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, 2021
OR

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

For the transition period from to
Commission File Number: 001-37686

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands	**98-1209416**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
c/o Mourant Governance Services (Cayman) Limited **94 Solaris Avenue, Camana Bay** **Grand Cayman** **Cayman Islands**	**KY1-1108**
(Address of principal executive offices)	(Zip Code)

+1 (345) 949-4123
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

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

As of April 30, 2021, 1,197,609,020 ordinary shares, par value $0.0001 per share, were outstanding, of which 973,810,305 ordinary shares were held in the form of 74,908,485 American Depositary Shares, each representing 13 ordinary shares.

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 ☒

BeiGene, Ltd.

Quarterly Report on Form 10-Q

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Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our American Depositary Shares ("ADSs") or ordinary shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, are summarized in "Part II – Item 1A – Risk Factors" and should be carefully considered, together with other information in this Form 10-Q and our other filings with the Securities and Exchange Commission ("SEC"), before making an investment decision regarding our ADSs or ordinary shares.

- Our medicines may fail to achieve and maintain the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.
- We have limited experience in launching and marketing our internally developed and in-licensed medicines. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our medicines, we may not be able to generate substantial product sales revenue.
- We face substantial competition, which may result in others discovering, developing, or commercializing competing medicines before or more successfully than we do.
- The market opportunities for our medicines may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- If we are not able to continue to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our medicines and drug candidates, and our ability to generate revenue will be materially impaired.
- We have limited manufacturing capability and must rely on third-party manufacturers to manufacture some of our commercial products and clinical supplies, and if they fail to meet their obligations, the development and commercialization of our medicines and drug candidates could be adversely affected.
- If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate level of reimbursement, our commercial success and business operations could be adversely affected.
- We depend substantially on the success of the clinical development of our medicines and drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals and commercialize our medicines and drug candidates, or experience significant delays in doing so, our business will be materially harmed.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, and we may face difficulties in complying with or be unable to comply with such regulations, which could have a material adverse effect on our business.
- The approval processes of regulatory authorities in the United States, China, Europe and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.
- Our medicines and any future approved drug candidates will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our medicines and drug candidates.
- Even if we are able to commercialize our medicines and any approved drug candidates, the medicines may become subject to unfavorable pricing regulations or third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

- We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may not become profitable.
- We have limited experience in obtaining regulatory approvals and commercializing pharmaceutical products, which may make it difficult to evaluate our current business and predict our future performance.
- We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development of our drug candidates or achieve profitability.
- If we are unable to obtain and maintain patent protection for our medicines and drug candidates through intellectual property rights, or if the scope of such intellectual property rights is not sufficiently broad, third parties may compete against us.
- If we fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.
- We rely on third parties to manufacture some of our commercial and clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.
- If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.
- We have entered into licensing and collaboration arrangements and may enter into additional collaborations, licensing arrangements, or strategic alliances in the future, and we may not realize the benefits of such arrangements.
- If we are not able to successfully develop and/or commercialize Amgen’s oncology products, the expected benefits of the collaboration will not materialize.
- We have significantly increased and expect to continue to increase our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our business is subject to complex and evolving industry-specific laws and regulations regarding the collection and transfer of personal data. These laws and regulations can be complex and stringent, and many are subject to change and uncertain interpretation, which could result in claims, changes to our data and other business practices, significant penalties, increased cost of operations, or otherwise adversely impact our business.
- We manufacture some of our medicines and intend to manufacture some of our drug candidates, if approved. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.
- Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments may materially and adversely affect our business, financial condition, and results of operations and may result in our inability to sustain our growth and expansion strategies.
- The audit report included in our Annual Report on Form 10-K filed with the SEC is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, and as such, investors are deprived of the benefits of such inspection.
- The trading prices of our ordinary shares and/or ADSs can be volatile, which could result in substantial losses to you.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BEIGENE, LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

