decreases the activity of potentially tumor-protective immunosuppressive cells. TRX518 has been specifically engineered to enhance the immune system's anti-tumor response by activating GITR signaling without causing the immune cells to be destroyed. We conducted clinical trials of TRX518 in patients with advanced solid tumors in combination with gemcitabine chemotherapy or with cancer immunotherapies known as PD-1 antagonists. In November 2019, we announced that we have deprioritized continued development of TRX518.

### Recent Developments

Since January 1, 2020, we have continued to make progress with the development of DKN-01 and our business development and financing strategy:

- **BEIGENE LICENSE AGREEMENT:** On January 3, 2020, we entered into the BeiGene Agreement for the clinical development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. We retain exclusive rights for the development, manufacturing, and commercialization of DKN-01 for the rest of the world. We received an upfront cash payment of \$3.0 million from BeiGene. Additionally, we are eligible to receive payments of up to \$132.0 million based upon the exercise of the option and the achievement of certain development, regulatory, and sales milestones, as well as tiered royalties on any product sales of DKN-01 in the licensed territory.
- **\$27M EQUITY FINANCING:** Simultaneous with the BeiGene Agreement, we also entered into a Securities Purchase Agreement pursuant to which we issued and sold to a lead investor 1,421,801 shares of our Series A Mandatorily Convertible Cumulative Non-Voting Perpetual Preferred Stock, (the "Series A Preferred Stock"), at a purchase price of \$10.54 per share, and sold to BeiGene and Perceptive Advisors an aggregate of 1,137,442 shares of our Series B Mandatorily Convertible Cumulative Non-Voting Perpetual Preferred Stock, (the "Series B Preferred Stock") at a purchase price of \$10.55 per share, and one (1) share of our Special Voting Stock, entitling the purchaser of the Series A Preferred Stock to elect one member of our board of directors, and received aggregate gross proceeds of \$27 million. On March 5, 2020, our stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock and the conversion of the Series B Preferred Stock into 11,531,133 shares of common stock. Each investor also received a warrant to purchase an equal number of shares at an exercise price of \$2.11 per share.

- **DKN-01 IN GYNECOLOGIC CANCERS:** We presented data from our study of DKN-01 as a monotherapy and in combination with paclitaxel in patients with relapsed/refractory epithelial endometrial cancer, epithelial ovarian cancer, or carcinosarcoma. As of the cut-off date of December 30, 2019, 105 heavily pretreated patients had been enrolled across the six groups of the study. Patients with endometrial cancer and carcinosarcoma had higher tumor DKK1 expression and a higher percentage of Wnt activating mutations than the ovarian cancer patients.
  - o **SINGLE AGENT ACTIVITY IN ENDOMETRIAL CANCER PATIENTS:** Twenty-nine endometrial cancer patients were enrolled in the DKN-01 monotherapy arm, over 75% of whom had experienced three or more prior lines of therapy. In the 20 evaluable patients with a Wnt signaling alteration, one patient (5%) has an ongoing complete response, one patient (5%) had a partial response, eight patients (40%) had a best response of stable disease, and 10 patients (50%) had progressive disease, representing an overall response rate (“ORR”) of 10% and a disease control rate (“DCR”) of 50%. In the group of six evaluable patients without any Wnt signaling alterations, one patient (16.6%) had a best response of stable disease and five patients (83.3%) had progressive disease.
  - o **COMBINATION THERAPY ACTIVITY IN CARCINOSARCOMA PATIENTS:** Fifteen patients with carcinosarcoma were enrolled in the DKN-01 plus paclitaxel arm, six of whom were evaluable for response as of the data-cut off date. Two patients (33%) have had a partial response, one patient (17%) has had a best response of stable disease, and three patients (50%) had progressive disease, representing an ORR of 33% and a DCR of 50%. Nine patients had not reached their first tumor assessment.
  - o **MONOTHERAPY PATIENTS WITH WNT ACTIVATING MUTATIONS HAVE LONGER PROGRESSION-FREE SURVIVAL (“PFS”) AND OVERALL SURVIVAL (“OS”):** In a pooled analysis of all DKN-01 monotherapy patients, patients with Wnt activating mutations have demonstrated a longer median PFS of 168 days as compared to patients without Wnt activating mutations with median PFS of 56 days. Median OS has not been reached in the Wnt activating mutation group in the pooled analysis as compared to median OS of 328 days in the non-Wnt activating mutation group.
  - o **MONOTHERAPY PATIENTS WITH DKK1-HIGH TUMORS HAVE LONGER PFS AND OS:** DKK1 expression as measured by *in situ* hybridization RNAscope assay was available for 68 of the patients on the study, 32 of whom were treated with DKN-01 monotherapy. Seven patients (22%) were identified as having DKK1-high tumoral expression. Consistent with the results from our study in patients with esophagogastric cancer, patients whose tumors are DKK1-high have prolonged median PFS of 168 days as compared to patients with tumors that are DKK1-low with median PFS of 56 days. Median OS was 450 days in the DKK1-high group in the pooled analysis as compared 276 days in the DKK1-low group.
- **DKN-01 IN ESOPHAGOGASTRIC CANCER:** We completed a multi-part Phase 1/2 clinical study of DKN-01 as a monotherapy and in combination with paclitaxel or KEYTRUDA® (pembrolizumab) in advanced esophagogastric cancer patients. The combination of DKN-01 and pembrolizumab in gastroesophageal junction cancer (GEJ) and gastric cancer (GC) patients demonstrated improved outcomes in DKK1-high patients and who had not previously been treated with PD-1/PD-L1 therapy. DKK1-high patients experienced over 22 weeks median PFS and nearly 32 weeks median OS, with a 50% ORR and 80% DCR in 10 evaluable patients. DKK1-low patients experienced nearly 6 weeks median PFS and over 17 weeks OS, with a 20% DCR in 15 evaluable patients.
- **DKN-01 PLUS TISLELIZUMAB COMBINATION STUDY:** As part of the collaboration with BeiGene, we intend to study the combination of DKN-01 and BeiGene’s anti-PD-1 antibody, tislelizumab. We plan to evaluate approximately 40 patients with second-line GC or GEJ whose tumors are DKK1-high. In addition, we will evaluate the combination of DKN-01 with tislelizumab and chemotherapy in approximately 20 patients with first-line GC or GEJ. Site initiation activities for this clinical trial are underway, and we expect to dose the first patient in the second half of 2020.

## Financial Overview

### Revenues

Our revenues relate to our performance obligations under the BeiGene Agreement and may include such things as providing intellectual property licenses, performing technology transfer, performing research and development consulting services and notifying the customer of any enhancements to licensed technology or new technology that we discover, among others. We have determined that our performance obligations under the BeiGene Agreement, as evaluated at contract inception, were not distinct and represented a single performance obligation. For this agreement, revenue is recognized using a proportional performance model, representing the transfer of goods or services as activities are performed over the term of the agreement. Upfront payments are also amortized to revenue on a straight-line basis over the performance period. Upfront payment contract liabilities resulting from our license agreement do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the license granted reflects research and development expenses already incurred by us. When no performance obligations are required of us, or following the completion of the performance obligation period, such amounts are recognized upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license revenues. Sales-based milestones and royalties under our license agreement will be recognized as royalty revenue in the period the related sale occurred. We generally invoice our licensee upon the completion of the effort or achievement of a milestone, based on the terms of the agreement. Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

### Research and Development Expenses

Our research and development activities have included conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for DKN-01 and TRX518. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock-based compensation;
- fees paid to consultants and CROs for our nonclinical and clinical trials, and other related clinical trial fees, including but not limited to laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial material; and
- costs related to compliance with regulatory requirements.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of DKN-01 and any other product candidates, subject to the availability of additional funding.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of internal and external costs, such as employee costs, including salaries and stock-based compensation, other internal costs, fees paid to consultants, central laboratories, contractors and CROs in connection with our clinical and preclinical trial development activities. We use internal resources to manage our clinical and preclinical trial development activities and perform data analysis for such activities.

We participate, through our subsidiary in Australia, in the Australian government's research and development ("R&D") Incentive program, such that a percentage of our eligible research and development expenses are reimbursed by the Australian government as a refundable tax offset and such incentives are reflected as other income.

The table below summarizes our research and development expenses incurred by development program and the R&D Incentive income for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Direct research and development by program:		
DKN-01 program	\$ 3,443	\$ 5,375
TRX518 program	1,160	1,415
Total research and development expenses	<u>\$ 4,603</u>	<u>\$ 6,790</u>
Australian research and development incentives	<u>\$ 85</u>	<u>\$ 75</u>

The successful development of our clinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

### **General and Administrative Expenses**

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include direct and allocated facility-related costs as well as professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

### **Interest income**

Interest income consists primarily of interest income earned on cash and cash equivalents.

### **Research and development incentive income**

Research and development incentive income includes payments under the R&D Incentive program from the government of Australia. The R&D Incentive program is one of the key elements of the Australian Government's support for Australia's innovation system. It was developed to assist businesses in recovering some of the costs of undertaking research and development. The research and development tax incentive provides a tax offset to eligible companies that engage in research and development activities.

Companies engaged in research and development may be eligible for either:

- a 43.5% refundable tax offset for entities with an aggregated turnover of less than A\$20 million per annum, or
- a 38.5% non-refundable tax offset for all other entities.

We recognize as income the amount we expect to be reimbursed for qualified expenses.

### **Foreign currency translation adjustment**

Foreign currency translation adjustment consists of gains (losses) due to the revaluation of foreign currency transactions attributable to changes in foreign currency exchange rates associated with our Australian subsidiary.

### **Critical Accounting Policies and Estimates**

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

On January 1, 2019, we adopted ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)* ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features, and Topic 842, *Leases*, ("ASU 2016-02"), which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements.

#### **Revenue Recognition**

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, using the full retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for the BeiGene Agreement, 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; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We utilize key assumptions to determine a stand-alone selling price for performance obligations, which may include revenue forecasts, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies.

Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 16, 2020 and the notes to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- revenue recognition;
- accrued research and development expenses;
- research and development incentive receivable; and
- stock-based compensation.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2020 and 2019

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2019:

	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2020</b>	<b>2019</b>	
	<b>(in thousands)</b>		
License revenue	\$ 375	\$ -	\$ 375
Operating expenses:			
Research and development	4,603	6,790	(2,187)
General and administrative	2,153	2,005	148
Total operating expenses	<u>6,756</u>	<u>8,795</u>	<u>(2,039)</u>
Loss from operations	(6,381)	(8,795)	2,039
Interest income	68	82	(14)
Interest expense	(12)	(7)	(5)
Australian research and development incentives	85	75	10
Foreign currency gains (loss)	(991)	42	(1,033)
Net loss	<u>\$ (7,231)</u>	<u>\$ (8,603)</u>	<u>\$ 1,372</u>

#### Revenues

License revenues for the three months ended March 31, 2020 were \$0.4 million and relate to the BeiGene Agreement for the development and commercialization of DKN-01 in Asia (excluding Japan), Australia, and New Zealand. The BeiGene Agreement became effective January 3, 2020. As the BeiGene Agreement is the first such license agreement, no license revenues were recorded during the three months ended March 31, 2019.

#### Research and Development Expenses

	<b>Three Months Ended March 31,</b>		<b>Increase (Decrease)</b>
	<b>2020</b>	<b>2019</b>	
	<b>(in thousands)</b>		
Direct research and development by program:			
DKN-01 program	\$ 3,443	\$ 5,375	\$ (1,932)
TRX518 program	1,160	1,415	(255)
Total research and development expenses	<u>\$ 4,603</u>	<u>\$ 6,790</u>	<u>\$ (2,187)</u>

Research and development expenses were \$4.6 million for the three months ended March 31, 2020, compared to \$6.8 million for the three months ended March 31, 2019. The decrease of \$2.2 million was primarily due to a decrease of \$1.8 million in clinical trial costs due to timing of patient enrollment and a decrease of \$0.5 million in consulting fees associated with research and development activities during the three months ended March 31, 2020 as compared to the same period in 2019. These decreases were partially offset by a \$0.1 million increase in payroll and other related expenses due to an increase in headcount in our research and development full time employees.

#### *General and Administrative Expenses*

General and administrative expenses were \$2.2 million for the three months ended March 31, 2020, compared to \$2.0 million for the three months ended March 31, 2019. The increase of \$0.2 million in general and administrative expenses was primarily due to a \$0.4 million increase in payroll and other related expenses during the three months ended March 31, 2020 as compared to the same period in 2019 and a \$0.2 million increase in legal, audit and consulting fees associated with corporate and business development activities. These increases were partially offset by a decrease of \$0.4 million in stock based compensation expense, primarily due to stock option grants made to our executive officers during the three months ended March 31, 2017 which fully vested in January 2020.

#### *Interest Income*

We recorded interest income of \$0.1 million in each of the three months ended March 31, 2020 and 2019.

#### *Australian Research and Development Incentives*

We recorded R&D incentive income of \$0.1 million in each of the three months ended March 31, 2020 and 2019, based upon the applicable percentage of eligible research and development activities under the Australian Incentive Program, which expenses included the cost of manufacturing clinical trial material.

The R&D incentive receivable has been recorded as “Research and development incentive receivable” in the condensed consolidated balance sheets.

#### *Foreign Currency Gains (loss)*

During the three months ended March 31, 2020 and 2019, we recorded foreign currency losses of \$1.0 million and \$0.1 million, respectively. Foreign currency gains and losses are due to changes in the Australian dollar exchange rate related to activities of the Australian entity.

### **Financial Position, Liquidity and Capital Resources**

Since our inception, we have been engaged in organizational activities, including raising capital, and research and development activities. We do not yet have a product that has been approved by the Food and Drug Administration (the “FDA”), have not generated any revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flows from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, our future operations are dependent on the success of efforts to raise additional capital, our research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of our products.

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. As of March 31, 2020, we had cash and cash equivalents of \$25.5 million. Additionally, we had an accumulated deficit of \$202.7 million at March 31, 2020, and during the three months ended March 31, 2020, we incurred a net loss of \$7.2 million. We expect to continue to generate operating losses in the foreseeable future.

We believe that our cash and cash equivalents of \$25.5 million as of March 31, 2020, will be sufficient to fund our operating expenses for at least the next 12 months from issuance of these financial statements. We have suspended enrollment of our TRX518 clinical trials and deprioritized development. In addition, we will seek additional funding through public or private equity financings and will seek funding or development program cost-sharing through collaboration agreements or licenses with larger pharmaceutical or biotechnology companies, such as the BeiGene Agreement. If we are unable to obtain additional funding or development program cost-sharing, or exceed our current spending forecasts or fail to receive the research and development tax incentive payment, we have the ability and would be forced to: delay, reduce or eliminate certain clinical trials or research and development programs, reduce or eliminate discretionary operating expenses, and delay company and pipeline expansion, any of which would adversely affect our business prospects. The inability to obtain funding, as and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

## Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
Cash used in operating activities	\$ (3,926)	\$ (6,868)
Cash provided by financing activities	25,605	12,322
Effect of exchange rate changes on cash and cash equivalents	(105)	(29)
Net increase in cash and cash equivalents	<u>\$ 21,574</u>	<u>\$ 5,425</u>

*Operating activities.* Net cash used in operating activities for the three months ended March 31, 2020 was primarily related to our net loss from the operation of our business of \$7.2 million and net changes in working capital, including a decrease in accounts payable and accrued expenses of \$0.8 million, an increase in contract acquisition costs of \$0.3 million, a decrease in lease liabilities of \$0.2 million and an increase in research and development receivable of \$0.1 million. There was also a decrease of \$0.2 million related to a noncash change in restricted stock liability. These changes were partially offset by a decrease of \$0.4 million in prepaid expenses and other assets, an increase of \$2.7 million in deferred revenue, noncash foreign currency losses of \$1.0 million related to activities in our Australian entity due to changes in the Australian dollar exchange rate, noncash stock based compensation expense of \$0.6 million and noncash lease expense of \$0.2 million.

Net cash used in operating activities for the three months ended March 31, 2019 was primarily related to our net loss from the operation of our business of \$8.6 million and net changes in working capital, including a decrease of \$0.1 million in lease liabilities due to rent payments and an increase in research and development receivable of \$0.1 million. These changes were partially offset by an increase of \$0.8 million in accounts payable and accrued expenses and noncash stock based compensation expense and amortization on right-of-use assets of \$0.9 million and \$0.2 million, respectively.

*Investing Activities.* There were no investing activities during the three months ended March 31, 2020 and 2019.

*Financing Activities.* Net cash provided by financing activities for the three months ended March 31, 2020 consisted of \$27.0 million in proceeds from the issuance of Series A Preferred Stock and Series B Preferred Stock in connection with the January 2020 Private Placement and \$0.1 million in proceeds from the issuance of common stock upon the exercise of warrants. These increases were partially offset by payments of \$1.8 million for deferred costs.

Net cash provided by financing activities for the three months ended March 31, 2019 consisted of \$12.3 million in proceeds from the issuance of common stock in connection with the 2019 Public Offering, net of underwriter commissions and discounts.

## Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

## Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable.

## Item 4. Controls and Procedures

### *Evaluation of 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 and Exchange Act of 1934, as amended (the "Exchange Act") is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our President and Chief Executive Officer, who is also serving as Chief Financial Officer and therefore currently serves as both our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of March 31, 2020, our management, with the participation of our Chief Executive Officer, who is also serving as Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013 Framework). 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 has concluded, based upon the evaluation described above, that, as of March 31, 2020, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such material information is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

### *Changes in Internal Control over Financial Reporting*

During the three months ended March 31, 2020, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that materially affected, or are reasonably likely to affect, internal control over financial reporting.

## Part II — OTHER INFORMATION

### Item 1. Legal Proceedings

None.

### Item 1A. Risk Factors

An investment in our ordinary shares involves a high degree of risk. You should carefully consider the risk factors discussed in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the SEC on March 16, 2020, which could materially affect our business, financial condition, operating results or cash flows. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties.

The information presented below updates, and should be read in conjunction with, the risk factors and information disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the SEC on March 16, 2020. Except as presented below, there have been no material changes from the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2019.

***The ongoing outbreak of the Coronavirus could have a material adverse impact on our business and operations, including on our development of our lead product candidate, DKN-01.***

As a result of the continuing novel Coronavirus outbreak, or COVID-19, we may experience disruptions that could severely affect our business, including our plans to clinically develop DKN-01, our lead product candidate. For example, our employees are all currently working remotely from our office and unable to work and collaborate physically in person. In addition, widespread business interruptions resulting from the novel Coronavirus may adversely affect our ability to initiate, conduct, and complete critical clinical trials and laboratory operations relating to DKN-01. Specifically, temporary closures or prioritization of COVID-19 related work at certain laboratories, offices, or hospitals at which our nonclinical studies and clinical trials for DKN-01 are conducted, or restrictions on the ability of our employees, clinicians, patients enrolled in our trials, or patients who we would like to recruit to enroll in our trials to travel to or enter into certain facilities due to COVID-19 could adversely affect our operations and our ability to conduct nonclinical studies and clinical trials for DKN-01. Further, governmental health protocols and mandates have restricted the ability of many businesses to operate normally. These measures may have a material adverse impact on the third parties with whom we collaborate, including our clinical trial sites, contract research organizations, contract manufacturing organizations, laboratory service providers, or BeiGene, Ltd., and on their ability to devote sufficient time and resources to us. This could negatively affect our ability to advance DKN-01 and cause delays and increased expenses in our projected development timelines and cost.

We are continuing to monitor and assess the real and potential effects of the COVID-19 pandemic on our business, including with respect to our development of DKN-01. However, the ultimate extent to which the novel Coronavirus impacts our business will depend upon future developments which are highly uncertain and cannot be accurately predicted at this time, such as the ultimate geographic spread of the virus, the severity of the disease, the duration of the current outbreak or subsequent outbreaks, travel restrictions, actions to contain the outbreak or mitigate its impact, and the effectiveness of actions taken in the United States and other countries to treat the disease.

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

#### *January 2020 - Private Placement*

In January 2020, the Company issued and sold 1,421,801 shares of its Series A Preferred Stock, at a purchase price of \$10.54 per share, and 1,137,442 shares of its Series B Preferred Stock, at a purchase price of \$10.55 per share, and one (1) share of its Special Voting Stock entitling the purchaser of Series A Preferred Stock to elect one member of its board of directors for aggregate net proceeds to the Company of approximately \$25,322.

On March 5, 2020, the Company’s stockholders approved the conversion of the Series A Preferred Stock into a pre-funded warrant to purchase 14,413,902 shares of common stock and the conversion of the Series B Preferred Stock into 11,531,133 shares of its common stock. Each investor also received warrants to purchase an equal number of shares at an exercise price of \$2.11 per share.

The proceeds are to be used for general corporate purposes, including the development of DKN-01.

These securities were sold in reliance on Section 4(a)(2) and Rule 506 of the Securities Act of 1933, as amended.

### Item 3. Defaults Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

None.

### Item 5. Other Information

On April 21, 2020, the Company entered into an unsecured promissory note, or the PPP Note, through Silicon Valley Bank under the Paycheck Protection Program, or PPP, a program administered by the Small Business Administration, or SBA, and established as part of the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. The PPP Note had an aggregate principal amount of approximately \$662,420. The Company applied for the PPP program in good faith. However, following further deliberations, the Company decided to cancel the PPP Note, and provided notice of cancellation to Silicon Valley Bank on April 22, 2020. Notwithstanding its notice of cancellation, the Company received the loan proceeds on April 23, 2020. The Company initiated the repayment process immediately on April 23, 2020. On April 28, 2020, the Company repaid the entire principal amount of the PPP Note to Silicon Valley Bank.

**Item 6. Exhibits**

See the Exhibit Index immediately prior to the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

## EXHIBIT INDEX

- [3.1](#) [Third Amended and Restated Certificate of Incorporation of Leap Therapeutics, Inc. \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K as filed on January 26, 2017\).](#)
- [3.2±](#) [Certificate of Amendment to Third Amended and Restated Certificate of Incorporation of Leap Therapeutics, Inc.](#)
- [3.3](#) [Certificate of Designation of Series A Mandatorily Convertible Cumulative Non-Voting Perpetual Preferred Stock of the Company \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [3.4](#) [Certificate of Designation of Series B Mandatorily Convertible Cumulative Non-Voting Perpetual Preferred Stock of the Company \(incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [3.5](#) [Certificate of Designation of Special Voting Stock of the Company \(incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [4.1](#) [Form of Pre-Funded Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [4.2](#) [Form of Series A Coverage Warrant \(incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [4.3](#) [Form of Series B Coverage Warrant \(incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [10.1±\\*](#) [Exclusive Option and License Agreement dated as of January 3, 2020, by and between the Company and BeiGene, Ltd.](#)
- [10.2](#) [Securities Purchase Agreement, dated January 3, 2020, by and among the Company and the institutional investors named therein \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [10.3](#) [Placement Agency Agreement, dated January 3, 2020, by and between the Company and Raymond James & Associates, Inc. \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [10.4](#) [Form of Voting Agreement \(incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [10.5](#) [Registration Rights Agreement dated as of January 3, 2020, by and between the Company and the persons listed on the attached Schedule A thereto \(incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [10.6](#) [Registration Rights Agreement dated as of January 3, 2020, by and between the Company and the persons listed on the attached Schedule A thereto \(incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K as filed on January 7, 2020\).](#)
- [31.1±](#) [Certification of Chief Executive Officer and Chief Financial Officer Required Under Rule 13a-14\(a\) of the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- [32.1±\\*\\*](#) [Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101 ± The following materials from Leap Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at March 31, 2020 and December 31, 2019, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2020 and 2019, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2020 and 2019, (iv) Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2020 and 2019, (v) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2020 and 2019, and (vi) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

± Filed herewith.

\* Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

\*\* This exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933, as amended, or the Securities and Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

**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.

LEAP THERAPEUTICS, INC.

Date: May 14, 2020

By: /s/ Douglas E. Onsi  
Douglas E. Onsi  
President, Chief Executive Officer and Chief Financial Officer

(Principal Executive Officer, Principal Financial Officer and Duly Authorized Signatory)

**CERTIFICATE OF AMENDMENT**  
**TO**  
**THIRD AMENDED AND RESTATED**  
**CERTIFICATE OF INCORPORATION**  
**OF**  
**LEAP THERAPEUTICS, INC.**

Pursuant to the provisions of Section 242 of the Delaware General Corporation Law (the "Act"), the undersigned corporation hereby certifies as follows:

1. The name of the corporation is Leap Therapeutics, Inc. (the "Corporation"). The date the Corporation filed its original Certificate of Incorporation with the Secretary of State of the State of Delaware was January 3, 2011.
2. The Certificate of Incorporation was amended by that certain Certificate of Amendment to the Certificate of Incorporation, dated as of May 29, 2014, as further amended by that certain Second Certificate of Amendment to the Certificate of Incorporation, dated as of April 17, 2015, as further amended by that certain Third Certificate of Amendment to the Certificate of Incorporation, dated as of November 16, 2015, as further amended and restated by that certain First Amended and Restated Certificate of Incorporation, dated as of December 10, 2015, and as further amended by that certain Second Amended and Restated Certificate of Incorporation, dated as of January 9, 2017.
3. This Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation has been duly adopted by the Board of Directors of the Corporation and the stockholders of the Corporation in accordance with Section 242 of the General Corporation Law of the State of Delaware.
4. The first sentence of Article Fourth of the Corporation's Third Amended and Restated Certificate of Incorporation is hereby amended and restated to read in its entirety as follows:

"FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is two hundred fifty million (250,000,000) shares, consisting of (a) two hundred forty million (240,000,000) shares of common stock, \$0.001 par value per share ("Common Stock"), and (b) ten million (10,000,000) shares of preferred stock, \$0.001 par value per share ("Preferred Stock"), of which (i) one million four hundred twenty-one thousand eight hundred one (1,421,801) shares shall be designated Series A Mandatorily Convertible Cumulative Non-Voting Perpetual Preferred Stock, (ii) one million one hundred thirty-seven thousand four hundred forty-two (1,137,442) shares shall be designated Series B Mandatorily Convertible Cumulative Non-Voting Perpetual Preferred Stock, and (iii) one (1) share shall be designated special voting stock."

5. The Third Amended and Restated Certificate of Incorporation, as amended in the manner provided above in this Certificate of Amendment, is hereby ratified and confirmed in all other respects.

*[The remainder of this page intentionally left blank]*

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IN WITNESS WHEREOF, the undersigned has caused this Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation to be duly executed on behalf of the Corporation on May 6, 2020.

**LEAP THERAPEUTICS, INC.**

By: /s/ Douglas E. Onsi

Name: Douglas E. Onsi

Title: President and Chief Executive Officer

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Information in this exhibit identified by [\*\*\*] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

## EXCLUSIVE OPTION AND LICENSE AGREEMENT

This EXCLUSIVE OPTION AND LICENSE AGREEMENT (this “**Agreement**”) is made as of January 3, 2020 (the “**Effective Date**”), by and between **Leap Therapeutics, Inc.**, a corporation organized and existing under the laws of Delaware (“**Leap**”), having a place of business at 47 Thorndike Street, Suite B1-1, Cambridge, MA 02141 USA, and **BeiGene, LTD.**, a Cayman Island exempted company incorporated with limited liability (“**BeiGene**”), having a place of business at c/o Maurant Ozannes Corporate Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, PO Box 1348, Grand Cayman KY1-1108, Cayman Islands. Leap and BeiGene are referred to in this Agreement individually as a “**Party**” and collectively as the “**Parties**.”

### BACKGROUND

- A. Leap is a biopharmaceutical company that is developing a proprietary antibody known as DKN-01 for the treatment of cancer and controls certain patents and know-how relating to DKN-01;
- B. BeiGene is a biopharmaceutical company engaged in the research, development and commercialization of pharmaceutical products; and
- C. BeiGene wishes to obtain from Leap an exclusive option to an exclusive license to develop and commercialize DKN-01 in the Field in the Territory, and Leap is willing to grant such a license to BeiGene, all in accordance with the terms and conditions set forth herein.

**NOW THEREFORE**, in consideration of the mutual covenants and agreements contained herein below, and other good and valuable consideration, the sufficiency of which is hereby acknowledged by both Parties, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS & INTERPRETATION

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, whether used in the singular or plural, shall have the meanings specified.

**1.1 “Acquiring Entity”** means a Third Party that merges or consolidates with or acquires a Party, or to which a Party transfers all or substantially all of its assets to which this Agreement pertains.

**1.2 “Active Ingredient”** means [\*\*\*].<sup>1</sup>

**1.3 “Affiliate”** means, with respect to a Person, any other Person controlling, controlled by or under common control with such Person, for so long as such control exists. For purposes of this Section 1.3 only, “control” means (i) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity or (ii) 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.

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<sup>1</sup> Competitive Information – Technical Information.

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

1.5 [\*\*\*].<sup>2</sup>

1.6 “**BeiGene Inventions**” means all Inventions that are owned solely by BeiGene pursuant to Section 14.1(a).

1.7 “**BeiGene IP**” means all Patent Rights and Know-How that (i) are Controlled by BeiGene or its Affiliates as of the Effective Date or (ii) thereafter come into BeiGene’s or its Affiliates’ Control independent of this Agreement, and in each case, that are generated, used or applied by or on behalf of BeiGene or its Affiliates or sublicensees in the Development, manufacture or Commercialization of Licensed Products.

1.8 “**BeiGene Patent Rights**” means all Patent Rights in the BeiGene IP.

1.9 “**Biosimilar Product**” means, with respect to a Licensed Product in a particular country in the Territory, any pharmaceutical product that: (a) has received all necessary approvals by the applicable Regulatory Authorities in such country to market and sell such product as a pharmaceutical product, including any and all required pricing and reimbursement approvals; (b) is marketed or sold in the Field by a Third Party that has not obtained the rights to market or sell such product as a licensee, sublicensee or distributor of Leap or BeiGene or any of their respective Affiliates, licensees or sublicensees with respect to such Licensed Product; and (c) is approved as (i) a “biosimilar” or “bioequivalent” (in the United States) of such Licensed Product, (ii) a “similar biological medicinal product” (in the EU) with respect to which such Licensed Product is the “reference medicinal product”, or (iii) if not in the US or EU, the foreign equivalent of a “biosimilar” or “similar biological medicinal product” or “bioequivalent” of such Licensed Product; in each case for use in such country pursuant to an expedited regulatory approval process governing approval of generic biologics based on the then-current standards for regulatory approval in such country (*e.g.*, the Biologics Price Competition and Innovation Act of 2009 or an equivalent under foreign law) and where such regulatory approval was based in significant part upon Clinical Data generated by Leap, BeiGene or their respective Affiliates or sublicensees with respect to such Licensed Product. For purposes of clarity, such a pharmaceutical product will be deemed to be Biosimilar Product for purposes of this definition if a Licensed Product is used as the reference product in the application or submission made with respect to such pharmaceutical product under Applicable Laws.

1.10 “**Business Day**” means a day other than a Saturday, Sunday or any other day on which banking institutions in Boston, Massachusetts or Beijing, China are authorized or required by Applicable Laws to remain closed.

1.11 “**Calendar Quarter**” means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, that, the final Calendar Quarter shall end on the last day of the Term.

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<sup>2</sup>Competitive Information – Commercially Sensitive Terms.

**1.12** “**Calendar Year**” means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that, the final Calendar Year shall end on the last day of the Term.

**1.13** “**cGMP**” means applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (d) the Applicable Laws in any relevant country or region corresponding to (a) through (c) above, each as may be amended and applicable from time to time.

**1.14** “**Clinical Data**” means any and all data (together with all clinical trial reports and the results of analyses thereof) derived or generated in any Clinical Trial conducted by or on behalf of a Party.

**1.15** “**Clinical Trial**” means any human clinical trial of a Licensed Product in the Field.

**1.16** “**Commercialization**” or “**Commercialize**” means any and all activities directed to the offering for sale and sale of any Licensed Product, including (a) marketing, promoting, advertising, exhibiting, distributing, detailing, selling (and offering for sale or contracting to sell) or otherwise commercially exploiting a Licensed Product in the Field in the Territory (including importing and exporting activities in connection therewith); (b) order processing, handling of returns and recalls, booking of sales and transporting such Licensed Product for commercial sale; (c) the conduct of any post-approval Clinical Trials involving such Licensed Product; (d) interacting with Regulatory Authorities regarding the above; and (e) seeking and obtaining pricing approvals and reimbursement approvals (as applicable) for that Licensed Product in the Territory. For clarity, Commercialization does not include manufacture.

**1.17** “**Commercially Reasonable Efforts**” means, with respect to a Party’s obligations or activities under this Agreement, the carrying out of such obligations or activities with a level of effort and resources consistent with the commercially reasonable practices normally devoted by such Party for the development and commercialization of a pharmaceutical product [\*\*\*], taking into account all relevant factors, including but not limited to, [\*\*\*], [\*\*\*], [\*\*\*], associated with the development and commercialization of such Licensed Product.<sup>3</sup>

**1.18** “**Confidential Information**” of a Party (a “**Disclosing Party**”) means, subject to Section 10.2, all Know-How, which is generated by or on behalf of such Disclosing Party under this Agreement and/or any other technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information that is disclosed by a Disclosing Party or its Affiliates to the other Party or its Affiliates (a “**Receiving Party**”) pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement) or which such Disclosing Party or any of its Affiliates or contractors has provided or otherwise made available to the Receiving Party or any of its Affiliates or contractors, whether made available orally, in writing, or in electronic form, including (a) such Know-How comprising or relating to concepts, discoveries, Inventions, data, designs or formulae arising from this Agreement and (b) any unpublished patent applications disclosed hereunder. For purposes of clarity, unless excluded pursuant to Section 10.2, (i) all Clinical Data and results generated in any Clinical Trial conducted pursuant to the Global Development Plan, shall be deemed Confidential Information of Leap, subject to the rights of BeiGene to use and reference such Clinical Data, without additional consideration, in accordance with Section 5.9; (ii) all Inventions shall be deemed the Confidential Information of the owning Party as set forth in Section 14.1(a); (iii) any scientific, technical, manufacturing or financial information, including (except as set forth in (i) above) Clinical Data and information disclosed through an audit report, Commercialization report, Development report or other report, shall constitute Confidential Information of the Disclosing Party; (iv) any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party; and (v) the existence and terms of this Agreement shall be deemed Confidential Information of both of the Parties.

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<sup>3</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

**1.19** “Control” or “Controlled” means with respect to any material, Know-How, or intellectual property right (including Patent Rights), that a Party has the power (whether by ownership, license, or otherwise other than pursuant to this Agreement) to grant to the other Party access, a license, or a sublicense (as applicable) to the same on the terms and conditions set forth in this Agreement without violating any obligations of the granting Party to a Third Party. Notwithstanding the foregoing, a Party will not be deemed to “Control” any material, Know-How, or intellectual property right (including Patent Rights) that, (i) prior to the consummation of the merger, consolidation or transfer making such Third Party an Acquiring Entity of such Party, is owned or in-licensed by (A) a Third Party that becomes an Affiliate of such acquired Party after the Effective Date as a result of such acquisition transaction or (B) any Person that is an Affiliate of such Third Party prior to the consummation of such acquisition transaction or (ii) that any Acquiring Entity or any of its Affiliates subsequently develops without accessing or practicing the Licensed IP or BeiGene IP unless (a) prior to the consummation of such acquisition transaction, such acquired Party or any of its Affiliates also Controlled such Patent Right or Know-How, or (b) the Know-How or Patent Rights owned or in-licensed by the applicable Third Party or any of its Affiliates were not used in the performance of activities under this Agreement prior to the consummation of such acquisition transaction, but after the consummation of such acquisition transaction, such acquired Party or any of its Affiliates uses any such Patent Rights or Know-How in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((a) and (b)), such Patent Rights or Know-How will be “Controlled” by such Party for purposes of this Agreement.

**1.20** “Cover” means, with respect to a Licensed Product in a particular country that the manufacture, use, sale or importation of such Licensed Product, as applicable, in such country would, but for the licenses granted herein, infringe a Valid Claim. Cognates of the word “Cover” shall have correlative meanings.

**1.21** “Develop” or “Development” or “Developing” means all development activities for any Licensed Product that are directed to obtaining Regulatory Approval(s) of such Licensed Product and to support appropriate usage for such Licensed Product in the Field, including: (a) all research, non-clinical, preclinical and clinical activities, testing and studies of such Licensed Product; toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies of such Licensed Product; (b) distribution of such Licensed Product for use in Clinical Trials (including placebos and comparators); (c) statistical analyses; (d) the preparation, filing and prosecution of any NDA for such Licensed Product in the Territory, with respect to Development activities conducted under the Territory Development Plan, and the preparation, filing and prosecution of any Biological License Application or New Drug Application (each as defined by the FDA) outside the Territory, with respect to Development activities conducted under the Global Development Plan; (e) all development activities directed to label expansion (including prescribing information) or obtaining Regulatory Approval for one or more additional Indications following initial Regulatory Approval; (f) all development activities conducted after receipt of Regulatory Approval that are required or requested in writing by a Regulatory Authority as a condition of, or in connection with, obtaining or maintaining a Regulatory Approval; (g) any pharmacoeconomic studies relating to the Indication for which the applicable Licensed Product is being developed; (h) any investigator- or institution-sponsored studies; and (i) all regulatory activities related to any of the foregoing. For clarity, Development does not include manufacture.

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

1.23 “**Field**” means the diagnosis, treatment, palliation or prevention of all indications, diseases and disorders in animals and humans.

1.24 “**First Commercial Sale**” means, with respect to any Licensed Product in any country or jurisdiction in the Territory, the first sale of such Licensed Product by BeiGene, its Affiliates, or sublicensees to a Third Party for distribution, use or consumption in such country or jurisdiction after Regulatory Approvals, as applicable, have been obtained for such Licensed Product in such country or jurisdiction; provided, that, the following shall not constitute a First Commercial Sale of a Licensed Product: (a) any sale to an Affiliate or sublicensee for purposes of resale, (b) any use of a Licensed Product in Clinical Trials, pre-clinical studies or other research or Development activities, or (c) [\*\*\*].<sup>4</sup>

1.25 “**GAAP**” means United States generally accepted accounting principles, consistently applied.

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

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

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

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<sup>4</sup> Competitive Information – Commercially Sensitive Terms.

**1.29** “**Indication**” means a generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition or a risk for a disease or condition. For the avoidance of doubt, [\*\*\*] for purposes of this Agreement.<sup>5</sup>

**1.30** “**Invention**” means any new and useful process, manufacture, or composition of matter, Know-How or other invention that is conceived and first reduced to practice, constructively or actually, by or on behalf of either Party or jointly by or on behalf of the Parties in connection with the Development, manufacture and/or Commercialization of Licensed Antibody(ies) and Licensed Products under this Agreement.

**1.31** “**Know-How**” means all technical information, know-how, data, inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, methods, protocols, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them, and all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data relevant to any of the foregoing. For clarity, Know-How excludes Patent Rights and physical substances.

**1.32** “**Leap Inventions**” means all Inventions that are owned solely by Leap pursuant to Section 14.1(a).

**1.33** “**Licensed IP**” means, collectively, Licensed Know-How and Licensed Patent Rights.

**1.34** “**Licensed Know-How**” means all Know-How Controlled by Leap or any of its Affiliates as of the Effective Date or during the Term of this Agreement that is necessary or useful for BeiGene to Develop, Commercialize, use, import, export, sell, offer for sale, and have sold the Licensed Antibody(ies) and/or any Licensed Products in the Field in the Territory.

**1.35** “**Licensed Patent Rights**” means all Patent Rights Controlled by Leap or its Affiliates as of the Effective Date or during the Term of this Agreement that (a) contain one or more claims that cover the composition, manufacture and/or use of the Licensed Antibody(ies) in the Field in the Territory and/or (b) are necessary or useful for BeiGene to research, Develop, Commercialize, use, import, export, make, have made, manufacture, use, sell, offer for sale, promote, market, distribute, import and export, and have sold the Licensed Antibody(ies) and/or any Licensed Products in the Field in the Territory.

**1.36** “**Licensed Antibody**” means any proprietary antibody(ies) of Leap that bind to DKK1, including DKN-01 and any derivatives, fragments or conjugates thereof.

**1.37** “**Licensed Product**” means any pharmaceutical, formulation or dosage form that contains the Licensed Antibody(ies), whether as its sole Active Ingredient or in combination with one or more other Active Ingredients, in final finished form.

**1.38** “**Manufacturing Cost**” means, with respect to any Licensed Product supplied by or on behalf of Leap to BeiGene hereunder

(a) if such Licensed Product (or any precursor or intermediate thereof) is manufactured by a Third Party manufacturer, (i) the [\*\*\*] costs of such supply of such Licensed Product (or precursor or intermediate) incurred by Leap or its Affiliate, to the extent specifically identifiable to the supply of such Licensed Product as determined in accordance with GAAP (including, but not limited to, [\*\*\*], the [\*\*\*] of such Licensed Product (including applicable [\*\*\*])),<sup>6</sup> or

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<sup>5</sup> Competitive Information – Commercially Sensitive Terms.

(b) if such Licensed Product (or any precursor or intermediate thereof, including [\*\*\*] and [\*\*\*] used in the production of the foregoing) is manufactured (in the case of [\*\*\*], generated or otherwise procured) by Leap or its Affiliate, the actual, fully burdened documented and verifiable direct and indirect costs and expenses incurred and recorded in manufacturing such Licensed Product consisting solely of (i) the cost of [\*\*\*], (ii) the reasonable allocation of [\*\*\*], to such manufacturing operation (including the allocable costs of [\*\*\*], if applicable, but excluding [\*\*\*]; (iii) [\*\*\*] (including [\*\*\*] but excluding any allocation for [\*\*\*]); (iv) [\*\*\*]; (v) [\*\*\*]; (vi) amounts (without markup) that are paid to a Third Party, in connection with the manufacture of such Licensed Product or any component thereof; and (vii) [\*\*\*] or [\*\*\*] and paid (excluding [\*\*\*]), in each case ((i) through (vii)), to the extent allocable to the manufacture of such Licensed Product as determined in accordance with GAAP.<sup>7</sup>

**1.39** “NDA” means a New Drug Application (as defined by the NMPA), or any successor application for Regulatory Approval having substantially the same function, or its foreign equivalent for approval to market or sell a pharmaceutical product in the Territory.