	Note	As of March 31, 2021 $ (unaudited)	As of December 31, 2020 $ (audited)
Assets			
Current assets:			
Cash and cash equivalents		1,901,819	1,381,950
Short-term restricted cash	4	305	307
Short-term investments	4	2,910,472	3,268,725
Accounts receivable, net	10	84,010	60,403
Inventories	5	72,974	89,293
Prepaid expenses and other current assets	10	171,399	160,012
Total current assets		5,140,979	4,960,690
Long-term restricted cash	4	8,282	7,748
Property, plant and equipment, net	6	373,949	357,686
Operating lease right-of-use assets		86,946	90,581
Intangible assets, net	8	4,813	5,000
Deferred tax assets	9	78,215	65,962
Other non-current assets	10	127,820	113,090
Total non-current assets		680,025	640,067
Total assets		5,821,004	5,600,757
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		146,923	231,957
Accrued expenses and other payables	10	312,134	346,144
Deferred revenue, current portion	3	71,651	—
Tax payable	9	27,463	20,380
Operating lease liabilities, current portion		13,993	13,895
Research and development cost share liability, current portion	3	135,333	127,808
Short-term debt	11	405,045	335,015
Total current liabilities		1,112,542	1,075,199
Non-current liabilities:			
Long-term bank loans	11	193,017	183,637
Deferred revenue, non-current portion	3	78,594	—
Operating lease liabilities, non-current portion		26,565	29,417
Deferred tax liabilities	9	10,794	10,792
Research and development cost share liability, non-current portion	3	340,585	375,040
Other long-term liabilities	10	55,320	57,429
Total non-current liabilities		704,875	656,315
Total liabilities		1,817,417	1,731,514
Commitments and contingencies	18		
Equity:			
Ordinary shares, US$0.0001 par value per share; 9,500,000,000 shares authorized; 1,197,322,617 and 1,190,821,941 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively		119	118
Additional paid-in capital		7,486,518	7,414,932
Accumulated other comprehensive income	15	3,204	6,942
Accumulated deficit		(3,486,254)	(3,552,749)
Total equity		4,003,587	3,869,243
Total liabilities and equity		5,821,004	5,600,757

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

BEIGENE, LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)
(Unaudited)

	Note	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
		$	$
Revenues			
Product revenue, net	12	106,117	52,059
Collaboration revenue	3	499,755	—
Total revenues		605,872	52,059
Expenses			
Cost of sales - product		32,685	14,149
Research and development		320,726	304,302
Selling, general and administrative		182,106	107,081
Amortization of intangible assets		188	283
Total expenses		535,705	425,815
Income (loss) from operations		70,167	(373,756)
Interest (expense) income, net		(4,179)	6,690
Other (expense) income, net		(4,123)	3,681
Income (loss) before income taxes		61,865	(363,385)
Income tax (benefit) expense	9	(4,630)	1,554
Net income (loss)		66,495	(364,939)
Less: net loss attributable to noncontrolling interests		—	(1,204)
Net income (loss) attributable to BeiGene, Ltd.		66,495	(363,735)
Earnings (loss) per share attributable to BeiGene, Ltd.			
Basic	13	0.06	(0.36)
Diluted	13	0.05	(0.36)
Weighted-average shares outstanding—basic		1,188,943,726	1,005,347,581
Weighted-average shares outstanding—diluted	13	1,257,489,671	1,005,347,581
Earnings (loss) per American Depositary Share ("ADS")			
Basic		0.73	(4.70)
Diluted		0.69	(4.70)
Weighted-average ADSs outstanding—basic		91,457,210	77,334,429
Weighted-average ADSs outstanding—diluted		96,729,975	77,334,429

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

BEIGENE, LTD.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
	$	$
Net income (loss)	66,495	(364,939)
Other comprehensive (loss) income, net of tax of nil:		
Foreign currency translation adjustments	(3,762)	(4,349)
Pension liability adjustments	497	—
Unrealized holding (loss) gain, net	(473)	5,698
Comprehensive income (loss)	62,757	(363,590)
Less: comprehensive loss attributable to noncontrolling interests	—	(1,308)
Comprehensive income (loss) attributable to BeiGene, Ltd.	62,757	(362,282)

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

BEIGENE, LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)
(Unaudited)