**1.40** “Multi-Regional Clinical Study” means a global Clinical Trial of the Licensed Product which will include Clinical Trial sites in the [\*\*\*] and may also include Clinical Trial sites in other countries in the Territory.<sup>8</sup>

**1.41** “Net Sales” means the gross amount invoiced by BeiGene, its Affiliates or sublicensees for sales or other transfers of Licensed Product less the following deductions:

- (a) [\*\*\*];<sup>9</sup>
- (b) [\*\*\*], adjustments arising from [\*\*\*];<sup>10</sup>
- (c) [\*\*\*];<sup>11</sup>
- (d) [\*\*\*] to the extent relating to the Licensed Product;<sup>12</sup>
- (e) [\*\*\*] allowed or paid for [\*\*\*];<sup>13</sup> and
- (f) [\*\*\*], in each case to the extent not reimbursed.<sup>14</sup>

Each of the foregoing deductions shall be determined as incurred in the ordinary course of business in type and amount consistent with good industry practice and in accordance with applicable accounting requirements on a basis consistent with BeiGene’s audited consolidated financial statements. In the case of any other sale [\*\*\*], such as [\*\*\*], other than [\*\*\*], Net Sales shall be calculated as above [\*\*\*], defined as [\*\*\*].<sup>15</sup>

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<sup>6</sup> Competitive Information – Commercially Sensitive Terms.

<sup>7</sup> Competitive Information – Commercially Sensitive Terms.

<sup>8</sup> Competitive Information – Commercially Sensitive Terms.

<sup>9</sup> Competitive Information – Financial Provisions.

<sup>10</sup> Competitive Information – Financial Provisions.

<sup>11</sup> Competitive Information – Financial Provisions.

<sup>12</sup> Competitive Information – Financial Provisions.

<sup>13</sup> Competitive Information – Financial Provisions.

<sup>14</sup> Competitive Information – Financial Provisions.

For purposes of this Agreement, a “sale” or “transfer” shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of Licensed Product at no charge (i) for academic research, preclinical, clinical, or regulatory purposes (including the use of a Licensed Product in Clinical Trials), (ii) [\*\*\*] or (iii) [\*\*\*].<sup>16</sup>

In the event a Licensed Product is sold as part of a Combination Product, the Net Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales (as determined above) of the Combination Product, during the applicable royalty reporting period, by the fraction,  $A/(A+B)$ , where A is [\*\*\*] of the Licensed Product when sold separately in finished form and B is [\*\*\*] of the other Active Ingredient(s) included in the Combination Product when sold separately in finished form, in each case during [\*\*\*]. In the event that such [\*\*\*] cannot be determined for both the Licensed Product and all other Active Ingredient(s) included in such Combination Product, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product 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 Active Ingredient(s) included in the Combination Product. In such event, the Parties shall negotiate in good faith to determine of the respective fair market values of the Licensed Product and all other Active Ingredient(s) included in the Combination Product based on the relative value contributed by each component. “**Combination Product**” means a Licensed Product comprising the Licensed Antibody in combination with at least one other active pharmaceutical ingredient, that is either co-formulated or separately formulated and packaged together, and/or sold together (including as a single unit) for a single price.<sup>17</sup>

**1.42** “**NMPA**” means the National Medical Products Administration of China, and local counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

**1.43** “**Patent Prosecution**” means activities directed to (a) preparing, filing and prosecuting applications (of all types) for any Patent Rights, (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding whether to abandon, extend or maintain Patent Rights, (d) listing in regulatory publications (as applicable), and (e) settling any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding, but excluding the defense of challenges to such patent or patent application as a counterclaim in an infringement proceeding with respect to the particular patent or patent application, and any appeals therefrom. For purposes of clarity, “Patent Prosecution” will not include any other enforcement actions taken with respect to a patent or patent application.

**1.44** “**Patent Rights**” means the rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, substitutions, continuations, continuations-in-part, continued prosecution applications including requests for continued examination, divisional applications and renewals, and all letters patent or certificates of invention granted thereon, and all reissues, reexaminations, extensions (including pediatric exclusivity patent extensions), term restorations, renewals, substitutions, confirmations, registrations, revalidations, revisions and additions of or to any of the foregoing, in each case, in any country.

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<sup>15</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

<sup>16</sup> Competitive Information – Commercially Sensitive Terms.

<sup>17</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

**1.45** “**Person**” means any individual, corporation, company, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

**1.46** “**Phase 3 Registrational Clinical Trial**” means a controlled or uncontrolled human Clinical Trial of a Licensed Product that would satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations, regardless of whether such trial is referred to as a “phase 3 clinical trial,” that is intended (as of the time the Clinical Trial is initiated) to obtain sufficient data and results to support the filing of an application for Regulatory Approval (but may not include the data that may be necessary to support the pricing and/or reimbursement approvals). A Phase 3 Registrational Clinical Trial includes any Clinical Trial that satisfies at least one of the following criteria:

(a) It would, based on interactions with a Regulatory Authority or otherwise prior to the initiation of such trial, satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations;

(b) It is designed in a manner to allow for the addition of patients such that it could satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations, provided that such Clinical Trial would only be deemed a Phase 3 Registrational Clinical Trial upon dosing the first patient among such additional patients; or

(c) It is otherwise intended, at the time of initiation, to support (either alone or together with another Phase 3 Registrational Clinical Trial) an application for marketing approval of a new product (or an indication or intended use for an already approved product).

**1.47** “**Regulatory Approval**” means all approvals from the relevant Regulatory Authority necessary to initiate marketing and selling a product (including Licensed Product) in any country. For clarity, to the extent necessary to initiate marketing and selling of a product in a particular country, Regulatory Approval shall include pricing or reimbursement approval.

**1.48** “**Regulatory Authority**” means any applicable Governmental Authority with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, research, non-clinical testing, clinical testing or sale of a pharmaceutical product (including any Licensed Product), which may include the authority to grant the required reimbursement and pricing approvals for such sale.

**1.49** “**Regulatory Exclusivity**” means any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority with respect to a Licensed Product, other than an issued and unexpired Patent Right, including any new chemical entity exclusivity, pediatric exclusivity or orphan drug exclusivity which grant an exclusive commercialization period during which BeiGene, its Affiliates or sublicensees have the exclusive right to market and sell such Licensed Product in such country.

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

1.51 “**Territory**” means Asia (excluding Japan), Australia and New Zealand. “Asia” means [\*\*\*].<sup>18</sup>

1.52 “**Third Party**” means any Person other than a Party or an Affiliate of a Party.

1.53 “**Third Party In-License Agreement**” means the License Agreement between Leap and Eli Lilly and Company, dated as of January 3, 2011, as amended.

1.54 “**United States**” or “**US**” means the United States of America and its territories and possessions.

1.55 “**USD**” means United States dollars.

1.56 “**Valid Claim**” means a claim of (a) an issued and unexpired patent or (b) a pending patent application, which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to being invalid or unenforceable through reissue, reexamination or disclaimer or otherwise; provided, that, if a pending patent application has been pending for at least [\*\*\*] from the date of filing of the initial priority application, then such corresponding claim in such pending patent application will not be deemed to be a Valid Claim unless and until it subsequently issues.<sup>19</sup>

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

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<sup>18</sup> Competitive Information – Commercially Sensitive Terms.

<sup>19</sup> Competitive Information – Commercially Sensitive Terms.

<b>Definition</b>	<b>Section</b>
Accounting Firm	9.10(b)(i)
Agreement	Preamble
Agreement Payments	9.11(a)
Alliance Manager	3.1
Anti-Corruption Laws	12.7(a)(i)
BeiGene	Preamble
BeiGene Drug	5.1(a)
BeiGene Drug Inventions	14.1(a)
BeiGene Inventions	14.1(a)
BeiGene Indemnitees	13.2
BeiGene Publication	11.1(b)
Breach Notification	15.2(b)(i)
Claims	13.1
Clinical Supply Agreement	7.3(a)
CMO	7.2
Commercialization Milestone Event	9.3
Commercialization Milestone Payment	9.3
Confidentiality Agreement	16.13
Continuing Technology Transfer	4.1
Development Milestone Event	9.2
Development Milestone Payment	9.2
Disclosing Party	1.18
Dispute	16.5(a)
Effective Date	Preamble
Existing Regulatory Materials	12.2(o)
Excluded Claim	16.5(e)
Executive Officers	3.2(f)
Global Development Plan	5.3(a)
ICC	16.5(a)
ICH Guidelines	1.32
Indemnified Party	13.3
Indemnifying Party	13.3
Initial Technology Transfer	4.1
Joint Patent Rights	14.1(c)
JCC	3.2(g)
JDC	3.2(a)
Leap	Preamble
Leap Inventions	14.1(a)
Leap Indemnitee(s)	13.1
Leap Manufacturing IP	7.2
Leap Publication	11.1(c)
License	2.2
Losses	13.1
Manufacturing Technology Transfer	7.2
Manufacturing Technology Transfer Plan	7.2
Notice of Dispute	16.5(a)
Option	2.1
Option Exercise Fee	5.1
Party/Parties	Preamble
POC Data Package	5.1
Product Infringement	14.3(a)
Product Marks	14.7
Public Official	12.7(d)
Publication	11.1(c)
Receiving Party	1.19
Review Period	11.1(b)
Royalty Term	9.5(b)
Rules	16.5(a)
Pharmacovigilance Agreement	6.4
SEC	11.4(c)
Securities Regulators	11.4(c)
Seller	1.40
Taxes	9.11(a)
Technology Transfer	4.1
Term	15.1
Territory Development Plan	5.4
Upfront Payment	9.1



**1.58 Interpretation.** The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. In the event of any conflict between the main body of this Agreement and any Exhibit hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (b) the word “day” or “year” means a calendar day or year unless otherwise specified; (c) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (e) the words “shall” and “will” have interchangeable meanings for purposes of this Agreement; (f) the word “or” shall have the inclusive meaning commonly associated with “and/or”; (g) provisions that require that a Party, the Parties or a committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (h) words of any gender include the other gender; (i) words using the singular or plural number also include the plural or singular number, respectively; (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; (k) neither Party or its Affiliates shall be deemed to be acting “under authority of” the other Party.

## **ARTICLE 2 OPTION AND LICENSE**

**2.1 Option Grant to BeiGene.** Subject to the terms and conditions of this Agreement, Leap hereby grants to BeiGene an exclusive option (the “**Option**”) to an exclusive license under the Licensed IP, to research, develop, use, import, export, make, have made, manufacture, use, offer for sale, promote, market, distribute, and sell the Licensed Antibody(ies) and/or Licensed Products in the Field in the Territory as set forth in Section 2.2. BeiGene may exercise the Option at its sole discretion by written notice to Leap at any time within [\*\*\*] after Leap delivers to BeiGene the complete POC Data Package (the “**Option Period**”). For avoidance of doubt, BeiGene may elect to exercise the Option at its sole discretion at any time prior to delivery of the complete POC Data Package.

**2.2 License Grants to BeiGene.** Subject to the terms and conditions of this Agreement, upon exercise of the Option and payment of the Option Exercise Fee, Leap hereby grants to BeiGene an exclusive (subject to Leap’s retained rights in Section 2.3), royalty-bearing license, with the right to grant sublicenses, under the Licensed IP, to research, develop, use, import, export, make, have made, manufacture, use, offer for sale, promote, market, distribute, and sell the Licensed Antibody(ies) and/or Licensed Products in the Field in the Territory (the “**License**”).

### 2.3 Right to Sublicense.

(a) Subject to the terms and conditions of this Agreement, BeiGene shall have the right to grant sublicenses under the License through multiple tiers: (i) to its Affiliates, provided that such sublicense shall automatically terminate if such sublicensee ceases to be an Affiliate of BeiGene; and (ii) subject to Section 5.10, to contract research organizations, distributors and other Third Party subcontractors for the sole purpose of performing BeiGene's obligations hereunder, on BeiGene's behalf with respect to the research, Development, (subject to Article 7) manufacture and Commercialization of Licensed Products in the Field in the Territory, in each case as is set forth in the Global Development Plan or Territory Development Plan; (iii) to any other Third Party with respect to the Development, manufacture and/or Commercialization of Licensed Products in the Field in the Territory, subject to Leap's prior written consent, not to be unreasonably withheld, conditioned or delayed; and (iv) to contract manufacturers of Licensed Product solely in accordance with Article 7 below. For purposes of clarity, BeiGene shall have the right, in connection with the grant of a sublicense to any Third Party pursuant to this Section 2.2(a)(ii), (iii) or (iv), to transfer to such Third Party such quantities of the Licensed Antibody as is reasonably necessary for such Third Party to conduct Development, manufacture and/or Commercialization activities in accordance with the sublicense grant.

(b) Each sublicense shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement, and BeiGene shall ensure that all of its direct or indirect sublicensees comply with the terms and conditions of this Agreement. BeiGene shall include, or cause to be included, in each sublicense agreement an obligation of the applicable subcontractor or sublicensee to cease all activities with respect to Licensed Products if BeiGene terminates such sublicense agreement. BeiGene will remain directly responsible for all its obligations under this Agreement, regardless of whether any such obligation is delegated, subcontracted or sublicensed to any of its Affiliates or sublicensees. In the event of any material breach by any such subcontractor or sublicensee of any sublicense granted pursuant to Section 2.3(a) that would be a material breach of this Agreement by BeiGene, BeiGene shall [\*\*\*]. BeiGene shall provide, or cause to be provided, to Leap a true and complete copy of each sublicense [\*\*\*], subject to the right of BeiGene or the applicable sublicensor to redact any confidential or proprietary information contained therein that is not necessary for Leap to determine compliance with this Agreement, and if such agreement is not in English, a certified translation into English thereof within [\*\*\*] after the execution of such sublicense agreement.<sup>20</sup>

**2.4 Leap Retained Rights.** Notwithstanding the exclusive nature of the License, Leap expressly retains the rights to use the Licensed IP in the Field in the Territory in order to (a) perform its obligations under this Agreement (b) to conduct research and Development activities that are assigned to Leap under the Global Development Plan and (c) to conduct research, Development, manufacturing, regulatory activities and otherwise to the extent permitted by this Agreement solely to support research, Development, manufacturing, regulatory activities or Commercialization outside of the Territory or outside of the Field. For clarity, Leap retains the exclusive right to practice, license and otherwise exploit the Licensed IP outside the scope of the License.<sup>21</sup>

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<sup>20</sup> Competitive Information – Commercially Sensitive Terms.

<sup>21</sup> Competitive Information – Commercially Sensitive Terms.

2.5 **License Grants to Leap.** Subject to the terms and conditions of this Agreement, BeiGene hereby grants to Leap:

(a) a non-exclusive, fully-paid, royalty-free and sublicensable (through multiple tiers) license under the BeiGene Inventions and BeiGene IP solely to Develop, make, have made and Commercialize Licensed Products outside the Territory;

(b) a non-exclusive, fully-paid, royalty-free and sublicensable (through multiple tiers) license under the BeiGene IP and BeiGene Inventions to Develop, make, have made and Commercialize Licensed Products in the Territory solely as necessary for Leap to perform its obligations under this Agreement and to conduct research and Development activities under the Global Development Plan and in any event solely to support Development and Commercialization of the Licensed Product outside the Territory.

2.6 **No Implied Licenses; Negative Covenants.** Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any trademarks, Patent Rights or patent applications of the other Party. BeiGene shall not, and shall not permit any of its Affiliates or sublicensees to, practice any Licensed IP outside the scope of the License.

2.7 **Non-Competition.**

(a) During the Term, BeiGene shall [\*\*\*].<sup>22</sup>

(b) During the Term, Leap shall [\*\*\*].<sup>23</sup>

### ARTICLE 3 GOVERNANCE

3.1 **Alliance Managers.** Each Party shall appoint an individual, who is an employee of such Party, to act as its alliance manager under this Agreement [\*\*\*] after the Effective Date (the “**Alliance Manager**”). The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party’s activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, provided that all communications between the Parties shall be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JDC and JCC meetings. An Alliance Manager may also bring any matter to the attention of the JDC or JCC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.<sup>24</sup>

3.2 **Joint Development Committee.**

(a) **Formation.** No later than [\*\*\*] following the Effective Date, the Parties shall establish a joint development committee (the “**JDC**”) to monitor and coordinate the Development and manufacture of Licensed Products in the Field in the Territory and outside of the Territory. The JDC will be composed of an equal number of representatives from each Party and a minimum of [\*\*\*] representatives of each Party. Each representative to the JDC shall be an employee of the applicable Party, unless otherwise agreed by both Parties.<sup>25</sup>

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<sup>22</sup> Competitive Information – Exclusivity and Technical Information.

<sup>23</sup> Competitive Information – Exclusivity and Technical Information.

<sup>24</sup> Competitive Information – Commercially Sensitive Terms.

(b) **Role.** The JDC shall (i) provide a forum for the discussion of the Parties' activities under this Agreement; (ii) review and discuss Leap's performance of Development activities under the Initial Development Plan and results and data included in the POC Data Package; (iii) review and discuss the overall strategy for the Development and manufacture of Licensed Products in the Field in the Territory; (iv) review and discuss the overall strategy for Development and manufacture of Licensed Products outside of the Territory; (v) review and discuss the progress of the Regulatory Approvals and Regulatory Submissions for Licensed Products in the Territory, including discussing relevant CMC information; (vi) review, discuss and approve the Manufacturing Technology Transfer Plan in accordance with Section 7.2; (vii) establish and oversee the JCC; (viii) to review, coordinate and approve supply of Licensed Product in accordance with Article 7; (ix) determine whether and when to develop companion or complementary diagnostic products to be used in connection with Licensed Products; (x) provide a forum for discussion of summaries of Clinical Trial activities by Leap and its Affiliates for the Licensed Product [\*\*\*]; and (xi) perform such other functions as expressly set forth in this Agreement or allocated to the JDC by the Parties' written agreement.<sup>26</sup>

(c) **Limitation of Authority.** The JDC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; or (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

(d) **Meetings.** The JDC shall hold meetings at such times as it elects to do so, but shall meet no less frequently than [\*\*\*] per Calendar Year until Regulatory Approval of the Licensed Product in the Territory, and thereafter, upon mutual agreement of the Parties, but no more than [\*\*\*] per Calendar Year. The first JDC meeting shall be within [\*\*\*] of the Effective Date. In addition, special meetings of the JDC may be convened by either Alliance Manager upon not less than [\*\*\*] (or, if such meeting is proposed to be conducted by teleconference, [\*\*\*]) written notice to the other Alliance Manager. The JDC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communication method; provided that at least [\*\*\*] each Calendar Year, such meetings will be conducted in person at locations selected alternatively by Leap and BeiGene or such other location as the Parties may agree. Each Party shall bear its own expenses related to participation in and attendance at such meetings by its respective JDC representatives. The Alliance Managers shall jointly prepare and circulate minutes for each JDC meeting within [\*\*\*] of each such meeting and shall ensure that such minutes are reviewed and approved by their respective companies within [\*\*\*] thereafter. Communications between the Parties pursuant to the JDC meetings shall be in English.<sup>27</sup>

(e) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of the JDC or JCC (in a non-voting capacity) in the event that the planned agenda for such JDC or JCC meeting would require such participants' expertise; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend, and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

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<sup>25</sup> Competitive Information – Commercially Sensitive Terms.

<sup>26</sup> Competitive Information – Commercially Sensitive Terms.

<sup>27</sup> Competitive Information – Commercially Sensitive Terms.

(f) **Decision-Making.** All decisions of the JDC shall be made by consensus, with each Party's representatives having, collectively, one vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JDC, the JDC cannot reach consensus as to such matter within [\*\*\*] after such matter was brought to the JDC for resolution, such matter shall be referred to the Chief Executive Officer of Leap (or an executive officer of Leap designated by the Chief Executive Officer of Leap who has the power and authority to resolve such matter) and the Chief Executive Officer of BeiGene (or an executive officer of BeiGene designated by the Chief Executive Officer of BeiGene who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**") for resolution. If the Executive Officers cannot resolve such matter within [\*\*\*] after such matter has been referred to them, then:<sup>28</sup>

(i) Subject to Section 3.2(f)(ii), BeiGene shall have the final decision-making authority for matters within the scope of the JDC's decision-making authority with respect to (1) any [\*\*\*] for Licensed Products in the Field in the Territory, (2) all [\*\*\*] with respect to Licensed Products, including [\*\*\*], in the Field in the Territory; and (3) all [\*\*\*] activities leading up to and including the [\*\*\*] and any [\*\*\*], as applicable, for Licensed Products in the Field from [\*\*\*] in the Territory; provided that: BeiGene shall not exercise its final decision-making authority in a manner that would reasonably be expected to [\*\*\*].<sup>29</sup>

(ii) Leap shall have the final decision-making authority for matters within the scope of the JDC's decision-making authority with respect to any Development, manufacture or Commercialization activities in the Territory that would reasonably be expected to (y) result in a [\*\*\*] related to a Licensed Product outside the Territory or outside the Field or (z) otherwise [\*\*\*]; provided, that, Leap shall not exercise its final decision-making authority in a manner that would: (A) [\*\*\*] under this Agreement, including (i) any of BeiGene's obligations or expenses [\*\*\*] agreed between the Parties and/or (ii) any [\*\*\*] involving a Licensed Product (including a Multi-Regional Clinical Trial), in any case; or (B) [\*\*\*], without BeiGene's written consent, which will not be unreasonably withheld, delayed or conditioned.<sup>30</sup>

(g) **Joint Commercialization Committee.** Not later than [\*\*\*] prior to the anticipated date of the filing of the first application for Regulatory Approval for a Licensed Product in the Territory, the Parties shall establish a joint commercialization committee (the "**JCC**") to review, discuss, coordinate and share information regarding (1) the progress of the Commercialization of Licensed Products in the Territory; and (2) commercial issues relevant to the Commercialization of Licensed Products in the Territory and Leap's commercialization of Licensed Products in other territories outside of the Territory and global harmonization of such activities. The JCC [\*\*\*], unless otherwise agreed by the Parties. The JCC and its activities shall be subject to the oversight of, and shall report to, the JDC and the JDC shall resolve all disputes that arise within the JCC within [\*\*\*] after any such matter is brought to the JDC for resolution. In no event shall the authority of the JCC exceed the authority of the JDC. Each Party shall be responsible for all of its own expenses of participating in the JCC.<sup>31</sup>

(h) **Discontinuation of Committees.** The JDC shall continue to exist until the Parties mutually agree to disband the JDC. Once the JDC is disbanded, the JDC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement and decisions of the JDC shall be decisions between the Parties, subject to the other terms and conditions of this Agreement. The JCC shall disband upon the disbandment of the JDC or earlier, as determined by the JDC.

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<sup>28</sup> Competitive Information – Commercially Sensitive Terms.

<sup>29</sup> Competitive Information – Commercially Sensitive Terms and Exclusivity Information.

<sup>30</sup> Competitive Information – Commercially Sensitive Terms and Exclusivity Information.

<sup>31</sup> Competitive Information – Commercially Sensitive Terms.

**ARTICLE 4  
TECHNOLOGY TRANSFER**

**4.1 Technology Transfer.** Within [\*\*\*] after the Effective Date, Leap will provide and transfer to BeiGene, [\*\*\*], the Licensed Know-How that exists on the Effective Date and was not previously provided to BeiGene by providing copies or samples of relevant documentation, materials and other embodiments of such Licensed Know-How, including data within reports, and electronic files, that exists on the Effective Date (the “**Initial Technology Transfer**”). Thereafter, during the Term, Leap shall (a) at each meeting of the JDC (and, in any event, on [\*\*\*] if any JDC meeting is not held in a particular [\*\*\*]), provide BeiGene with a summary of additional Licensed Know-How, if any, developed since the last meeting of the JDC, (b) transfer any such Licensed Know-How to BeiGene promptly following BeiGene’s reasonable request, and (c) provide BeiGene with reasonable access to Leap personnel involved in the research and Development of Licensed Products, either in-person at Leap’s facility or by teleconference (the “**Continuing Technology Transfer**,” and together with the Initial Technology Transfer, the “**Technology Transfer**”). For the avoidance of doubt, Leap’s personnel shall not be obligated to travel to BeiGene’s facilities, and Leap’s transfer obligations under this Section 4.1 shall apply solely to the extent the Licensed Know-How is reasonably necessary to support BeiGene’s Development and Commercialization of the Licensed Product in the Field in the Territory in accordance with this Agreement. Notwithstanding the foregoing, Leap’s technology transfer obligations hereunder shall not include the obligation to transfer [\*\*\*], except as set forth in [\*\*\*] or unless otherwise mutually agreed by the Parties in writing.<sup>32</sup>

**4.2 Updates by BeiGene.** During the Term, BeiGene shall (a) at each meeting of the JDC (and, in any event, on [\*\*\*] if any JDC meeting is not held in a particular [\*\*\*]), provide Leap with a summary of any BeiGene Inventions and Know-How within the BeiGene IP, if any, developed since the last meeting of the JDC, (b) transfer any such BeiGene Inventions and Know-How to Leap promptly following Leap’s reasonable request, and (c) provide Leap with reasonable access to BeiGene personnel involved in the research and Development of Licensed Products, either in-person at BeiGene’s facility or by teleconference. For the avoidance of doubt, BeiGene’s personnel shall not be obligated to travel to Leap’s facilities, and BeiGene’s transfer obligations under this Section 4.2 shall apply solely to the extent the BeiGene Inventions and Know-How within the BeiGene IP is reasonably necessary to support Leap’s Development and Commercialization of the Licensed Product outside of the Territory.<sup>33</sup>

**ARTICLE 5  
DEVELOPMENT PROGRAM**

**5.1 Initial Development Responsibility.**

(a) [\*\*\*], Leap shall be responsible for the Development of the Licensed Products in the Field [\*\*\*]. Leap shall Develop Licensed Products in the Field in accordance with a written development plan and timeline attached to this Agreement as **Exhibit A** (the “**Initial Development Plan**”). Leap will not perform any activities under the Initial Development Plan in the BeiGene Territory. Leap shall conduct such activities in compliance with all Applicable Laws, including GLP, GCP and cGMP. Upon completion of its activities under the Initial Development Plan, Leap will provide BeiGene with all results of its activities under the Initial Development Plan, including all clinical data and analysis thereof, including all of the information agreed to be included under the Initial Development Plan (the “**POC Data Package**”) which POC Data Package will be deemed delivered to BeiGene after BeiGene confirms that the POC Data Package is complete. BeiGene will provide such confirmation within [\*\*\*] after receipt of the POC Data Package if BeiGene reasonably determines that such POC Data Package is complete or will provide written notice to Leap of any missing required information, in which case the [\*\*\*] will be tolled until Leap provides such missing information. Leap will not disclose the POC Data Package or any portion thereof to any potential licensees or potential acquirers of rights to a Licensed Antibody or Licensed Product in the [\*\*\*] during the Option Period.<sup>34</sup>

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<sup>32</sup> Competitive Information – Commercially Sensitive Terms.

<sup>33</sup> Competitive Information – Commercially Sensitive Terms.

(b) **Supply of BeiGene Drug.** BeiGene will use Commercially Reasonable Efforts to supply to Leap quantities of [\*\*\*] (the “**BeiGene Drug**”) necessary for performance of the Initial Development Plan according to the terms and conditions of a clinical supply agreement to be entered into by the Parties within [\*\*\*] after the Effective Date. Leap agrees to use the BeiGene Drug for the sole purpose of performing the Initial Development Plan and not to use the BeiGene Drug for any other purpose.<sup>35</sup>

**5.2 Diligence and Responsibilities.** [\*\*\*], BeiGene shall be responsible for the Development of the Licensed Products in the Field in the Territory in accordance with this Article 5. BeiGene shall use Commercially Reasonable Efforts to (i) [\*\*\*], and (ii) [\*\*\*]. BeiGene shall conduct such tasks in compliance with all Applicable Laws, including GLP, GCP and cGMP.<sup>36</sup>

**5.3 Global Development Plan.**

(a) The Parties’ collaborative work to support the global Development of Licensed Products within and outside of the Territory after BeiGene’s exercise of the Option will be conducted pursuant to a written development plan (as amended from time to time in accordance with this Section 5.3, the “**Global Development Plan**”), which the Parties agree may include one or more additional Multi-Regional Clinical Studies. An initial high-level global development plan is attached to this Agreement as **Exhibit B** and will be used by the Parties to create the first Global Development Plan for JDC review and discussion within [\*\*\*] after BeiGene’s exercise of the Option. The Global Development Plan shall include (i) [\*\*\*], (ii) [\*\*\*], (iii) [\*\*\*], (iv) [\*\*\*], and (v) [\*\*\*]. From time to time, Leap may make and implement amendments to the then-current Global Development Plan. To the extent such amendments relate to the Territory or include a combination with an Active Ingredient Controlled by BeiGene, Leap shall submit such proposed amendments to the JDC for review, discussion and approval before adopting such amendments. Prior JDC approval shall not be required for amendments to the Global Development Plan that are outside of the Territory and do not include a combination with an Active Ingredient Controlled by BeiGene.<sup>37</sup>

(b) BeiGene shall use Commercially Reasonable Efforts to perform the Development activities assigned to BeiGene under the Global Development Plan to support the global Development and registration of Licensed Products, [\*\*\*]. The Parties acknowledge and agree [\*\*\*].<sup>38</sup>

**5.4 Territory Development Plan.** Except for the activities allocated to BeiGene under the Global Development Plan pursuant to Section 5.3, all Development of Licensed Products in the Territory under this Agreement shall be conducted by BeiGene pursuant to a written development plan (as amended from time to time in accordance with this Section 5.4 and Section 3.2, the “**Territory Development Plan**”). BeiGene shall provide the first Territory Development Plan for JDC review and discussion [\*\*\*] after exercise of the Option by BeiGene. From time to time after the Effective Date, but not [\*\*\*], BeiGene shall propose amendments to the Territory Development Plan in consultation with Leap and submit such proposed updated or amended Territory Development Plan to the JDC for review and discussion. For clarity, the Territory Development Plan and amendments thereto shall be consistent with the Global Development Plan and the Global Development Plan shall take precedent in case of any conflict or inconsistency between the Territory Development Plan and the Global Development Plan.<sup>39</sup>

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<sup>34</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>35</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>36</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>37</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>38</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

**5.5 Development Costs.** Except for the costs and expenses incurred in Leap's performance of Development activities under the Initial Development Plan, BeiGene shall be solely responsible for the costs and expenses incurred by BeiGene in the Development of Licensed Products in the Territory, including [\*\*\*], not to exceed [\*\*\*] without BeiGene's prior written consent. In the event that Leap and BeiGene agree to conduct Development activities or Clinical Trials that combine a Licensed Product with an Active Ingredient Controlled by BeiGene, Leap and BeiGene will agree on [\*\*\*].<sup>40</sup>

**5.6 Development Records.** BeiGene shall maintain reasonably complete, current and accurate records of all Development activities conducted by or on behalf of BeiGene, its Affiliates or its sublicensees pursuant to this Agreement and all data and other information resulting from such activities, in each case in accordance with all Applicable Laws. BeiGene shall maintain such records during the Term and for a period of time after the Term consistent with Applicable Laws and reasonable industry practices on record retention and destruction (which shall not be less than [\*\*\*]). Such records will be in English (or include complete English translations) and shall fully and properly reflect all work done and results achieved by or on behalf of BeiGene in the performance of the Development activities in the Territory hereunder, in good scientific manner appropriate for regulatory and patent purposes. BeiGene shall document all non-clinical studies and Clinical Trials of the Licensed Product in formal written study reports in accordance with Applicable Laws and national and international guidelines (*e.g.*, GCP, GLP and GMP). Upon Leap's request, BeiGene shall, and shall cause its Affiliates and sublicensees to, provide Leap with copies of such records.<sup>41</sup>

**5.7 Clinical Trial Audits.**

**(a)** Upon reasonable notification by Leap and at Leap's cost and expense, Leap or its representatives shall be entitled to conduct an audit of any Clinical Trial sites engaged, or other facilities used, by BeiGene or its Affiliates or sublicensees to conduct BeiGene's obligations under the [\*\*\*]. No later than [\*\*\*] following the completion of any such audit, Leap will provide BeiGene with a written summary of Leap's findings, including any deficiencies or other areas of remediation that Leap reasonably identifies during the audit, and the Parties shall promptly meet to discuss any such deficiencies or other areas of remediation identified by Leap. BeiGene will use Commercially Reasonable Efforts to remediate such deficiencies promptly following BeiGene's receipt of such report.<sup>42</sup>

**(b)** BeiGene will provide Leap with copies of all quality oversight or audit reports, including certified translations into English thereof, prepared in connection with any audit that BeiGene, its Affiliates or sublicensees conduct of a Clinical Trial site that BeiGene, its Affiliates or sublicensees have engaged or are evaluating to potentially engage to fulfill BeiGene's obligations under the Global Development Plan or the Territory Development Plan no later than [\*\*\*] after receiving or preparing, as applicable, any such report.<sup>43</sup>

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<sup>39</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>40</sup> Competitive Information – Commercially Sensitive Terms.

<sup>41</sup> Competitive Information – Commercially Sensitive Terms.

<sup>42</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

## 5.8 Development Reports.

(a) Prior to exercise by BeiGene of the Option, Leap shall provide BeiGene with [\*\*\*] written reports, [\*\*\*], summarizing its, its Affiliates' and its sublicensees' Development of Licensed Products, including a summary of the results of such Development, which reports shall be in English. Without limiting the foregoing, such reports shall contain sufficient detail to enable BeiGene to assess Leap's compliance with its Development obligations hereunder. Subject to BeiGene's right to use and disclose data and results in accordance with Section 5.9 and the licenses and rights granted to BeiGene in Section 2.2, such reports shall be Confidential Information of BeiGene pursuant to Article 10.<sup>44</sup>

(b) BeiGene shall provide Leap with [\*\*\*] written reports, [\*\*\*], summarizing its, its Affiliates' and its sublicensees' Development of Licensed Products, including a summary of the results of such Development, which reports shall be in English. Without limiting the foregoing, such reports shall contain sufficient detail to enable Leap to assess BeiGene's compliance with its Development obligations hereunder. Subject to Leap's right to use and disclose data and results in accordance with Section 5.9 and the licenses and rights to BeiGene IP and BeiGene Inventions granted to Leap in Section 2.5, such reports shall be Confidential Information of BeiGene pursuant to Article 10. BeiGene shall promptly respond to Leap's reasonable requests from time to time for additional information regarding material Development activities. The Parties shall discuss the status, progress and results of Development activities at JDC meetings, and Leap shall keep BeiGene reasonably informed through the JDC as to any material developments with respect to the Development of Licensed Products outside the Territory.<sup>45</sup>

**5.9 Data Exchange and Use.** In addition to its adverse event and safety data reporting obligations pursuant to Section 6.4, each Party shall promptly (but in any event no later than [\*\*\*] from the other Party's request) provide the other Party with copies of and access to all data and results, including all Clinical Data, and all supporting documentation (e.g. protocols, CRFs, analysis plans) Controlled by such Party or its Affiliates that are generated by or on behalf of such Party or its Affiliates or sublicensees, if applicable, in the Development of Licensed Products. BeiGene shall have the right to use and reference such data and results provided by Leap, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field in the Territory. Leap and its designees shall have the right to use and reference such data and results provided by BeiGene, without additional consideration, for the purpose of Developing, manufacturing and Commercializing Licensed Products in accordance with the licenses granted under Section 2.5, filing Patent Rights covering Leap Inventions and obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products outside of the Territory or outside the Field in the Territory. For clarity, any such data or results that are Inventions will be owned in accordance with Section 14.1 and subject to the licenses, rights and obligations set forth herein.<sup>46</sup>

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<sup>43</sup> Competitive Information – Commercially Sensitive Terms.

<sup>44</sup> Competitive Information – Commercially Sensitive Terms.

<sup>45</sup> Competitive Information – Commercially Sensitive Terms.

<sup>46</sup> Competitive Information – Commercially Sensitive Terms.

## 5.10 Subcontractors.

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

(b) Leap may conduct any activities assigned to it under the Global Development Plan or this Agreement, through one or more Affiliate or Third Party designees.

## ARTICLE 6 REGULATORY

**6.1 Regulatory Responsibilities; Holder of Regulatory Approvals and Regulatory Submissions.** After exercise of the Option and payment of the Option Exercise Fee, BeiGene shall have the sole responsibility, [\*\*\*], for the conduct of all regulatory activities in Field in the Territory that are necessary or useful to obtain Regulatory Approval for Licensed Products, including, without limitation, (i) developing regulatory plans and strategies in support of obtaining such Regulatory Approval, and (ii) preparing, obtaining, submitting, engaging and maintaining Regulatory Submissions with Regulatory Authorities in the Territory in furtherance of such Regulatory Approval. BeiGene shall be the holder of Regulatory Approvals and Regulatory Submission for Licensed Products in the Field in the Territory. Leap shall reasonably cooperate with BeiGene, [\*\*\*], to enable BeiGene to obtain any or all such Regulatory Approvals and Regulatory Submissions in the Field in the Territory.<sup>47</sup>

### 6.2 Review of Regulatory Submissions.

(a) BeiGene shall provide to Leap all Regulatory Submissions (including certified English translations thereof) prepared by or on behalf of BeiGene at least [\*\*\*] prior to submission and shall consider in good faith any reasonable comments received from Leap with respect thereto.<sup>48</sup>

(b) In addition, each Party shall notify the other Party of any comments or other correspondence regarding any Regulatory Submissions that are received from any Regulatory Authority in the Territory or, with respect to Multi-Regional Clinical Trials outside the Territory, and shall provide the other Party with copies thereof as soon as reasonably practicable, but in all events within [\*\*\*] of receipt (or such longer time period as may be necessary to obtain translations thereof). Each Party will provide [\*\*\*] updates, [\*\*\*], regarding its activities and progress with respect to all Clinical Trials of the Licensed Product.<sup>49</sup>

(c) Each Party shall keep the other Party reasonably informed of regulatory developments related to Licensed Products in the Field in the Territory and outside the Territory of which it becomes aware and shall promptly notify the other Party in writing of any material decision by any Regulatory Authority in the Field, in the Territory and outside the Territory, of which it becomes aware regarding any Licensed Product.

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<sup>47</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>48</sup> Competitive Information – Commercially Sensitive Terms.

<sup>49</sup> Competitive Information – Commercially Sensitive Terms.

(d) Each Party shall provide the other Party with notice no later than [\*\*\*] after receiving notice of any meeting or discussion with any Regulatory Authority in the Territory related to any Licensed Product in the Field. Each Party shall provide the other Party with a written summary of each such meeting or discussion in English promptly following such meeting or discussion.<sup>50</sup>

**6.3 Right of Reference.** Each Party hereby grants to the other Party the right of reference to all Regulatory Submissions pertaining to Licensed Products in the Field submitted by or on behalf of such Party or its Affiliates, solely to the extent reasonably necessary for the purposes set forth in this Section 6.3 and requested by such other Party. BeiGene may use such right of reference to Leap's Regulatory Submissions solely for the purpose of seeking, obtaining and maintaining Regulatory Approval and any pricing or reimbursement approvals, as applicable, of Licensed Products in the Field in the Territory. Leap may use the right of reference to BeiGene's Regulatory Submissions and Regulatory Approvals solely for the purpose of seeking, obtaining and maintaining regulatory approval of Licensed Products outside the Territory and with respect to Multi-Regional Clinical Trials in the Territory. The Party requesting such right of reference shall bear the reasonable costs and expenses of the other Party associated with providing the right of reference pursuant to this Section 6.3. Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 6.3 and to give the other Party the benefit of the rights of reference to the granting Party's Regulatory Submissions in the other Party's territory as provided herein.

**6.4 Adverse Events Reporting.** Within [\*\*\*] after the Effective Date, and in no case [\*\*\*], BeiGene and Leap shall develop and agree in a written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "Pharmacovigilance Agreement").<sup>51</sup>

**6.5 Safety and Regulatory Inspections.** BeiGene shall promptly notify Leap of any inspection of BeiGene, its Affiliates, CMOs, sublicenses or subcontractors (including Clinical Trial sites) by any Regulatory Authority relating to Licensed Products and shall provide Leap with all information in BeiGene's Control pertinent thereto. Without limiting the foregoing, BeiGene shall permit Regulatory Authorities outside the Territory to conduct inspections of BeiGene, its Affiliates, CMOs, sublicenses or subcontractors (including Clinical Trial sites) relating to Licensed Products, and shall ensure that such Affiliates, sublicensees and subcontractors permit such inspections. Leap shall have the right, but not the obligation, to be present at and participate in any such inspection described in this Section 6.5 [\*\*\*]. BeiGene will provide Leap with a written summary in English of any findings of a Regulatory Authority relating to Licensed Products following a regulatory audit within [\*\*\*] following any such audit, and will provide Leap with an unredacted copy of any report issued by such Regulatory Authority, including if applicable, a certified English translation thereof [\*\*\*] following such audit.<sup>52</sup>

**6.6 No Harmful Actions.** If either Party reasonably believes that the other Party is taking or intends to take any action with respect to a Licensed Product in such other Party's territory that would reasonably be expected to have a material adverse impact upon the regulatory status of any Licensed Product in the Field in such Party's territory, then such Party shall have the right to bring the matter to the attention of the JDC, and the Parties shall discuss in good faith a resolution to such concern. Without limiting the foregoing, unless the Parties otherwise agree (or unless otherwise set forth herein or in the Global Development Plan or Territory Development Plan): (a) neither Party shall communicate with any Regulatory Authority having jurisdiction outside of its respective territory with respect to any Licensed Product, unless required by such Regulatory Authority, in which case such Party shall notify the other Party of such order within [\*\*\*] of such communication; and (b) neither Party shall submit any Regulatory Submissions or seek regulatory approvals for any Licensed Product in the other Party's respective territory.<sup>53</sup>

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<sup>50</sup> Competitive Information – Commercially Sensitive Terms.

<sup>51</sup> Competitive Information – Discovery Information and Commercially Sensitive Terms.

<sup>52</sup> Competitive Information – Commercially Sensitive Terms.

**6.7 Notice of Regulatory Action.** If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of BeiGene relating to the Licensed Product, then BeiGene shall notify Leap of such notice within [\*\*\*] of its receipt thereof. Leap shall have the right to review and comment on any responses to Regulatory Authorities that pertain to a Licensed Product promptly and in any event [\*\*\*] of receipt of such proposed response. BeiGene will [\*\*\*] to a Licensed Product in the Territory if BeiGene is the holder of Regulatory Approvals and Regulatory Submissions for such Licensed Product in the Territory and will [\*\*\*]. The costs and expenses of any regulatory action in the Territory will be borne by BeiGene. In addition, each Party shall promptly notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from a Third Party that, in the case of notice to Leap, would reasonably be expected to materially affect the Development or Commercialization of the Licensed Products, and in the case of notice to BeiGene, would reasonably be expected to materially affect the Development or Commercialization of the Licensed Products in the Field in the Territory.<sup>54</sup>

## ARTICLE 7. MANUFACTURING

**7.1 Manufacture of Licensed Product for the Territory.** Subject to the terms and conditions of this Article 7 and only after BeiGene's exercise of the Option and payment of the Option Exercise Fee, BeiGene shall have the right to (a) purchase Development supply of Licensed Product from Leap or its Affiliates or Leap's CMO pursuant to the Clinical Supply Agreement, or (b) exercise its license under Section 2.2 to manufacture commercial supply of Licensed Product for the Territory itself or have such Licensed Product manufactured by a Third Party CMO in the Territory agreed upon by the Parties, in each case after successful completion of the Manufacturing Technology Transfer.