	Note	Three months ended March 31, 2021	Three months ended March 31, 2020
		$	$
Operating activities:			
Net income (loss)		66,495	(364,939)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization expense		9,632	7,750
Share-based compensation expenses	14	45,833	38,255
Unrealized gains on equity method investments	4	3,327	(6,964)
Acquired in-process research and development		8,500	43,000
Amortization of research and development cost share liability	3	(26,930)	(27,634)
Deferred income tax benefits		(12,251)	(206)
Other items, net		5,263	3,489
Changes in operating assets and liabilities:			
Accounts receivable		(23,656)	3,236
Inventories		16,319	(222)
Prepaid expenses and other current assets		(11,453)	(36,075)
Other non-current assets		(6,495)	(2,710)
Accounts payable		(73,178)	(21,450)
Accrued expenses and other payables		(34,010)	15,775
Tax payable		7,149	6,080
Deferred revenue		150,245	—
Operating lease liabilities		1,215	1,927
Other long-term liabilities		(910)	(1,256)
Net cash provided by (used in) operating activities		125,095	(341,944)
Investing activities:			
Purchases of property, plant and equipment		(42,389)	(21,533)
Purchases of investments		(764,163)	(1,307,179)
Proceeds from sale or maturity of investments		1,107,000	256,743
Purchase of in-process research and development		(8,500)	(43,000)
Net cash provided by (used in) investing activities		291,948	(1,114,969)
Financing activities:			
Proceeds from sale of ordinary shares, net of cost	16	—	2,162,407
Proceeds from research and development cost share liability		—	616,834
Proceeds from long-term loan	11	10,664	—
Proceeds from short-term loans	11	71,001	11,298
Proceeds from option exercises and employee share purchase plan		25,754	11,629
Net cash provided by financing activities		107,419	2,802,168
Effect of foreign exchange rate changes, net		(4,061)	(6,212)
Net increase in cash, cash equivalents, and restricted cash		520,401	1,339,043
Cash, cash equivalents, and restricted cash at beginning of period		1,390,005	620,775
Cash, cash equivalents, and restricted cash at end of period		1,910,406	1,959,818
Supplemental cash flow information:			
Cash and cash equivalents		1,901,819	1,957,101
Short-term restricted cash		305	282
Long-term restricted cash		8,282	2,435
Income taxes paid		478	531
Interest paid		6,927	1,136
Supplemental non-cash information:			
Acquisitions of equipment included in accounts payable		30,906	26,412

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

BEIGENE, LTD.

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

(Unaudited)

	Attributable to BeiGene, Ltd.							
	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total	Noncontrolling Interests	Total
	Shares	Amount						
		$	$	$	$	$	$	$
Balance at December 31, 2020	1,190,821,941	118	7,414,932	6,942	(3,552,749)	3,869,243	—	3,869,243
Use of shares reserved for share option exercises	(123,097)	—	—	—	—	—	—	—
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	6,623,773	1	25,753	—	—	25,754	—	25,754
Share-based compensation	—	—	45,833	—	—	45,833	—	45,833
Other comprehensive loss	—	—	—	(3,738)	—	(3,738)	—	(3,738)
Net income	—	—	—	—	66,495	66,495	—	66,495
Balance at March 31, 2021	1,197,322,617	119	7,486,518	3,204	(3,486,254)	4,003,587	—	4,003,587
Balance at December 31, 2019	801,340,698	79	2,925,970	(8,001)	(1,955,843)	962,205	16,150	978,355
Issuance of ordinary shares in connection with collaboration	206,635,013	21	2,162,386	—	—	2,162,407	—	2,162,407
Use of shares reserved for share option exercises	(3,705,468)	—	—	—	—	—	—	—
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	3,706,573	1	11,628	—	—	11,629	—	11,629
Share-based compensation	—	—	38,255	—	—	38,255	—	38,255
Other comprehensive income	—	—	—	1,453	—	1,453	(104)	1,349
Net loss	—	—	—	—	(363,735)	(363,735)	(1,204)	(364,939)
Balance at March 31, 2020	1,007,976,816	101	5,138,239	(6,548)	(2,319,578)	2,812,214	14,842	2,827,056

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

BEIGENE, LTD.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands of U.S. Dollar (“$”) and Renminbi (“RMB”), except for number of shares and per share data)

(Unaudited)

1. Description of Business, Basis of Presentation and Consolidation and Significant Accounting Policies

Description of business

BeiGene, Ltd. (the "Company", "BeiGene", "it", "its") is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and expand access for patients worldwide.