**7.2 Manufacturing Technology Transfer.** In addition to the Licensed Know-How provided to BeiGene pursuant to the Initial Know-How Transfer, upon BeiGene's written request and approximately [\*\*\*] in advance of the date on which BeiGene intends to commence manufacture of Licensed Product, Leap will promptly prepare and submit to the JDC, for its review, a plan ("**Manufacturing Technology Transfer Plan**") for the transfer to BeiGene of all Know-How Controlled by Leap with respect to the Manufacture of Licensed Product ("**Leap Manufacturing IP**"), and the conduct by Leap of such consultation activities, [\*\*\*] (as provided in this Section 7.2), as are necessary to enable BeiGene or any Third Party contract manufacturing organization (the "**CMO**") designated by BeiGene and reasonably acceptable to Leap, such acceptance not to be unreasonably withheld, to manufacture for the Territory (a) the Licensed Antibody as the Active Ingredient of the applicable Licensed Product and/or (b) the applicable Licensed Product (such actions, "**Manufacturing Technology Transfer**"). Following the review and approval by the JDC of the Manufacturing Technology Transfer Plan, Leap will perform (or cause one or more applicable Third Parties (including, as applicable, any CMO engaged by Leap to manufacture the Licensed Product) to perform) [\*\*\*] in accordance with such Manufacturing Technology Transfer Plan to either BeiGene or to a CMO designated by BeiGene, [\*\*\*]. Leap will complete the Manufacturing Technology Transfer for each Licensed Product promptly (and in any event within [\*\*\*] after agreement by the Parties with respect to the Manufacturing Technology Transfer Plan and the CMO to receive such transfer, as applicable) following BeiGene's request and in accordance with the Manufacturing Technology Transfer Plan. Thereafter during the Term, Leap will provide BeiGene with additional Leap Manufacturing IP as part of the Continuing Know-How Transfer in accordance with Section 4.1. After completion of the Manufacturing Technology Transfer to a facility, the use of such facility to manufacture the Licensed Product shall be subject to the successful completion of any necessary inspections required by applicable Regulatory Authorities. BeiGene may use Licensed Product manufactured at its facilities or those of the CMO to which the Manufacturing Technology Transfer is made, for clinical or commercial purposes in the Territory. All Licensed Product manufactured by or on behalf of BeiGene or its CMO shall be manufactured in compliance with all Applicable Laws and applicable specifications for the Licensed Product. Leap will invoice BeiGene for any expenses for technology transfer activities under this Section 7.2 [\*\*\*], for up to [\*\*\*] for a period of up to [\*\*\*], at a rate of [\*\*\*], prorated to \$[\*\*\*], assuming [\*\*\*]. BeiGene's liability for technology transfer activities under this Section 7.2 will in no event exceed [\*\*\*] in total.<sup>55</sup>

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<sup>53</sup> Competitive Information – Commercially Sensitive Terms.

<sup>54</sup> Competitive Information – Commercially Sensitive Terms.

### 7.3 Clinical Supply by Leap.

(a) Subject to, and in accordance with, the terms of this Section 7.3, Leap shall use Commercially Reasonable Efforts, either by itself or through a Third Party contract manufacturer, to manufacture and supply to BeiGene all Licensed Products required by BeiGene for Development use in the Territory. Subject to Section 7.2, the Parties shall use Commercially Reasonable Efforts to enter into an agreement governing the supply by Leap of such Licensed Products for such Development use by BeiGene (“**Clinical Supply Agreement**”) within [\*\*\*] after the Effective Date.<sup>56</sup>

(i) Leap shall supply the Licensed Products pursuant to the Clinical Supply Agreement and this Section 7.3(a) at a transfer price [\*\*\*]. Leap shall invoice BeiGene for the Licensed Product upon delivery in accordance with Section 7.3(a)(ii) and BeiGene shall, subject to the terms of the Clinical Supply Agreement, pay the undisputed invoiced amounts within [\*\*\*] after the date of such invoice. Notwithstanding the foregoing, in the event Leap incurs [\*\*\*], Leap may invoice BeiGene for such fee or charge, [\*\*\*] and BeiGene shall, pay such invoiced amounts within [\*\*\*] after the date of such invoice.<sup>57</sup>

(ii) Delivery of Licensed Products supplied by Leap for Development will be made [\*\*\*]. BeiGene shall be responsible for [\*\*\*]. BeiGene shall also be responsible for [\*\*\*].<sup>58</sup>

**7.4 Commercial Supply.** BeiGene will be responsible for commercial supply of Licensed Products in the Territory. Upon BeiGene’s request, Leap will assist BeiGene in negotiating in good faith and executing, a manufacturing and supply agreement pursuant to which Leap’s Third Party CMO engaged by Leap for the commercial manufacture of the Licensed Products will supply BeiGene with its requirements of Licensed Products for commercial sale on an exclusive basis in the Territory. BeiGene acknowledges that any agreement regarding the terms of a manufacturing and supply agreement shall be solely determined by BeiGene and the Third Party CMO and that Leap shall have no responsibility or authority with respect thereto.

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<sup>55</sup> Competitive Information – Commercially Sensitive Terms.

<sup>56</sup> Competitive Information – Commercially Sensitive Terms.

<sup>57</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

<sup>58</sup> Competitive Information – Commercially Sensitive Terms.

**ARTICLE 8  
COMMERCIALIZATION**

**8.1 Commercialization Responsibility.**

(a) BeiGene shall be solely responsible for Commercializing the Licensed Products in the Field in the Territory in accordance with this Article 8 and shall book all sales of such Licensed Product in the Territory. BeiGene shall use Commercially Reasonable Efforts to Commercialize each Licensed Product that obtains Regulatory Approval in the Field in each country or region in the Territory. BeiGene shall conduct all Commercialization of Licensed Products in the Field in the Territory in accordance with the Commercialization Plan for such Licensed Product and all Applicable Laws, [\*\*\*].<sup>59</sup>

(b) As between the Parties, Leap shall have the sole right to Commercialize each Licensed Product outside of the Territory, and to book all such sales of Licensed Product.

**8.2 Commercialization Reports.** For [\*\*\*] following receipt of the first Regulatory Approval for any Licensed Product in any country or region in the Territory, BeiGene shall provide to Leap [\*\*\*] within [\*\*\*] after the end of such [\*\*\*] a written report that summarizes the Commercialization activities on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis, as applicable, performed by or on behalf of BeiGene, its Affiliates and sublicensees in the Territory since the prior report provided by BeiGene and shall propose amendments to update to the Commercialization Plan to reflect any changes in such plan. Such reports shall be Confidential Information of BeiGene, subject to Article 10. BeiGene shall provide updates to any such report or amended Commercialization Plan at each meeting of the JCC for review and discussion.<sup>60</sup>

**8.3 Coordination of Commercialization Activities.**

(a) The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of Licensed Products in and outside the Territory. As such, the Parties shall coordinate such activities where appropriate, which may include [\*\*\*]. To facilitate coordination, BeiGene shall deliver an initial draft of a Commercialization Plan to the JCC for its review and discussion not later than [\*\*\*] to the anticipated date of the first filing of the first Regulatory Approval for a Licensed Product in the Territory. The Commercialization Plan shall contain in reasonable detail the major Commercialization activities planned for such Licensed Product in the Territory. Leap shall have the right to comment through the JCC on such Commercialization Plan.<sup>61</sup>

(b) BeiGene shall keep Leap timely informed on the status of any application for pricing or reimbursement approval for Licensed Products in the Field in the Territory, including any discussion with the applicable Regulatory Authority with respect thereto. Each Party shall have the right to determine the price of Licensed Products sold in its territory and neither Party shall have the right to direct, control or approve the pricing of Licensed Products sold by the other Party in such other Party's territory.

**8.4 Diversion.** Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates and sublicensees shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory; provided that each Party shall have the right to attend conferences and meetings of congresses in the other Party's territory and to promote and market Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 8.4 and coordination through the JCC. Neither Party shall engage, nor permit its Affiliates or sublicensees to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of Licensed Products located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliate or sublicensee receives any order for Licensed Products for use from a prospective Third Party purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Subject to Article 7, neither Party shall, nor permit its Affiliates or sublicensees to, deliver or tender (or cause to be delivered or tendered) any Licensed Products for use in the other Party's territory.

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<sup>59</sup> Competitive Information – Commercially Sensitive Terms.

<sup>60</sup> Competitive Information – Commercially Sensitive Terms.

<sup>61</sup> Competitive Information – Commercially Sensitive Terms.

**ARTICLE 9  
PAYMENTS**

**9.1 Option Fee; Upfront Fee.**

(a) In partial consideration of Leap’s granting of the Option to BeiGene hereunder and Leap’s undertaking of the activities required under this Agreement, BeiGene shall pay to Leap a one-time, non-refundable non-creditable upfront payment of three million U.S. dollars (USD 3,000,000) (the “**Upfront Payment**”) within [\*\*\*] following the Effective Date.<sup>62</sup>

(b) In partial consideration of Leap’s granting of the licenses and rights to BeiGene hereunder and Leap’s undertaking of the activities required under this Agreement, BeiGene shall pay to Leap a one-time, non-refundable non-creditable upfront payment of [\*\*\*] U.S. dollars (USD [\*\*\*]) (the “**Option Exercise Fee**”) within [\*\*\*] following BeiGene’s exercise of the Option.<sup>63</sup>

**9.2 Development Milestones.** Within [\*\*\*] after the achievement of each milestone event set forth in the table below for each applicable Licensed Product (each, a “**Development Milestone Event**”), BeiGene shall make the corresponding milestone payment to Leap (each, a “**Development Milestone Payment**”) in accordance with Section 9.4(a). Each Development Milestone Payment shall be payable [\*\*\*] of the corresponding Development Milestone Event for the first Licensed Product to achieve such Development Milestone Event.<sup>64</sup>

Milestone Event <sup>65</sup>	Milestone Payment <sup>66</sup>
<b>Development Milestones Events</b>	
<u>Milestone Event</u>	<u>Milestone Payment (M)</u>
1.[***]	USD [***]
2.[***]	USD [***]
3.[***]	USD [***]
4.[***]	USD [***]
5.[***]	USD [***]

<sup>62</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

<sup>63</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

<sup>64</sup> Competitive Information – Financial Provisions, Discovery Information and Commercially Sensitive Terms.

<sup>65</sup> Competitive Information – Financial Provisions and Discovery Information.

<sup>66</sup> Competitive Information – Financial Provisions.

**9.3 Commercialization Milestones.** Upon the [\*\*\*] of each milestone event set forth in the table below with respect to the first Licensed Product to achieve such milestone (each, a “**Commercialization Milestone Event**”), BeiGene shall make the corresponding milestone payment to Leap (each, a “**Commercialization Milestone Payment**”) in accordance with Section 9.4(b):<sup>67</sup>

Milestone Event <sup>68</sup>	Milestone Payment <sup>69</sup>
<b>Commercial Milestones Events</b>	
1.[***]	USD [***]
2.[***]	USD [***]
3.[***]	USD [***]
4.[***]	USD [***]

For clarity, each of the foregoing Commercialization Milestone Payments will be payable only [\*\*\*]. In the event that [\*\*\*], BeiGene shall pay Leap [\*\*\*]. For example, if [\*\*\*], BeiGene shall pay Leap USD [\*\*\*] in Commercialization Milestone Payments pursuant to this Section 9.3.<sup>70</sup>

**9.4 Payment Terms.**

(a) **Milestone Payments.** BeiGene shall provide Leap with notice of the achievement of each Development Milestone Event within [\*\*\*] thereafter. Leap will invoice BeiGene for the corresponding Development Milestone Payment, and BeiGene will make the corresponding Development Milestone Payment within [\*\*\*] after receipt of Leap’s invoice.<sup>71</sup>

(b) **Commercialization Milestone Payments and Royalty Payments.** During the Term, following the First Commercial Sale of a Licensed Product, BeiGene shall furnish to Leap a written report for each Calendar Quarter showing the Net Sales by Licensed Product sold by BeiGene and its Affiliates and sublicensees during the reporting Calendar Quarter and the Licensed Product royalties payable under this Agreement in sufficient detail to allow Leap to verify the amount of Licensed Product royalties paid by BeiGene with respect to such Calendar Quarter. Each such report shall include, [\*\*\*], and shall specify [\*\*\*]. Reports shall be due no later than [\*\*\*] following the end of each Calendar Quarter. The corresponding Commercialization Milestone Payment(s) and Licensed Product royalties shown to have accrued by each report provided under this Section 9.4(b) shall be due and payable [\*\*\*].<sup>72</sup>

<sup>67</sup> Competitive Information – Discovery Information.

<sup>68</sup> Competitive Information – Financial Provisions and Discovery Information.

<sup>69</sup> Competitive Information – Financial Provisions.

<sup>70</sup> Competitive Information – Financial Provisions, Discovery Information and Commercially Sensitive Terms.

<sup>71</sup> Competitive Information – Commercially Sensitive Terms.

**9.5 Royalty Payments to Leap.**

(a) **Royalty Rates.** In further consideration of Leap’s grant of the rights and licenses to BeiGene hereunder, BeiGene shall, during each applicable Royalty Term, pay to Leap a tiered royalty on aggregate Net Sales of Licensed Products in the Territory for each Calendar Year (“**Annual Net Sales**”), at the percentage rates set forth below (subject to Section 9.5(c)):

<b><u>For Annual Net Sales of Licensed Products</u></b> <sup>73</sup>	<b><u>Royalty Rate (%)</u></b> <sup>74</sup>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

By way of illustration, assume in a Calendar Year that (i) Annual Net Sales of Licensed Product in the Territory in US Dollars total [\*\*\*] US Dollars (\$[\*\*\*]) and (ii) no adjustments or deductions to payments under Section 9.5(c) apply. The total royalties due and payable by BeiGene to Leap for such Net Sales would be [\*\*\*] US Dollars (\$[\*\*\*]), calculated as follows:<sup>75</sup>

$$\$[***] \times [***]\% = \$[***]^{76}$$

$$\$[***] \times [***]\% = \$[***]^{77}$$

$$\$[***] \times [***]\% = \$[***]^{78}$$

$$\$[***] \times [***]\% = \$[***]^{79}$$

$$\$[***] \times [***]\% = \$[***]^{80}$$

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$$\text{Total Royalty} = \$[***]^{81}$$

<sup>72</sup> Competitive Information – Commercially Sensitive Terms.

<sup>73</sup> Competitive Information – Financial Provisions.

<sup>74</sup> Competitive Information – Financial Provisions.

<sup>75</sup> Competitive Information – Financial Provisions.

<sup>76</sup> Competitive Information – Financial Provisions.

<sup>77</sup> Competitive Information – Financial Provisions.

<sup>78</sup> Competitive Information – Financial Provisions.

<sup>79</sup> Competitive Information – Financial Provisions.

<sup>80</sup> Competitive Information – Financial Provisions.

<sup>81</sup> Competitive Information – Financial Provisions.

(b) **Royalty Term.** BeiGene's obligation to make royalty payments will commence on the date of First Commercial Sale of a Licensed Product in each country in the Territory and continue until the later of (a) ten (10) years following the First Commercial Sale of such Licensed Product in such country, (b) the expiration of the last-to-expire Valid Claim of any Licensed Patent Rights that Covers such Licensed Product or its use in such country, or (c) the expiration of Regulatory Exclusivity for such Licensed Product in such country (the "**Royalty Term**").

(c) **Royalty Reductions.**

(i) **No Valid Claim.** Subject to Section 9.5(c)(iv), on a Licensed Product-by-Licensed Product and country by country basis, if there is no Valid Claim within the Licensed Patent Rights that Covers such Licensed Product in a given country in the Territory and there is no Regulatory Exclusivity for such Licensed Product in such country, then, commencing in the first Calendar Quarter after the date on which this Section 9.5(c)(i) applies and continuing for each Calendar Quarter thereafter for so long as there is no Valid Claim that Covers such Licensed Product in such country and there is no Regulatory Exclusivity for such Licensed Product in such country, the applicable royalty rate that would otherwise be owed on such Net Sales of such Licensed Product in such country under Section 9.5(a) during any such Calendar Quarter will be reduced by [\*\*\*] of the rates set forth in Section 9.5(a).<sup>82</sup>

(ii) **Biosimilar Product.** If (A) a Licensed Product is generating Net Sales in the Field in a country in the Territory during the applicable Royalty Term at a time when a Biosimilar Product with respect to such Licensed Product is being sold in such country; and (B) the market share of the Biosimilar Product(s) in such country [\*\*\*], then, subject to Section 9.5(c)(iv), the royalty rate applicable to Net Sales of such Licensed Product in such country in such Calendar Quarter shall be reduced by [\*\*\*].<sup>83</sup>

(iii) **Third Party Payments.** If during the Term BeiGene reasonably determines that a license under any Patent Rights controlled by a Third Party is necessary to avoid infringement of such Patent Rights (including any infringement that may arise from issuance of any patent application among such Patent Rights) arising from the practice and use of the Licensed IP pursuant to this Agreement in connection with the manufacture, Development or Commercialization of any Licensed Product in the Field in the Territory, BeiGene will have the right to acquire rights to such Patent Rights from such Third Party to manufacture, Develop or Commercialize any such Licensed Product in the Field in the Territory and, subject to Section 9.5(c)(iv), on a Licensed Product-by-Licensed Product and country by country basis, during any Calendar Quarter, BeiGene may credit against the royalty payments payable to Leap pursuant to Section 9.5(a) with respect to such Licensed Product in such country in such Calendar Quarter up to [\*\*\*] of any upfront payments, milestone payments and royalty payments for which BeiGene is responsible to such Third Party under the definitive agreement pursuant to which BeiGene acquired rights to such Patent Rights from such Third Party.<sup>84</sup>

(iv) **Royalty Floor.** In no event will the aggregate amount of royalty payments due to Leap pursuant to this Section 9.5 with respect to Net Sales for a Licensed Product in a country in the Territory in any given Calendar Quarter during the Royalty Term for such Licensed Product in such country be reduced (after giving cumulative effect to all reductions provided for under this Section 9.5(c)) to an amount of royalty payments that would be less than [\*\*\*]; provided, that, BeiGene will be entitled to carry forward to future Calendar Years any amounts with respect to which BeiGene would have been entitled to make a deduction pursuant to this Section 9.5(c) but for such maximum annual reduction pursuant to this Section 9.5(c)(iv).<sup>85</sup>

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<sup>82</sup> Competitive Information – Financial Provisions.

<sup>83</sup> Competitive Information – Commercially Sensitive Terms.

<sup>84</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

**9.6 Payments to Third Parties.** Except as expressly set forth herein, each Party shall be solely responsible for any payments due to Third Parties under any agreement entered into by such Party with respect to the Licensed Product, as a result of activities hereunder. Without limiting the foregoing, Leap will be solely responsible for any payments due pursuant to the Third Party In-License Agreement.

**9.7 Payment Currency; Exchange Rate.** All payments to be made under this Agreement shall be made in USD. Payments to Leap shall be made by electronic wire transfer of immediately available funds to the account of Leap, as designated in writing to BeiGene. If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion shall be made in a manner consistent with BeiGene's normal practices used to prepare its audited financial statements for external reporting purposes; provided that such practices use a widely accepted source of published exchange rates.

**9.8 Timing of Royalty Payments.** Royalties payable under Section 9.5(a) shall accrue at the time the invoice for the sale of the Licensed Product is delivered. Royalty obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within [\*\*\*] after the end of each Calendar Quarter during which the royalty obligation accrued, following the submission of the royalty report for such Calendar Quarter.<sup>86</sup>

**9.9 Late Payments.** Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [\*\*\*] percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue or (b) the maximum rate permitted by Applicable Laws; in each case calculated on the number of days such payment is delinquent, [\*\*\*].<sup>87</sup>

**9.10 Records and Audit Rights.**

**(a) Records.** BeiGene will keep (and will cause its Affiliates and sublicensees to keep) complete, true and accurate books and records in sufficient detail for Leap to determine payments due to Leap under this Agreement, including Licensed Product royalty payments. BeiGene will keep such books and records for at least [\*\*\*] following the end of the Calendar Year to which they pertain.<sup>88</sup>

**(b) Audit Rights.**

**(i)** Leap shall have the right during the [\*\*\*] period described in Section 9.10(a) to (a) appoint at its expense an independent certified public accountant of nationally recognized standing (the "**Accounting Firm**") reasonably acceptable to BeiGene to audit the relevant records of BeiGene and its Affiliates to verify that the amount of such payments were correctly determined and/or (b) require BeiGene to (i) appoint such an Accounting Firm to conduct such an audit of the applicable sublicensee and (ii) provide the results of such audit to Leap. BeiGene and its Affiliates shall each make its records available for audit by the Accounting Firm during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from Leap, solely to verify the payments hereunder were correctly determined. Such audit right shall not be exercised by Leap more than [\*\*\*] nor more than once with respect to sales of a particular Licensed Product in a particular period and may cover a period ending not more than [\*\*\*] prior to the date of such request. All records made available for audit pursuant to this Section 9.10(b) shall be deemed to be Confidential Information of BeiGene. The results of each audit, if any, shall be binding on both Parties. If the amount of any payment hereunder was underreported, BeiGene shall promptly (but in any event no later than [\*\*\*] after its receipt of the Accounting Firm's report so concluding) make payment to Leap of the underreported amount. Leap shall bear the full cost of an audit that it conducts pursuant to this Section 9.10(b) unless such audit discloses an under reporting by BeiGene of more than [\*\*\*] percent ([\*\*\*]%) of the aggregate amount of the payments hereunder reportable in any Calendar Year, in which case BeiGene shall reimburse Leap for the reasonable audit fees for such audit, in addition to paying the underreported amount.<sup>89</sup>

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<sup>85</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

<sup>86</sup> Competitive Information – Commercially Sensitive Terms.

<sup>87</sup> Competitive Information – Commercially Sensitive Terms.

<sup>88</sup> Competitive Information – Commercially Sensitive Terms.

(ii) The Accounting Firm will disclose to Leap only whether the payments subject to such audit are correct or incorrect and the specific details concerning any discrepancies. No other information regarding the results of such audit will be provided to Leap without the prior consent of BeiGene. BeiGene is entitled to require the Accounting Firm to execute a reasonable confidentiality agreement prior to commencing any such audit. The Accounting Firm shall provide a copy of its report and findings to BeiGene.

#### 9.11 Taxes and Blocked Currency

(a) **Taxes.** Each Party shall be responsible for its own tax liabilities arising under this Agreement. Subject to this Section 9.11, Leap shall be liable for all of its income and other taxes (including interest) (“**Taxes**”) imposed upon any payments made by BeiGene to Leap under this Agreement (“**Agreement Payments**”). If Applicable Laws require the withholding of Taxes, BeiGene shall make such withholding payments in a timely manner and shall subtract the amount thereof from the Agreement Payments. BeiGene shall promptly (as available) submit to Leap appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time. BeiGene shall provide Leap reasonable assistance in order to allow Leap to obtain the benefit of any present or future treaty against double taxation or refund or reduction in Taxes which may apply to the Agreement Payments. [\*\*\*].<sup>90</sup>

(b) **Blocked Currency.** If by Applicable Law in a country or region in the Territory, conversion into USD or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then BeiGene shall promptly notify Leap and, thereafter, amounts accrued in such country or region under this Article 9 shall be paid to Leap (or its designee) in such country or region in local currency by deposit in a local bank designated by Leap and to the credit of Leap, unless the Parties otherwise agree.

### ARTICLE 10 CONFIDENTIALITY

**10.1 Duty of Confidence.** During the Term and for [\*\*\*] thereafter, all Confidential Information disclosed by a Disclosing Party to a Receiving Party hereunder, including (a) with respect to BeiGene as Receiving Party, Licensed Know-How and (b) with respect to Leap as Receiving Party, BeiGene IP, shall be maintained in confidence by the Receiving Party and shall not be disclosed to any Third Party or used for any purpose, except as set forth herein, without the prior written consent of the Disclosing Party; provided, however, that with respect to any Confidential Information that is specifically identified at the time of disclosure to be a trade secret under Applicable Laws, such obligations shall survive the expiration of such [\*\*\*] period for so long as such Confidential Information remains a trade secret. The Receiving Party may only use Confidential Information of the Disclosing Party for purposes of exercising its rights and fulfilling its obligations under this Agreement and may disclose Confidential Information of the Disclosing Party and its Affiliates to employees, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates, licensees and sublicensees to the extent reasonably necessary for such purposes; provided that such persons and entities are bound by confidentiality and non-use of the Confidential Information consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party.<sup>91</sup>

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<sup>89</sup> Competitive Information – Commercially Sensitive Terms.

<sup>90</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

**10.2 Exceptions.** The obligations under this Article 10 shall not apply to any information to the extent the recipient Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party or its Affiliates;

(b) was known to, or was otherwise in the possession of, the Receiving Party or its Affiliates prior to the time of disclosure by the Disclosing Party;

(c) is disclosed to the Receiving Party or an Affiliate on a non-confidential basis by a Third Party that is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party or any of its Affiliates; or

(d) is independently developed by or on behalf of the Receiving Party or its Affiliates, as evidenced by its written records, without use of or reference to the Confidential Information disclosed by the Disclosing Party or its Affiliates under this Agreement.

**10.3 Authorized Disclosures.** Subject to this Section 10.3, the Receiving Party may disclose Confidential Information belonging to the other Party to the extent permitted as follows:

(a) such disclosure is deemed necessary by counsel to the Receiving Party to be disclosed to such Receiving Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party;

(b) disclosure by a Receiving Party or its Affiliates to governmental or other regulatory agencies in order to obtain and maintain Patent Rights consistent with Article 14;

(c) disclosure by a Receiving Party to any Affiliate, or to its or its Affiliates' employees, consultants, contractors, subcontractors, agents or sublicensees on a need-to-know basis in order to enable such Receiving Party to exercise its rights, or to carry out its responsibilities, under this Agreement including, with respect to BeiGene as the Receiving Party, to any Third Party that is engaged by BeiGene to perform services in connection with the Development, manufacture and/or Commercialization of the Licensed Antibody and/or any Licensed Products in accordance with this Agreement; provided, in each case, that such persons and entities are bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party;

(d) disclosure by BeiGene or a BeiGene Affiliate or sublicensee as reasonably necessary to gain or maintain approval to conduct Clinical Trials for a Licensed Product, to obtain and maintain Regulatory Approval or to otherwise Develop, manufacture and Commercialize Licensed Products in the Territory, in accordance with this Agreement;

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<sup>91</sup> Competitive Information – Commercially Sensitive Terms.

(e) disclosure by Leap or a Leap Affiliate or sublicensee as reasonably necessary to gain or maintain approval to conduct Clinical Trials for a Licensed Product, to obtain and maintain Regulatory Approval or to otherwise Develop, manufacture and Commercialize Licensed Products outside the Territory;

(f) disclosure by a Party required in connection with any judicial or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable laws, court orders or governmental regulations (or the rules of any recognized stock exchange or quotation system); or

(g) disclosure by a Party to potential or actual investors or potential or actual acquirers or actual or potential sublicensees in connection with due diligence or similar investigations by such Third Parties; provided, in each case, that any such potential or actual investor or acquirer or sublicensee agrees to be bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party.

If the Receiving Party is required by judicial or administrative process to disclose Confidential Information that is subject to the non-disclosure provisions of this Article 10, such Receiving Party shall promptly inform the Disclosing Party of the disclosure that is being sought in order to provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the Disclosing Party, cooperate in all reasonable respects with the Disclosing Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the Disclosing Party's expense. Confidential Information that is disclosed as permitted by this Section 10.3 shall remain otherwise subject to the confidentiality and non-use provisions of this Article 10, and the Party disclosing Confidential Information as permitted by this Section 10.3 shall take all steps reasonably necessary, including obtaining an order of confidentiality and otherwise cooperating with the other Party, to ensure the continued confidential treatment of such Confidential Information.

## ARTICLE 11 PUBLICATIONS & PUBLICITY

### 11.1 Publications.

(a) BeiGene acknowledges that some of the Clinical Trials in accordance with the Global Development Plan are part of Multi-Regional Clinical Studies. Accordingly and notwithstanding anything to the contrary herein, BeiGene shall not publish or present the Clinical Trial Results, Clinical Data, non-clinical data or any associated results or conclusions of any Clinical Trial from a Multi-Regional Clinical Study until after the first publication or presentation regarding the overall global study is completed by Leap, such publication to be at the sole discretion of Leap. Thereafter, BeiGene may publish or disclose Clinical Data, non-clinical data or any associated results or conclusions of any Multi-Regional Clinical Study in the Territory in accordance with Section 11.1(b).

(b) BeiGene may publicly present or publish any Clinical Data, non-clinical data or any associated results or conclusions generated by or on behalf of BeiGene pursuant to this Agreement solely to the extent that such data, results and conclusions are specific to the Territory and the Field (each such proposed presentation or publication, a "**BeiGene Publication**"), and subject to the additional limitations set forth in this Article 11. In the event BeiGene desires to publicly present or publish a BeiGene Publication in accordance with the foregoing sentence, BeiGene shall provide Leap (including the JDC) with a copy of such proposed BeiGene Publication at least [\*\*\*] prior to the earlier of its presentation or intended submission for publication; provided that in the case of abstracts, this period shall be at least [\*\*\*] (such applicable period, the "**Review Period**"). BeiGene agrees that it will not submit or present any BeiGene Publication (i) until Leap has provided written comments during such Review Period on the material in such BeiGene Publication or (ii) until the applicable Review Period has elapsed without written comments from Leap, in which case BeiGene may proceed and the BeiGene Publication will be considered approved in its entirety. If BeiGene receives written comments from Leap during the applicable Review Period, it shall consider the comments of Leap in good faith, but will retain the sole authority to submit the manuscript for BeiGene Publication; provided that BeiGene agrees to (A) delete any Confidential Information of Leap that Leap identifies for deletion in Leap's written comments, (B) delete any Clinical Data, non-clinical data results, conclusions or other related information that is not specific to the Territory or the Field, or the publication of which Leap reasonably determines, in its sole discretion, would conflict with Leap's global publication strategy or materially and adversely impact the Licensed Product, and (C) delay such BeiGene Publication for a period of up to an additional [\*\*\*] after the end of the applicable Review Period to enable Leap to draft and file Patent Rights with respect to any subject matter to be made public in such BeiGene Publication and to which Leap has the applicable intellectual property rights to file such Patent Rights. BeiGene shall provide Leap a copy of the BeiGene Publication at the time of the submission or presentation. BeiGene agrees to acknowledge the contributions of Leap, and the employees of Leap, in all BeiGene Publications as scientifically appropriate. BeiGene shall require its Affiliates, sublicensees and contractors to comply with the obligations of Section 11.1.<sup>92</sup>

(c) Without limiting Section 11.1(a), Leap shall have the right to publicly present or publish any Clinical Trial Results or Clinical Data, including non-clinical data or any results or conclusions associated therewith (each such proposed presentation or publication, a “**Leap Publication**” and, collectively with any BeiGene Publication, a “**Publication**”), and subject to the limitations set forth in this Section 11.1(c). In the event Leap desires to publicly present or publish a Leap Publication that includes data from a Clinical Trial site in the Territory in accordance with the foregoing sentence, Leap shall provide BeiGene (including the JDC) with a copy of such proposed Leap Publication consistent with the applicable Review Period. Leap agrees that it will not submit or present any Leap Publication (i) until BeiGene has provided written comments during such Review Period on the material in such Leap Publication or (ii) until the applicable Review Period has elapsed without written comments from BeiGene, in which case Leap may proceed and the Leap Publication will be considered approved in its entirety. If Leap receives written comments from BeiGene during the applicable Review Period, it shall consider the comments of BeiGene in good faith, but will retain the sole authority to submit the manuscript for Leap Publication; provided that Leap agrees to (A) delete any Confidential Information of BeiGene that BeiGene identifies for deletion in BeiGene’s written comments and (B) delay such Leap Publication for a period of up to an additional [\*\*\*] after the end of the applicable Review Period to enable BeiGene to draft and file Patent Rights with respect to any subject matter to be made public in such Leap Publication and to which BeiGene has the applicable intellectual property rights to file such Patent Rights. Leap shall provide BeiGene a copy of the Leap Publication at the time of the submission or presentation. Leap agrees to acknowledge the contributions of BeiGene, and the employees of BeiGene, in all Leap Publications as scientifically appropriate. Leap shall require its Affiliates, sublicensees and contractors to comply with the obligations of this Section 11.1(c).<sup>93</sup>

(d) Notwithstanding anything to the contrary in this Section 11.1, the contents of any press release or other publication that has been reviewed and approved by a reviewing Party in accordance with this Article 11 may be re-released by such reviewing Party or publishing Party without a requirement for re-approval.

**11.2 Attorney-Client Privilege.** In the event of a dispute or potential dispute where the Parties: (a) share a common legal and commercial interest in such disclosure that is subject to attorney work product protections, attorney-client privileges or similar protections and privileges; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party’s Confidential Information covered by such protections and privileges relates; and (d) intend that both the Receiving Party and the Disclosing Party will have the right to assert such protections and privileges, the Parties may negotiate and enter into a common or joint defense agreement. Notwithstanding the foregoing, nothing in this Section 11.2 will apply with respect to a Dispute between the Parties (including their respective Affiliates).

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<sup>92</sup> Competitive Information – Commercially Sensitive Terms.

<sup>93</sup> Competitive Information – Commercially Sensitive Terms.

**11.3 Publication and Listing of Clinical Trials.** Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; provided that any listings or publications made pursuant to this Section 11.3 shall be considered a Publication hereunder and shall be subject to Section 11.1.

**11.4 Publicity.**

(a) The Parties will agree to a joint press release with respect to this Agreement promptly after the Effective Date. Either Party may make subsequent public disclosure of the contents of such press release. Subject to the foregoing, each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), provided, however, that neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or pursuant to the rules of any recognized stock exchange or quotation system, subject to that Party notifying the other Party of such duty and limiting such disclosure as reasonably requested by the other Party (and giving the other Party sufficient time to review and comment on any proposed disclosure).

(b) Notwithstanding Section 11.4(a), to the extent required by Applicable Laws or by any Securities Regulator, Leap has the right to publicly disclose (i) the achievement of material milestones under this Agreement, (ii) the amount of any payment received by Leap under this Agreement, and (iii) the commencement, completion, material data and key results of Clinical Trials conducted under this Agreement. After a publication has been made available to the public, each Party may post such publication or link to it on its corporate website without the prior written consent of the other party.

(c) The Parties hereby acknowledge and agree that either Party may be required by Applicable Laws to submit a copy of this Agreement to the U.S. Securities and Exchange Commission (the “SEC”) or any national or sub-national securities regulatory body in any jurisdiction (collectively, the “**Securities Regulators**”). If a Party is required by Applicable Laws to submit a description of the terms of this Agreement to and/or file a copy of this Agreement with any Securities Regulator, such Party agrees to consult and coordinate with the other Party with respect to such disclosure and/or the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party is required by Applicable Laws to submit a description of the terms of this Agreement to and/or file a copy of this Agreement with any Securities Regulator and such Party has (a) promptly notified the other Party in writing of such requirement and any respective timing constraints, (b) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure and (c) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Applicable Laws or the applicable Securities Regulator. If a Party seeks to make a disclosure or filing as set forth in this Section 11.4(c) and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will in good faith consider incorporating such comments.

**ARTICLE 12**  
**REPRESENTATIONS, WARRANTIES, AND COVENANTS**

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

(a) it is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by Applicable Laws and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity); and

(d) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not (a) conflict with or result in a breach of any provision of its organizational documents, (b) result in a breach of any agreement to which it is a party; or (c) violate any Applicable Laws.

**12.2 Representations and Warranties of Leap.** Leap represents and warrants to BeiGene as of the Effective Date that:

(a) Schedule 12.2(a) sets forth a complete and accurate list of all Licensed Patent Rights Controlled by Leap as of the Effective Date.

(b) Leap owns or is the exclusive licensee of all right, title, and interest in and to the Licensed Patent Rights set forth on Schedule 12.2(a);

(c) Leap has the right under the Licensed IP to grant the License to BeiGene, and it has not granted any license or other right under the Licensed IP that is inconsistent with the License;

(d) Neither Leap nor any of its respective Affiliates has [\*\*\*] any [\*\*\*] of any kind on the Licensed Patent Rights or Licensed Know-How in the Territory, and the Licensed Patent Rights and Licensed Know-How are [\*\*\*] of any kind in the Territory, in each case that would adversely affect the rights granted to BeiGene herein;<sup>94</sup>

(e) there are no claims, judgments or settlements against Leap pending, or to Leap's Knowledge, threatened that invalidate or seek to invalidate any Licensed Patent Rights in the Territory;

(f) Leap is not a party to any agreement with any [\*\*\*] or an [\*\*\*] thereof pursuant to which such [\*\*\*] or such [\*\*\*] of any of the Licensed Patent Rights or Licensed Know-How and which gives such [\*\*\*] or such [\*\*\*] to any Licensed Patent Rights or Licensed Know-How that conflicts with, or limits the scope of, the License granted to BeiGene hereunder;<sup>95</sup>

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

(h) to Leap's Knowledge, the Licensed IP is not the subject of any interference proceeding, *inter partes* review or post-grant review and there is no pending or threatened action, suit, proceeding or claim by a Third Party challenging Leap's ownership rights in, or the validity or scope of, any Licensed IP in the Territory;

(i) there are no pending or, to its Knowledge, no threatened (in writing), adverse actions, suits or proceedings against Leap involving the Licensed IP or Licensed Product;

(j) to its Knowledge, the Licensed IP includes all Know-How owned or licensed by Leap or its Affiliates that is necessary or reasonably useful to Develop, manufacture and Commercialize the Licensed Antibody and/or Licensed Products in the Field in the Territory as such Development, manufacture and Commercialization is currently being conducted by Leap or contemplated to be conducted by the Parties hereunder;

(k) to its Knowledge, Leap has complied with all Applicable Laws applicable to (i) the prosecution and maintenance of the Licensed Patent Rights and (ii) its Development and manufacture of Licensed Products in the Field;

(l) to its Knowledge, there are no acts or omissions of Leap that would constitute inequitable conduct, fraud, or misrepresentation to the applicable patent office with respect to any Licensed Patent Rights;

(m) (i) Leap has obtained, or caused its Affiliates to obtain, assignments from the inventors of all rights and embodiments in and to the Licensed IP that is solely owned by Leap or its Affiliates, (ii) to its Knowledge, all such assignments are valid and enforceable, and (iii) the inventorship of the Licensed Patent Rights that are solely owned by Leap or its Affiliates is properly identified on each issued patent or patent application in such Licensed Patent Rights;

(n) Leap and its Affiliates have used reasonable and diligent efforts consistent with industry practices to protect the secrecy, confidentiality and value of all Licensed Know-How that constitutes trade secrets under Applicable Laws;

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<sup>94</sup> Competitive Information – Commercially Sensitive Terms and Exclusivity Information.

<sup>95</sup> Competitive Information – Commercially Sensitive Terms and Exclusivity Information.

(o) Leap has provided to BeiGene all material documentation, data, and information under its control requested by BeiGene relating to the Licensed Antibody and the use thereof in the Field. Without limiting the foregoing, Leap has made available to BeiGene through an electronic data room complete and accurate copies of (a) all existing material Regulatory Filings made by Leap or its Affiliates (the “**Existing Regulatory Materials**”), and (b) all other material correspondence to/from any Regulatory Authority and Leap, in each case related to the Licensed Antibody or any Licensed Product. Other than the Existing Regulatory Materials, neither Leap nor any of its Affiliates has, as of the Effective Date, obtained, or filed, any INDs, CTAs or any other form of regulatory application with Regulatory Approvals for approval of Clinical Trials, marketing or other purpose, for the Licensed Antibody or any Licensed Product. The Existing Regulatory Materials are, to the Knowledge of Leap, in good standing, and neither Leap nor any of its Affiliates has received any notice in writing from any Regulatory Authority that the Existing Regulatory Materials are not currently in, or may not remain in, good standing with the applicable Regulatory Authority;

(p) Leap has provided to BeiGene all material adverse event information with respect to the Licensed Antibody or any Licensed Product Known to Leap or its Affiliates;

(q) all information and data provided by or on behalf of Leap to BeiGene regarding the Licensed Antibody or Licensed Product on or before the Effective Date in contemplation of this Agreement or the transactions contemplated hereby was and is as of the Effective Date, to the Knowledge of Leap, accurate in all material respects, and, to the Knowledge of Leap, Leap has not failed to disclose, or cause to be disclosed, any material information or data known to Leap that could reasonably be expected to cause the information and data that has been disclosed by Leap to BeiGene to be misleading in any material respect; and

(r) The Third Party In-License Agreement is the only agreement by and between Leap and any Third Party that provides for the license to Leap of any Know-How or Patent Rights that are included as part of the Licensed IP. Without limiting the generality of the foregoing, the Third Party In-License Agreement is in full force and effect and is the valid and binding obligation of Leap, enforceable in accordance with its terms and is binding on the parties thereto. Leap has not materially breached and is not currently in material breach of its obligations under the Third Party In-License Agreement in a manner that has, or would reasonably be expected to have, a material adverse effect on the rights granted to BeiGene under this Agreement, and to Leap’s Knowledge, the party to the Third Party In-License Agreement has not materially breached, and is not currently in material breach of, its obligations under the Third Party In-License Agreement.

**12.3 Representations and Warranties of BeiGene.** BeiGene represents and warrants to Leap as of the Effective Date that: (a) BeiGene and its Affiliates is not, and has not been, debarred or disqualified by any Regulatory Authority; and (b) none of BeiGene or its Affiliates’ employees or contractors who will be involved in the Development, manufacture or Commercialization of the Licensed Product are, or have been, debarred or disqualified by any Regulatory Authority.

**12.4 Covenants of BeiGene.** BeiGene covenants to Leap that:

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

(b) BeiGene will only engage Clinical Trial sites under the Territory Development Plan and the Global Development Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the NMPA or the applicable Regulatory Authority;

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

(d) except as otherwise expressly permitted in this Agreement, commencing on the Effective Date and continuing until the end of the Term, BeiGene and its Affiliates will not (i) assign or otherwise transfer ownership of any BeiGene Inventions outside the Territory, except to the extent such assignment or transfer does not conflict with or adversely affect any of the licenses granted to Leap hereunder, or (ii) grant to any Third Party any license rights to any BeiGene Inventions or BeiGene IP outside the Territory if such license grant conflicts with any of the licenses granted to Leap hereunder.