The Company has delivered ten molecules into the clinic in its first ten years, including its two lead commercial medicines, BRUKINSA®, a small molecule inhibitor of Bruton’s Tyrosine Kinase (“BTK”) for the treatment of various blood cancers, and tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers. The Company is marketing BRUKINSA® in the world’s two largest pharmaceutical markets, the United States and the People's Republic of China ("China" or the "PRC"), and tislelizumab in China, with an established, science-based commercial organization. The Company has built state-of-the-art biologic and small molecule manufacturing facilities in China to support the potential future demand of its medicines, and it also works with high quality contract manufacturing organizations (“CMOs”) to manufacture its internally developed clinical and commercial products.

The Company is a leader in China-inclusive global clinical development, which it believes can facilitate faster and more cost-effective development of innovative medicines. Its internal clinical development capabilities are deep, including a more than 1,600-person global clinical development team that is running more than 100 ongoing or planned clinical trials. This includes more than 25 pivotal or registration-enabling trials for three drug candidates that have enrolled more than 12,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of March 2021. The Company has over 45 medicines and drug candidates in commercial stage or clinical development, including 7 approved medicines, 5 pending approval, and over 30 in clinical development.

Supported by its development and commercial capabilities, the Company has entered into collaborations with world-leading biopharmaceutical companies such as Amgen and Novartis to develop and commercialize innovative medicines globally. Since its inception in 2010 in Beijing, the Company has become a fully integrated global organization of approximately 6,000 employees in 16 countries and regions, including China, the United States, Europe and Australia.

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of March 31, 2021, the condensed consolidated statements of operations and comprehensive income/(loss) for the three months ended March 31, 2021 and 2020, the condensed consolidated statements of cash flows for the three months ended March 31, 2021 and 2020, and the condensed consolidated statements of shareholders' equity for the three months ended March 31, 2021 and 2020, and the related footnote disclosures are unaudited. The accompanying unaudited interim condensed financial statements were prepared in accordance with U.S. generally accepted accounting principles (“GAAP”), including guidance with respect to interim financial information and in conformity with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for annual financial statements. These financial statements should be read in conjunction with the consolidated financial statements and related footnotes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 (the "Annual Report").

The unaudited interim condensed consolidated interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all normal recurring adjustments, necessary to present a fair statement of the results for the interim periods presented. Results of the operations for the three months ended March 31, 2021 are not necessarily indicative of the results expected for the full fiscal year or for any future annual or interim period.

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

Noncontrolling interests are recognized to reflect the portion of the equity of subsidiaries which are not attributable, directly or indirectly, to the controlling shareholders. For a portion of fiscal 2020, the Company consolidated its interests in its joint venture, BeiGene Biologics Co., Ltd. ("BeiGene Biologics") and MapKure, LLC ("MapKure"), under the voting model

and recognized the minority shareholder's equity interest as a noncontrolling interest in its condensed consolidated financial statements. In June 2020, the Company deconsolidated MapKure and recorded an equity method investment for its remaining ownership interest in the joint venture (see Note 4). In November 2020, the Company acquired the remaining equity interest in BeiGene Biologics. Subsequent to the share purchase, BeiGene Biologics is a wholly-owned subsidiary of the Company (see Note 7).

Use of estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating variable consideration in product sales and collaboration revenue arrangements, identifying separate accounting units and determining the standalone selling price of each performance obligation in the Company's revenue arrangements, estimating the fair value of net assets acquired in business combinations, assessing the impairment of long-lived assets, valuation and recognition of share-based compensation expenses, realizability of deferred tax assets, estimating uncertain tax positions, valuation of inventory, estimating the allowance for credit losses, determining defined benefit pension plan obligations, measurement of right-of-use assets and lease liabilities and the fair value of financial instruments. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

Recent accounting pronouncements

New accounting standards which have been adopted

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

Significant accounting policies

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

There have been no material changes to the Company's significant accounting policies as of and for the three months ended March 31, 2021, as compared to the significant accounting policies described in the Annual Report.

2. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value. Fair value is determined based upon the exit price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as determined by either the principal market or the most advantageous market. Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy, as follows:

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

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in market with insufficient volume or infrequent transactions (less active markets); or model-derived valuations in which all significant inputs are observable or can be derived principally from or corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the asset or liability.

The Company considers an active market to be one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis, and considers an inactive market to be one in which

there are infrequent or few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers.