**12.5 Covenants of Leap.** Leap covenants to BeiGene that:

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

(b) Leap will only engage Clinical Trial sites under the Global Development Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the applicable Regulatory Authority;

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

(d) except as otherwise expressly permitted in this Agreement, commencing on the Effective Date and continuing until the end of the Term, Leap and its Affiliates will not (i) assign or otherwise transfer ownership of any Licensed Patent Rights or Leap Know-How in the Territory, except to the extent such assignment or transfer does not conflict with or adversely affect any of the Licenses granted to BeiGene hereunder, or (ii) grant to any Third Party any license rights to any Licensed Patent Rights or Leap Know- How in the Territory if such license grant conflicts with any of the Licenses granted to BeiGene hereunder.

**12.6 NO OTHER WARRANTIES.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 12, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF LEAP OR BEIGENE; AND (B) ALL OTHER REPRESENTATIONS, AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY REPRESENTATIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

**12.7 Compliance with Anti-Corruption Laws.**

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

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

(ii) it shall adhere to its own internal anti-corruption policies and Leap's anti-corruption policies and shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it will (A) promptly provide written notice to the other Party of any violations of Anti-Corruption Laws by such Party, its Affiliates or sublicensees, or persons employed by or subcontractors used by such Party or its Affiliates or sublicensees in the performance of this Agreement of which it becomes aware; and (B) no later than forty-five (45) days following the end of each Calendar Year, verify in writing that to the best of its knowledge, there have been no violations of Anti-Corruption Laws by such Party, its Affiliates or sublicensees, or persons employed by or subcontractors used by such Party or its Affiliates or sublicensees in the performance of this Agreement, or shall provide details of any exception to the foregoing; and

(iv) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Agreement in order to document or verify compliance with the provisions of this Section 12.7, and upon request of the other Party, up to one time per Calendar Year and upon reasonable advance notice, shall provide the other Party or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 12.7.

(b) Each Party represents and warrants that, to its knowledge, neither such Party nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of such Party or any of its Affiliates:

(i) has taken any action in violation of any applicable Anti-Corruption Laws; or

(ii) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

- (1) influencing any act or decision of any Public Official in his or her official capacity;
- (2) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;
- (3) securing any improper advantage; or

(4) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

(c) Each Party further represents and warrants that, as of the Effective Date, none of the officers, directors or employees of such Party or of any of its Affiliates or agents acting on behalf of such Party or any of its Affiliates, is a Public Official.

(d) For purposes of this Section 12.7, "**Public Official**" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and (iv) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

**ARTICLE 13**  
**INDEMNIFICATION**

**13.1 Indemnification by BeiGene.** BeiGene shall indemnify and hold harmless Leap, its Affiliates, and their respective directors, officers, employees, contractors, agents and assigns (individually and collectively, the “**Leap Indemnitee(s)**”) from and against all losses, liabilities, damages and expenses (including reasonable attorneys’ fees and costs) (individually and collectively, “**Losses**”) incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, “**Claims**”) to the extent arising from (a) the Development, manufacture or Commercialization of the Licensed Products by or on behalf of BeiGene or any of its Affiliates or sublicensees, including product liability Claims, in the Territory, (b) BeiGene’s actions (or omissions) in the performance of its obligations with respect to Regulatory Submissions and interactions with Regulatory Authorities, in each case, with respect to the Licensed Products in the Territory, (c) the gross negligence or willful misconduct of BeiGene or its Affiliates or sublicensees, (d) BeiGene’s breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in this Agreement, or (e) the failure of BeiGene or its Affiliates or sublicensees to abide by any Applicable Laws, in each case of clauses (a) through (e) above, except to the extent such Losses or Claims arise out of an Leap Indemnitee’s gross negligence or willful misconduct, breach of this Agreement, or material failure to abide by any Applicable Laws.

**13.2 Indemnification by Leap.** Leap shall indemnify and hold harmless BeiGene, its Affiliates, and their directors, officers, employees, contractors, agents and assigns (individually and collectively, the “**BeiGene Indemnitee(s)**”) from and against all Losses incurred in connection with Claims against such BeiGene Indemnitee to the extent arising from (a) the Development, manufacture or Commercialization of the Licensed Products by or on behalf of Leap or any of its Affiliates or sublicensees (not including BeiGene or its Affiliates or sublicensees) including product liability Claims, outside the Territory, (b) the Development or manufacture of the Licensed Products by or on behalf of Leap or any of its Affiliates or sublicensees (not including BeiGene or its Affiliates or sublicensees) in the Territory as contemplated by this Agreement, (c) Leap’s actions (or omissions) in the performance of its obligations with respect to Regulatory Submissions and interactions with Regulatory Authorities, in any case, with respect to the Licensed Products, (d) the gross negligence or willful misconduct of Leap or its Affiliates hereunder, (e) Leap’s breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in this Agreement, or (f) failure of Leap or its Affiliates to abide by any Applicable Laws in its performance hereunder, in each case of clauses (a) through (f) above, except to the extent such Losses or Claims arise out of any of a BeiGene Indemnitee’s gross negligence or willful misconduct, breach of this Agreement or material failure to abide by any Applicable Laws.

**13.3 Indemnification Procedure.** If either Party is seeking indemnification under Sections 13.1 or 13.2 (the “**Indemnified Party**”), it shall inform the other Party (the “**Indemnifying Party**”) of the Claim giving rise to the obligation to indemnify pursuant to such Section within ten (10) Business Days after receiving written notice of the Claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Claim shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party shall have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party shall have the right to assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party’s written consent, which consent shall not be unreasonably withheld, conditioned or delayed. If the Parties cannot agree as to the application of Section 13.1 or 13.2 as to any Claim, pending resolution of the dispute pursuant to Section 16.5, the Parties may conduct separate defenses of such Claims, with each Party retaining the right to Claim indemnification from the other Party in accordance with Section 13.1 or 13.2 upon resolution of the underlying Claim.

**13.4 Mitigation of Loss.** Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary in order to mitigate any Losses (or potential losses or damages) under this Article 13. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

**13.5 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 13.1 OR 13.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO CONFIDENTIALITY.

**13.6 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold in the Territory and/or outside of the Territory. All such insurance coverage may be maintained through a self-insurance plan that substantially complies with the foregoing limits and requirements and may be satisfied through one or more policies, including an umbrella policy; provided, however, that the other Party will provide to the requesting Party a letter(s) affirming appropriate self-insurance and/or a certificate of insurance evidencing such coverage in accordance with this Agreement. Each Party will maintain such insurance or self-insurance coverage without interruption during the Term and for a period of [\*\*\*] thereafter, and, if applicable, will provide certificates and/or letters evidencing such insurance coverage without interruption as reasonably requested during the period of time for which such coverage must be maintained. Each Party will be provided at least [\*\*\*] prior written notice of any cancellation or material decrease in the other Party's insurance coverage limits described above. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance will not relieve that Party of its obligations set forth in this Agreement.<sup>96</sup>

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<sup>96</sup> Competitive Information – Commercially Sensitive Terms.

**ARTICLE 14**  
**INTELLECTUAL PROPERTY**

**14.1 Inventions.**

(a) **Ownership.** As between the Parties, BeiGene will solely own all Inventions conceived and first reduced to practice solely by employees or agents of BeiGene or any of its Affiliates (“**BeiGene Inventions**”) and Leap will solely own all Inventions conceived and first reduced to practice solely by employees or agents of Leap or any of its Affiliates (“**Leap Inventions**”). Inventions conceived and first reduced to practice jointly by employees or agents of BeiGene and Leap or their respective Affiliates (“**Joint Inventions**”) will be jointly owned, with each Party having the right to freely practice and license any such jointly-owned Inventions without accounting to the other, subject to the terms of the Agreement. Notwithstanding the foregoing, Leap agrees that any Inventions (i) that cover a modification or improvement to the composition of the BeiGene Drug, or (ii) that cover a new method of using or administering the BeiGene Drug as a single agent or in combination with any drug (“**BeiGene Drug Inventions**”) will be and are hereby assigned to BeiGene, and BeiGene shall be the exclusive owner of any such BeiGene Drug Inventions. Leap will (a) cooperate fully in obtaining patent and other proprietary protection for any patentable or protectable BeiGene Drug Inventions, in the name of BeiGene and [\*\*\*]; and (b) execute and deliver all requested applications, assignments, and other documents and take such other measures as BeiGene reasonably requests, in order to perfect and enforce BeiGene’s rights in the BeiGene Drug Inventions.

(b) **Disclosure.** Each Party shall promptly disclose to the other Party all Inventions, including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates’ employees, agents, or independent contractors relating thereto, and shall also promptly respond to reasonable requests from the other Party for additional information relating thereto.

(c) **Joint Inventions.** Subject to the rights granted under and the restrictions set forth in this Agreement, it is understood that neither Party shall have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit any Joint Inventions (or any Patent Rights claiming the same, “**Joint Patent Rights**”), by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting.

**14.2 Patent Prosecution.**

(a) **Licensed Patent Rights.**

(i) Subject to Section 14.2(c), as between the Parties, Leap shall have the right to control the Patent Prosecution of all Licensed Patent Rights at Leap’s expense outside of the Territory or outside of the Field, and as between the Parties and subject to Section 14.5, BeiGene shall have the right to control the Patent Prosecution of all Licensed Patent Rights [\*\*\*] in the Field in the Territory.<sup>97</sup>

(ii) BeiGene shall provide Leap with a reasonable opportunity to consult with BeiGene regarding such Licensed Patent Rights in the Field in the Territory and keep Leap reasonably informed of the Patent Prosecution of the Licensed Patent Rights in the Field in the Territory. BeiGene shall provide Leap with a reasonable opportunity to review and comment on material communications from any patent authority regarding such Licensed Patent Rights in the Field in the Territory and drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Further, BeiGene shall notify Leap of any decision to cease Patent Prosecution or maintenance of any Licensed Patent Rights in the Territory. BeiGene will consider Leap’s comments on Patent Prosecution in good faith but will have final decision-making authority under this Section 14.2(a)(ii).

(b) **BeiGene Patent Rights.** As between the Parties, BeiGene shall have the sole right to control the Patent Prosecution of all BeiGene Patent Rights and Patent Rights in the BeiGene Drug Inventions throughout the world, [\*\*\*].<sup>98</sup>

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<sup>97</sup> Competitive Information – Commercially Sensitive Terms.

<sup>98</sup> Competitive Information – Commercially Sensitive Terms.

(c) **Joint Patent Rights.** In the event that any jointly-owned Invention is created hereunder, at either Party's request, the Parties shall discuss a mutually acceptable filing and prosecution strategy for any Joint Patent Rights; provided that absent such agreement, BeiGene shall control the Patent Prosecution of any Joint Patent Rights in the Field in the Territory and Leap shall control the Patent Prosecution of any Joint Patent Rights outside of the Territory and outside of the Field, as set forth in this Section 14.2(c). Unless the Parties agree in writing on an alternative arrangement, BeiGene shall be responsible for all of its costs of Patent Prosecution of Joint Patent Rights in the Field in the Territory and Leap shall be responsible for all of its costs of Patent Prosecution outside of the Territory or outside of the Field. With respect to Joint Patent Rights to be filed in the Field in the Territory, BeiGene shall (A) consult with Leap regarding such Joint Patent Rights, and any amendment, submission or response with respect to such Joint Patent Rights and keep Leap reasonably informed of the Patent Prosecution of the Joint Patent Rights, and (B) provide Leap with all material correspondence received from any patent authority in connection therewith in sufficient time to allow for review and comment by Leap. Further, BeiGene shall notify Leap of any decision to cease Patent Prosecution of any Joint Patent Rights in the Territory. BeiGene will consider Leap's comments on Patent Prosecution in good faith but will have final decision-making authority in the Territory under this Section 14.2(c).

(d) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 14.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

(e) **Abandonment.** If BeiGene decides to cease the Patent Prosecution, or to allow to lapse, any Licensed Patent Rights in the Field in the Territory or any Joint Patent Rights in the Field in the Territory, BeiGene shall inform Leap of such decision promptly and, in any event, so as to provide Leap a reasonable amount of time to meet any applicable deadline to establish or preserve such Patent Rights in such country or region. Leap shall have the right, but not the obligation, to assume responsibility for continuing the Patent Prosecution of such Patent Rights in Leap's name (or both Parties' names, with respect to Joint Patent Rights), [\*\*\*], through patent counsel or agents of its choice and, to the extent that Leap assumes such responsibility, BeiGene shall promptly deliver to Leap copies of all necessary files related to any Patent Rights with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Leap to assume such Patent Prosecution activities, at Leap's request and expense.<sup>99</sup>

### 14.3 Patent Enforcement.

(a) **Notice.** Each Party shall notify the other within [\*\*\*] of becoming aware of any alleged or threatened infringement by a Third Party of (i) any of the Licensed Patent Rights or Joint Patent Rights in the Territory or (ii) any of the BeiGene Patent Rights in the Territory, which infringement of such BeiGene Patent Rights adversely affects or is reasonably expected to adversely affect any Licensed Product in the Field in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any Licensed Patent Rights or Joint Patent Rights in the Field in the Territory or any such BeiGene Patent Rights in the Territory (collectively "**Product Infringement**"). For clarity, Product Infringement excludes any adversarial Patent Prosecution proceedings.<sup>100</sup>

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<sup>99</sup> Competitive Information – Commercially Sensitive Terms.

<sup>100</sup> Competitive Information – Commercially Sensitive Terms.

(b) **Enforcement Rights.**

(i) BeiGene shall have the first right to bring and control any legal action to enforce Licensed Patent Rights or Joint Patent Rights against any Product Infringement in the Territory [\*\*\*] as it reasonably determines appropriate; provided, that: (A) BeiGene shall discuss with Leap such Product Infringement, the enforcement of Licensed Patent Rights or Joint Patent Rights against any Product Infringement in the Field in the Territory and any reasonable rationale that Leap may have for BeiGene not pursuing such enforcement action and BeiGene shall consider in good faith the interests of Leap in such enforcement of the Licensed Patent Rights and/or Joint Patent Rights; (B) BeiGene shall keep Leap reasonably informed about such enforcement; (C) BeiGene shall not take any position with respect to, or compromise or settle, any such Product Infringement in any way that materially and adversely affects the scope, validity or enforceability of any Licensed Patent Rights or Joint Patent Rights in the Territory, without the prior consent of Leap, which consent shall not be unreasonably withheld, delayed or conditioned; and (D) if BeiGene does not intend to prosecute or defend a Product Infringement, or ceases to diligently pursue an enforcement with respect to such a Product Infringement, it shall promptly inform Leap in such a manner that such enforcement will not be prejudiced and Section 14.3(b)(ii) shall apply.<sup>101</sup>

(ii) If BeiGene or its designee fails to abate such Product Infringement in the Field in the Territory or to file an action to abate such Product Infringement in the Field in the Territory within [\*\*\*] after a written request from Leap to do so, or if BeiGene discontinues the prosecution of any such action after filing without abating such Product Infringement, then Leap shall have the right to enforce the Licensed Patent Rights or Joint Patent Rights, as applicable, against such Product Infringement in the Field in the Territory at its sole expense as it reasonably determines appropriate and shall keep BeiGene reasonably informed with respect to any such enforcement action; provided that (A) if BeiGene provides a reasonable rationale for not pursuing or continuing to pursue such Product Infringement (including a substantive concern regarding counter-claims by the infringing Third Party), Leap shall not pursue any action against such Product Infringement, and BeiGene and Leap shall discuss in good faith whether to consider the appropriate steps to be taken to address BeiGene's concerns as well as the effect of such Product Infringement on Leap and (B) Leap shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Licensed Patent Rights or Joint Patent Rights in the Field in the Territory without the prior written consent of BeiGene, which consent shall not be unreasonably withheld, delayed or conditioned.<sup>102</sup>

(iii) BeiGene shall have the sole right to bring and control any legal action to enforce BeiGene Patent Rights against any Product Infringement in the Territory [\*\*\*] as it reasonably determines appropriate, and shall keep Leap reasonably informed with respect to any such legal action.<sup>103</sup>

(iv) BeiGene shall not have the right to enforce any Licensed Patent Rights or Joint Patent Rights outside of the Territory or outside the Field. Leap shall have the sole right to enforce any Licensed Patent Rights or Joint Patent Rights outside of the Territory or outside of the Field.

(c) **Cooperation.** At the request of the Party bringing an action related to Product Infringement, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Laws to pursue such action, at each such Party's sole cost and expense.

(d) **Recoveries.** Any recoveries resulting from an enforcement action relating to a claim of Product Infringement in the Territory will first be applied to costs and expenses incurred by each Party in connection with such action (including, for this purpose, a reasonable allocation of expenses of internal counsel) (provided that if the amount of such recovery is not sufficient to cover all such costs and expenses of each Party, then the amount of the recovery will be proportionately shared by the Parties based on the amount of such costs and expenses incurred by each Party); and with respect to any remaining proceeds, (i) the Parties shall negotiate in good faith an appropriate allocation of such remaining proceeds to reflect the economic interests of the Parties under this Agreement with respect to such Product Infringement and (ii) unless otherwise agreed in subsection (i), [\*\*\*] of such remaining proceeds will be allocated to the enforcing Party and [\*\*\*] of such remaining proceeds will be allocated to the non-enforcing Party.<sup>104</sup>

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<sup>101</sup> Competitive Information – Commercially Sensitive Terms.

<sup>102</sup> Competitive Information – Commercially Sensitive Terms.

<sup>103</sup> Competitive Information – Commercially Sensitive Terms.

#### 14.4 Infringement of Third Party Rights.

(a) **Notice.** If any Licensed Product used or sold by BeiGene, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any Patent Rights or other intellectual property rights in the Territory that are owned or controlled by such Third Party, BeiGene shall promptly notify Leap within [\*\*\*] after receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof), including, if applicable, a certified translation into English, received regarding the foregoing. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.<sup>105</sup>

(b) **Defense.** In the event that a claim is brought against either Party alleging the infringement, violation or misappropriation of any Third Party intellectual property right based on the manufacture, use, sale or importation of the Licensed Products in the Field in the Territory, the Parties shall promptly meet to discuss the defense of such claim, and the Parties shall, as appropriate, enter into a joint defense agreement with respect to the common interest privilege protecting communications regarding such claim in a form reasonably acceptable to the Parties; provided, that, unless otherwise agreed by the Parties, BeiGene will have the sole right, but not the obligation, to defend and dispose (including through settlement or license) such claim at [\*\*\*]; provided that (i) BeiGene will discuss in good faith and coordinate with Leap in connection therewith and BeiGene will consider in good faith and reasonably address Leap's input and comments with respect thereto and (ii) BeiGene will not, without the consent of Leap, enter into any such settlement, consent judgment or other disposition of any action or proceeding that would (A) impose any liability or obligation on Leap, (B) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the rights of Leap with respect to the Licensed Products outside of the Territory or outside of the Field, or (C) otherwise adversely affect the rights of Leap with respect to the Licensed Products outside of the Territory or outside of the Field. Notwithstanding the foregoing, Leap shall have the right to participate, at its sole cost and expense and with counsel of its choice, in the defense of any claim that is controlled by BeiGene pursuant to this Section 14.4(b).<sup>106</sup>

**14.5 Patent Rights Licensed from Third Parties.** Each Party's rights under this Article 14 with respect to the prosecution and enforcement of any Licensed Patent Rights that is licensed by Leap from a Third Party, including under the Third Party In-Licensing Agreement, shall be subject to the rights of such Third Party to prosecute and enforce such Patent Rights.

**14.6 Patent Term Extensions.** BeiGene will reasonably cooperate with Leap, including providing reasonable assistance to Leap in its efforts to seek and obtain patent term restoration or supplemental protection certificates or the like or their equivalents in any country in the Territory, where applicable to Licensed Patent Rights, including as may be available to the Parties under the provisions of the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States of America, in each case, in connection with any Licensed Product. Notwithstanding anything to the contrary contained herein, if elections with respect to obtaining such patent term restoration or supplemental protection certificates or the like or their equivalents in the Territory are to be made in connection therewith, the Parties will mutually agree upon the election. In the event that the Parties are unable to agree upon the election, Leap shall have the right to make the election in its discretion.

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<sup>104</sup> Competitive Information – Commercially Sensitive Terms.

<sup>105</sup> Competitive Information – Commercially Sensitive Terms.

<sup>106</sup> Competitive Information – Commercially Sensitive Terms.

**14.7 Product Trademarks.** Subject to Section 8.3(c), BeiGene shall have the right to brand Licensed Products in the Territory using trademarks, logos, and trade names it determines appropriate for such Licensed Products, which may vary by country or region or within a country or region (the “**Product Marks**”); provided, however, that BeiGene shall provide Leap with a reasonable opportunity to review and provide comments on each proposed Product Mark, shall give due consideration to Leap’s comments before selecting any Product Mark, and shall not use any trademarks or house marks of Leap (including Leap’s corporate name) or any trademark confusingly similar thereto without Leap’s prior written consent. BeiGene shall own all rights in the Product Marks in the Territory (excluding any such marks that include, in whole or part, any corporate name or logos of Leap or its Affiliates or sublicensees) and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary, [\*\*\*].<sup>107</sup>

**14.8 Patent Marking.** BeiGene shall mark all Licensed Products in accordance with Applicable Laws, including the applicable patent marking laws, and shall require all of its Affiliates and sublicensees to do the same. To the extent permitted by Applicable Laws, BeiGene shall indicate on the product packaging, advertisement and promotional materials that such Licensed Product is in-licensed from Leap.

## ARTICLE 15 TERM AND TERMINATION

**15.1 Term.** This Agreement shall be effective as of the Effective Date, and shall continue in effect until the earlier of: (i) [\*\*\*] after the end of the Option Period, if BeiGene has not exercised the Option and paid the Option Exercise Fee by such date; and (ii) on a country-by-country and Licensed Product-by-Licensed Product basis, the expiration of the Royalty Term applicable to such Licensed Product in such country (the “**Term**”). On a country-by-country basis, upon the expiration of the Royalty Term, the License in such country shall become fully paid-up, royalty-free, perpetual, irrevocable and non-exclusive; provided, that, any remaining Development Milestone Events or Commercialization Milestones Events that are achieved with respect to a Licensed Product after such expiration shall be and remain subject to BeiGene’s obligation to pay the corresponding Development Milestone Payments or Commercialization Milestone Payments (as applicable) in accordance with Section 9.2 and 9.3, which shall survive such expiration.<sup>108</sup>

### 15.2 Termination

(a) **Termination by BeiGene for Convenience.** At any time, BeiGene may terminate this Agreement by providing written notice of termination to Leap, which notice includes an effective date of termination at [\*\*\*] after the date of the notice.<sup>109</sup>

(b) **Termination for Material Breach.**

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<sup>107</sup> Competitive Information – Commercially Sensitive Terms.

<sup>108</sup> Competitive Information – Commercially Sensitive Terms.

<sup>109</sup> Competitive Information – Commercially Sensitive Terms.

(i) If either BeiGene or Leap is in material breach of any obligation hereunder, the non-breaching Party may give notice to the breaching Party specifying the claimed particulars of such breach (a “**Breach Notification**”). If the Party receiving a Breach Notification fails to cure, or fails to dispute, that material breach on or before [\*\*\*] from the date of the Breach Notification, the Party delivering the Breach Notification may terminate this Agreement.<sup>110</sup>

(ii) If the allegedly breaching Party disputes in good faith the existence, materiality, or cure of the applicable material breach and provides written notice of such dispute to the other Party within the [\*\*\*] period set forth above, then the matter will be addressed under the dispute resolution provisions in Section 16.5 and the termination will not become effective unless and until it has been determined under Section 16.5 that the allegedly breaching Party is in material breach of any of its obligations under this Agreement and has failed to cure the same. During the pendency of such a dispute, all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.<sup>111</sup>

(c) **Termination for Patent Challenge.** Leap may terminate this Agreement upon [\*\*\*] written notice to BeiGene in the event that BeiGene or its Affiliates challenges or contests, or materially assists any other person to challenge or contest, the validity or enforceability of any of the Licensed Patent Rights, unless, prior to the expiration of such [\*\*\*], BeiGene or its Affiliates withdraws such challenge or contest; provided, however, that Leap shall not be entitled to terminate this Agreement if BeiGene or its Affiliates so challenges the Licensed Patent Rights in connection with defense, cross-claim or counterclaim to an action brought by Leap or its Affiliates with respect to a product other than a Licensed Product; and further provided that Leap shall not be entitled to terminate this Agreement if the challenge was initiated by an Affiliate of BeiGene prior to such Affiliate being an Affiliate of BeiGene (e.g., through an acquisition or other change of control).<sup>112</sup>

(d) **Termination for Insolvency.** Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [\*\*\*] of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.<sup>113</sup>

(e) **Full Force and Effect During Notice Period.** This Agreement shall remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if any milestone event is achieved under Section 9.2 or 9.3 or royalty payments become payable under Section 9.5 during the termination notice period, the corresponding milestone payment or royalty payment, as applicable, is accrued and BeiGene shall remain responsible for the payment of such milestone payment or royalty payment, as applicable, even if the due date of such milestone payment or royalty payment, as applicable, may come after the effective date of the termination.

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<sup>110</sup> Competitive Information – Commercially Sensitive Terms.

<sup>111</sup> Competitive Information – Commercially Sensitive Terms.

<sup>112</sup> Competitive Information – Commercially Sensitive Terms.

<sup>113</sup> Competitive Information – Commercially Sensitive Terms.

**15.3 Effect of Termination.** Except as provided in Section 15.4, if this Agreement is terminated the following shall apply:

(a) **License Grant to BeiGene.** The License and all other rights granted by Leap to BeiGene under the Licensed IP pursuant to this Agreement shall terminate.

(b) **License Grants to Leap.** The licenses granted by BeiGene to Leap pursuant to Section 2.4 shall continue following the effective date of termination and, except as otherwise provided in this Section 15.3, all other rights and licenses granted by BeiGene to Leap pursuant to this Agreement shall terminate.

(c) **Sublicenses.** If the License granted to BeiGene terminates as a result of a termination of this Agreement with respect to one or more Licensed Products or in its entirety, the terms of this Section 15.3(c) will apply with respect to any sublicense agreement existing as of the effective date of such termination, but only if the applicable sublicensee did not contribute to any material breach of this Agreement that was the cause of the termination by Leap of this Agreement and is not otherwise in material breach of the applicable sublicense agreement at such time: (i) all of such sublicensee's obligations under the applicable sublicense agreement to BeiGene will remain in effect as obligations to Leap and will be enforceable solely by Leap as a third party beneficiary, and, in the case of any sublicensee that is not a party to a sublicense agreement with BeiGene, all of such sublicensee's obligations under the applicable sublicense agreement with the applicable sublicensor of such sublicensee shall remain in full force and effect in accordance with their respective terms; (ii) such sublicensee's rights under the sublicense agreement that do not exceed and are consistent with Leap's obligations to BeiGene under this Agreement, whether in scope, duration, nature or otherwise, will survive termination; provided, that, the foregoing will in no way be interpreted to increase the scope, duration, territory or other aspect of the rights sublicensed to such sublicensee; and (iii) all of BeiGene's rights under such sublicense agreement will remain in effect, may be exercised solely by Leap and will inure to the exclusive benefit of Leap.

(d) **Negotiation of License.** [\*\*\*].<sup>114</sup>

(e) **Regulatory Submissions.** Upon Leap's written request to the extent delivered on or before the effective date of termination or within [\*\*\*] thereafter, BeiGene shall provide Leap with copies of all Regulatory Submissions for Licensed Products in the Territory. To the extent permissible under Applicable Law and commercially feasible, BeiGene shall assign to Leap or shall provide Leap with a right of reference with respect to such Regulatory Submissions, as Leap determines at its reasonable discretion, [\*\*\*]. In addition, upon Leap's written request, BeiGene shall, [\*\*\*], provide to Leap copies of all material related documentation, including material non-clinical, preclinical and clinical data that are held by or reasonably available to BeiGene, its Affiliates or sublicensees. The Parties shall discuss and establish appropriate arrangements with respect to safety data exchange, provided that Leap will assume all safety and safety database activities no later than [\*\*\*] after termination.<sup>115</sup>

(f) **Trademarks.** BeiGene shall transfer and assign, and shall ensure that its Affiliates transfer and assign, to Leap, at no cost to Leap, all Product Marks relating to any Licensed Product and any applications therefor (excluding any such marks that include, in whole or part, any corporate name or logos of BeiGene or its Affiliates or sublicensees). Leap and its Affiliates and licensees shall have the right to use other identifiers specific to any Licensed Product (e.g., BeiGene compound identifiers). BeiGene shall also transfer to Leap any in-process applications for generic names for any Licensed Product.

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<sup>114</sup> Competitive Information – Commercially Sensitive Terms.

<sup>115</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

(g) **Inventory.** At Leap's election and request, BeiGene shall transfer to Leap or its designee some or all inventory of Licensed Products (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or control of BeiGene, its Affiliates or sublicensees; provided that, Leap will pay BeiGene a price [\*\*\*] for such transferred Licensed Products (if manufactured by Leap) or at BeiGene's Manufacturing Cost (if manufactured by BeiGene).<sup>116</sup>

(h) **Wind Down and Transition.** BeiGene shall be responsible, [\*\*\*], for the wind-down of BeiGene's and its Affiliates' and, subject to Section 15.3(c), its sublicensees Development, manufacture and Commercialization activities for Licensed Products. BeiGene shall, and shall cause its Affiliates and, subject to Section 15.3(b), its sublicensees to, reasonably cooperate with Leap to facilitate orderly transition of the Development, manufacture and Commercialization of Licensed Products to Leap or its designee, including (i) [\*\*\*] or, to the extent any such [\*\*\*]; and (ii) [\*\*\*] (i), [\*\*\*].<sup>117</sup>

(i) **Ongoing Clinical Trial.** If, at the time of such termination, BeiGene or its Affiliates are conducting any Clinical Trials, then, at Leap's election on a Clinical Trial-by-Clinical Trial basis to the extent delivered on or before the effective date of termination or within the [\*\*\*] period immediately thereafter: (i) [\*\*\*]; and (ii) [\*\*\*] under clause (i) above.<sup>118</sup>

(j) **Return of Confidential Information.** At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to any Licensed Product that are in the Receiving Party's or its Affiliates' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); provided, that, the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

#### 15.4 Termination by BeiGene for Breach.

(a) Notwithstanding anything to the contrary in this Article 15, if BeiGene has the right to terminate this Agreement pursuant to Section 15.2(b) then, at BeiGene's option (which may be exercised by BeiGene by written notice to Leap within [\*\*\*] of the date of delivery by BeiGene of the notice of termination), (i) BeiGene may elect [\*\*\*], in which case the rights and obligations of the Parties under this Agreement shall [\*\*\*], including the License granted by Leap to BeiGene pursuant to Section 2.2, and BeiGene shall have the right to off-set any actual damages that BeiGene suffered as a direct result of the uncured material breach by Leap described in the Breach Notification against the right of Leap to receive the milestone and royalty payments pursuant to Article 9; provided that Leap's rights and BeiGene's obligations under Sections 3.2 and 8.3 [\*\*\*]; or (ii) BeiGene may elect to [\*\*\*], in which case (A) Leap will be responsible for the [\*\*\*]; (B) the licenses granted by BeiGene to Leap pursuant to Section 2.4 shall terminate, and (C) the provisions of Section 15.3(d) shall terminate. In the case of Subsection (a)(ii) above, BeiGene will invoice Leap [\*\*\*] for the [\*\*\*] incurred by or on behalf of BeiGene in such [\*\*\*], and Leap will pay the invoiced amounts within [\*\*\*] after the date of any such invoice.<sup>119</sup>

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<sup>116</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

<sup>117</sup> Competitive Information – Commercially Sensitive Terms.

<sup>118</sup> Competitive Information – Financial Provisions and Commercially Sensitive Terms.

**15.5 Survival.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Article 1 (as applicable), Article 10, Article 11, Article 13, Article 14 and Article 16 (as applicable), and Sections 2.6, 5.9 (with respect to Leap's use rights), 5.10 (with respect to responsibility for subcontractors), 6.3 (with respect to Leap's right of reference thereunder), 9.10, 12.6, 15.1, 15.3, 15.4, 15.5 and 15.6 shall survive the expiration or termination of this Agreement.

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

## **ARTICLE 16 MISCELLANEOUS**

**16.1 Assignment.** Except as provided in this Section 16.1, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; provided, however, that (and notwithstanding anything elsewhere in this Agreement to the contrary) either Party may, without the written consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party and (a) BeiGene may, without the written consent of Leap, assign this Agreement and its rights and obligations hereunder (or under a transaction under which this Agreement is assumed) in connection with the transfer or sale of all or substantially all of its assets or business, or in the event of its merger or consolidation or similar transaction; and (b) Leap may, without the written consent of BeiGene, assign this Agreement and its rights and obligations hereunder (or under a transaction under which this Agreement is assumed) in connection with the transfer or sale of all or substantially all of its assets or business related to the subject matter of this Agreement, or in the event of its merger or consolidation or similar transaction. Any attempted assignment not in accordance with this Section 16.1 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Any permitted assignment of this Agreement shall not operate to release the assigning Party from any of its obligations under this Agreement unless the Parties otherwise agree in writing.

**16.2 Extension to Affiliates.** Except as expressly set forth otherwise in this Agreement, each Party shall have the right to extend the rights and obligations granted in this Agreement to one or more of its Affiliates by providing written notice to the other Party. All applicable terms and provisions of this Agreement, except this right to extend, shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and obligations. The Party extending the rights and obligations granted hereunder shall remain primarily liable for any acts or omissions of its Affiliates.

**16.3 Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Laws, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

**16.4 Governing Law; English Language.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

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<sup>119</sup> Competitive Information – Commercially Sensitive Terms.

## 16.5 Dispute Resolution.

(a) If any dispute, claim or controversy of any nature arising out of or relating to this Agreement, including any action or claim based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement (each, a “**Dispute**”), arises between the Parties and the Parties cannot resolve such Dispute through good faith discussions, within [\*\*\*] of a written request by either Party to the other Party (“**Notice of Dispute**”), either Party may refer the Dispute to senior representatives of each Party for resolution. Each Party, within [\*\*\*] after a Party has received such written request from the other Party to so refer such Dispute, shall notify the other Party in writing of the senior representative to whom such dispute is referred. If, after an additional [\*\*\*] after the Notice of Dispute, such representatives have not succeeded in negotiating a resolution of the Dispute, and a Party wishes to pursue the matter, each such Dispute, controversy or claim that is not an “Excluded Claim” (defined below) shall be finally resolved by binding arbitration administered by the International Chamber of Commerce (“**ICC**”) (or any successor entity thereto) pursuant to its arbitration rules and procedures then in effect (the “**Rules**”), as modified in this Section 16.5.<sup>120</sup>

(b) The arbitration shall be conducted by a tribunal of arbitrators experienced in the business of pharmaceuticals (including biologicals). The tribunal shall be comprised of three (3) arbitrators, one of whom shall be nominated by each Party and a third of whom, who shall serve as the presiding arbitrator, shall be nominated by mutual agreement of the two party-nominated arbitrators. If the two party-nominated arbitrators do not nominate the third arbitrator within [\*\*\*] of the second arbitrator’s appointment, then the third arbitrator shall be appointed by the ICC Court. If the issues in dispute involve scientific, technical or commercial matters, the arbitrators chosen hereunder shall engage experts that have educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. Within [\*\*\*] after initiation of arbitration, the Parties shall select the arbitrators. The place of arbitration shall be New York City, New York, and all proceedings and communications shall be in English.<sup>121</sup>

(c) Prior to the arbitrators being selected, either Party, without waiving any remedy under this Agreement, may seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party until final resolution of the issue by the arbitrator or other resolution of the controversy between the Parties. Once the arbitrators have been selected, either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved, and either Party may apply to a court of competent jurisdiction to enforce interim injunctive relief granted by the arbitrators. Any final award by the arbitrators may be entered by either Party in any court having appropriate jurisdiction for a judicial recognition of the decision and applicable orders of enforcement. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration, unless the arbitrators agree otherwise.

(d) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrators may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

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<sup>120</sup> Competitive Information – Commercially Sensitive Terms.

<sup>121</sup> Competitive Information – Commercially Sensitive Terms.

(e) As used in this Section 16.5, the term “**Excluded Claim**” means any dispute, controversy or claim that concerns (a) the validity, enforceability or infringement of any patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. Any Excluded Claim may be submitted by either Party to any court of competent jurisdiction over such Excluded Claim.

**16.6 Force Majeure.** Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder (excluding, in each case, the obligation to make payments when due) if such delay or nonperformance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, act of God or of the government of any country or of any local government, or by any other cause unavoidable or beyond the control of any Party hereto. In such event, the Party affected will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto. If any such failure or delay in a Party’s performance hereunder continues for more than [\*\*\*], the other Party may terminate this Agreement upon written notice to the delayed Party.<sup>122</sup>

**16.7 Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

**16.8 Relationship of the Parties.** Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Leap and BeiGene, or to constitute one as the agent of the other. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

**16.9 Notices.** All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file), and sent as an attachment to an e-mail message, where, when such message is received, a read receipt e-mail is received by the sender (and such read receipt e-mail is preserved by the Party sending the notice), provided further that a copy is promptly sent by an internationally recognized overnight delivery service (receipt requested)(although the sending of the e-mail message shall be when the notice is deemed to have been given), or (b) the earlier of when received by the addressee or five (5) days after it was sent, if sent by registered letter or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):

If to Leap:Leap Therapeutics, Inc.

47 Thorndike Street, Suite B1-1  
Cambridge, MA 02141 USA  
Attention: [\*\*\*]<sup>123</sup>  
Tel: [\*\*\*]<sup>124</sup>

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<sup>122</sup> Competitive Information – Commercially Sensitive Terms.

<sup>123</sup> Personal Information – Contact Information.

<sup>124</sup> Personal Information – Contact Information.

E-mail address: [\*\*\*]<sup>125</sup>

With a copy to:

[\*\*\*]<sup>126</sup>

Morgan Lewis & Bockius L.L.P.

One Federal Street

Boston, MA 02110

If to BeiGene:

BeiGene, Ltd.

c/o Mourant Ozannes Corporate Services (Cayman) Limited

94 Solaris Avenue

Camana Bay

PO Box 1348

Grand Cayman, KY1-1108,

Cayman Islands

Attention: [\*\*\*]<sup>127</sup>

Fax: [\*\*\*]<sup>128</sup>

E-mail address: []

With copies to:

BeiGene, Ltd.

55 Cambridge Parkway, Suite 700W

Cambridge, MA 02142

Attn: [\*\*\*]<sup>129</sup>

Tel: [\*\*\*]<sup>130</sup>

E-mail address: [\*\*\*]<sup>131</sup>

**16.10 Further Assurances.** BeiGene and Leap hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all documents and take any action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

**16.11 Compliance with Law.** Each Party shall perform its obligations under this Agreement in accordance with all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Laws.

**16.12 No Third Party Beneficiary Rights.** This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except as otherwise expressly provided for in this Agreement.

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<sup>125</sup> Personal Information – Contact Information.

<sup>126</sup> Personal Information – Contact Information.

<sup>127</sup> Personal Information – Contact Information.

<sup>128</sup> Personal Information – Contact Information.

<sup>129</sup> Personal Information – Contact Information.

<sup>130</sup> Personal Information – Contact Information.

<sup>131</sup> Personal Information – Contact Information.

**16.13 Entire Agreement.** This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter. The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information disclosed pursuant to the Confidentiality Agreement by a Party or its Affiliates shall be included in the Confidential Information subject to this Agreement and the Confidentiality Agreement is hereby superseded in its entirety; provided, that the foregoing shall not relieve any Person of any right or obligation accruing under the Confidentiality Agreement prior to the Effective Date. “**Confidentiality Agreement**” means the Mutual Confidentiality Agreement between Leap and BeiGene dated [\*\*\*].<sup>132</sup>

**16.14 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**16.15 Expenses.** Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

**16.16 Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

**16.17 Construction.** The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

**16.18 Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

**16.19 Export.** Each Party acknowledges that the laws and regulations of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without appropriate United States and foreign government licenses.

**16.20 Notification and Approval.** In the event that this Agreement or the transaction(s) set forth herein are subject to notification or regulatory approval in one or more countries, then development and commercialization in such country(ies) will be subject to such notification or regulatory approval. The Parties will reasonably cooperate with each other with respect to such notification and the process required thereunder, including in the preparation of any filing. BeiGene will be responsible for any and all costs, expenses, and filing fees associated with any such filing.

*[Remainder of page left blank intentionally.]*

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<sup>132</sup> Competitive Information – Commercially Sensitive Terms.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

**LEAP THERAPEUTICS, INC.**

By: /s/ Christopher Mirabelli

\_\_\_\_\_  
Name: Christopher Mirabelli, Ph.D.

Title: President and Chief Executive Officer

**BEIGENE, LTD.**

By: /s/ Scott A. Samuels

\_\_\_\_\_  
Name: Scott A. Samuels, Esq.

Title: Senior Vice President, General Counsel

**List of Exhibits**

<b>Exhibit A:</b>	<b>Initial Development Plan</b>
<b>Exhibit B:</b>	<b>Global Development Plan</b>
<b>Schedule 12.2(a)</b>	<b>Licensed Patent Rights</b>

**EXHIBIT A  
INITIAL DEVELOPMENT PLAN**

[\*\*\*]<sup>133</sup>

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<sup>133</sup> Competitive Information – Discovery Information and Technical Information.

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**EXHIBIT B**  
**GLOBAL DEVELOPMENT PLAN**

[\*\*\*]<sup>134</sup>

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<sup>134</sup> Competitive Information – Discovery Information and Technical Information.

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**SCHEDULE 12.2(A)**

**LICENSED PATENT RIGHTS**

[\*\*\*]<sup>135</sup>

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<sup>135</sup> Competitive Information – Technical Information and Exclusivity Information.

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
AND CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Douglas E. Onsi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Leap Therapeutics, Inc.;
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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 14, 2020

Date

/s/ DOUGLAS E. ONSI

Douglas E. Onsi

President, Chief Executive Officer and Chief Financial Officer  
(Principal Executive Officer and Principal Financial Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Leap Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Douglas E. Onsi, as Chief Executive Officer, President and Chief Financial Officer, hereby 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, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2020

By: /s/ DOUGLAS E. ONSI

Douglas E. Onsi  
President, Chief Executive Officer and Chief Financial Officer

(Principal Executive Officer and Principal Financial Officer)

This certification accompanies the 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 Leap Therapeutics, Inc. 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 the Quarterly Report), irrespective of any general incorporation language contained in such filing.

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