The following tables present the Company's financial assets and liabilities measured and recorded at fair value on a recurring basis using the above input categories as of March 31, 2021 and December 31, 2020:

As of March 31, 2021	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Cash equivalents			
U.S. treasury securities	652,519	—	—
Money market funds	268,697	—	—
Short-term investment (Note 4):			
U.S. Treasury securities	2,910,472	—	—
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	9,129	5,299	—
Total	3,840,817	5,299	—

As of December 31, 2020	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Cash equivalents			
U.S. treasury securities	286,072	—	—
Money market funds	80,838	—	—
Short-term investment (Note 4):			
U.S. Treasury securities	3,268,725	—	—
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	10,810	6,669	—
Total	3,646,445	6,669	—

The Company's cash equivalents are highly liquid investments with original maturities of 3 months or less. Short-term investments represent the Company's investments in available-for-sale debt securities. The Company determines the fair value of cash equivalents and available-for-sale debt securities using a market approach based on quoted prices in active markets.

The Company's equity securities carried at fair value consist of holdings in common stock and warrants to purchase additional shares of common stock of Leap Therapeutics, Inc. ("Leap"), which were acquired in connection with a collaboration and license agreement entered into in January 2020. The common stock investment in Leap, a publicly-traded biotechnology company, is measured and carried at fair value and classified as Level 1. The warrants to purchase additional shares of common stock in Leap are classified as a Level 2 investment and are measured using the Black-Scholes option-pricing valuation model, which utilizes a constant maturity risk-free rate and reflects the term of the warrants, dividend yield and stock price volatility, that is based on the historical volatility of similar companies. Refer to Note 4, Restricted Cash and Investments for details of the determination of the carrying amount of private equity investments without readily determinable fair values and equity method investments.

As of March 31, 2021 or December 31, 2020, the fair values of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and short-term debt approximated their carrying values due to their short-term nature. Long-term

bank loans approximate their fair value due to the fact that the related interest rates approximate the rates currently offered by financial institutions for similar debt instrument of comparable maturities.

3. Collaborative Arrangements

The Company enters into collaborative arrangements for the research and development, manufacture and/or commercialization of medicines and drug candidates. To date, these collaborative arrangements have included out-licenses of internally developed products and drug candidates to other parties, in-licenses of products and drug candidates from other parties, and profit- and cost-sharing arrangements. These arrangements may include non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost-sharing and reimbursement arrangements, royalty payments, and profit sharing.

Out-Licensing Arrangements

For the three months ended March 31, 2021, the Company's collaboration revenue consisted entirely of revenue recognized under its out-licensing collaborative agreement with Novartis Pharma AG ("Novartis"). There was no collaboration revenue recognized for the three months ended March 31, 2020.

The following table summarizes total collaboration revenue recognized for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
Revenue from Collaborators	$	$
License revenue	484,646	—
Research and development service revenue	15,109	—
Total	499,755	—

Novartis

In January 2021, the Company entered into a collaboration and license agreement with Novartis, granting Novartis rights to develop, manufacture and commercialize tislelizumab in North America, Europe, and Japan (the "Novartis Territory"). The Company and Novartis have agreed to jointly develop tislelizumab in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and the Company has an option to co-detail the product in North America, funded in part by Novartis.

Under the agreement the Company received an upfront cash payment of $650,000 from Novartis. The Company is eligible to receive up to $1,300,000 upon the achievement of regulatory milestones, $250,000 upon the achievement of sales milestones, and royalties on future sales of tislelizumab in the licensed territory. Under the terms of the agreement, the Company is responsible for funding ongoing clinical trials of tislelizumab, Novartis has agreed to fund new registrational, bridging, or post-marketing studies in its territory, and each party will be responsible for funding clinical trials evaluating tislelizumab in combination with its own or third party products. Each party retains the worldwide right to commercialize its propriety products in combination with tislelizumab.

The Company evaluated the Novartis agreement under ASC 606 as all the material units of account within the agreement represented transactions with a customer. The Company identified the following material components under the agreement: (1) exclusive license for Novartis to develop, manufacture, and commercialize tislelizumab in the Novartis Territory, transfer of know-how and use of the tislelizumab trademark; (2) conducting and completing ongoing trials of tislelizumab ("R&D services"); and (3) supplying Novartis with required quantities of the tislelizumab drug product, or drug substance, upon receipt of an order from Novartis.

The Company determined that the license, transfer of know-how and use of trademarks are not distinct from each other and represent a single performance obligation. The R&D services represent a material promise and were determined to be a separate performance obligation at the outset of the agreement as the promise is distinct and has standalone value to Novartis. The Company evaluated the supply component of the contract and noted the supply will not be provided at a significant incremental discount to Novartis. The Company concluded that, for the purpose of ASC 606, the provision related to providing clinical and commercial supply of tislelizumab in the Novartis Territory was an option but not a performance obligation of the Company at

the outset of the Novartis collaboration agreement. A performance obligation for the clinical and commercial supply will be established as quantities of drug product or drug substance are ordered by Novartis.

The Company determined that the transaction price as of the outset of the arrangement was the upfront payment of $650,000. The potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained due to uncertainty of achievement. The transaction price was allocated to the two identified performance obligations based on a relative fair value basis. The standalone selling price of the license, transfer of know-how and use of trademarks performance obligation was determined using the adjusted market assessment approach. Based on the valuation performed by the Company, the standalone selling price of the license, transfer of know-how and use of trademarks was valued at $1,231,000. The standalone selling price of the R&D services was valued at $420,000 using a cost plus margin valuation approach. Based on the relative standalone selling prices of the two performance obligations, $484,646 of the total transaction price was allocated to the license and $165,354 was allocated to the R&D services.

The Company satisfied the license performance obligation at a point in time when the license was delivered and the transfer of know-how completed which occurred during the three months ended March 31, 2021. As such, the Company recognized the entire amount of the transaction price allocated to the license as collaboration revenue during the three months ended March 31, 2021. The portion of the transaction price allocated to the R&D services was deferred and is being recognized as collaboration revenue as the R&D services are performed using a percentage-of-completion method. Estimated costs to complete are reassessed on a periodic basis and any updates to the revenue earned are recognized on a prospective basis. The Company recognized R&D service revenue of $15,109 during the three months ended March 31, 2021.

In-Licensing Arrangements - Commercial

Amgen

In October 2019, the Company entered into a global strategic oncology collaboration with Amgen (the "Amgen Collaboration Agreement") for the commercialization and development in China, excluding Hong Kong, Taiwan and Macao, of Amgen's XGEVA®, KYPROLIS®, and BLINCYTO®, and the joint global development of a portfolio of oncology assets in Amgen's pipeline, with BeiGene responsible for development and commercialization in China. The agreement became effective on January 2, 2020, following approval by the Company's shareholders and satisfaction of other closing conditions.

Under the agreement, the Company is responsible for the commercialization of XGEVA®, KYPROLIS® and BLINCYTO® in China for five or seven years. Amgen is responsible for manufacturing the products globally and will supply the products to the Company at an agreed upon price. The Company and Amgen will share equally in the China commercial profits and losses during the commercialization period. Following the commercialization period, the Company has the right to retain one product and is entitled to receive royalties on sales in China for an additional five years on the products not retained. XGEVA® was approved in China in 2019 for patients with giant cell tumor of the bone and in November 2020 for the prevention of skeletal-related events in cancer patients with bone metastases. In July 2020, the Company began commercializing XGEVA® in China. In December 2020, BLINCYTO® was approved in China for injection for the treatment of adult patients with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL). Additionally, a new drug application has been filed in China for KYPROLIS® as a treatment for patients with multiple myeloma.

Amgen and the Company are also jointly developing a portfolio of Amgen oncology pipeline assets under the collaboration. The Company is responsible for conducting clinical development activities in China and co-funding global development costs by contributing cash and development services up to a total cap of $1,250,000. Amgen is responsible for all development, regulatory and commercial activities outside of China. For each pipeline asset that is approved in China, the Company will receive commercial rights for seven years from approval. The Company has the right to retain approximately one out of every three approved pipeline assets, other than sotorasib (AMG 510), Amgen's investigational KRAS G12C inhibitor, for commercialization in China. The Company and Amgen will share equally in the China commercial profits and losses during the commercialization period. The Company is entitled to receive royalties from sales in China for pipeline assets returned to Amgen for five years after the seven-year commercialization period. The Company is also entitled to receive royalties from global sales of each product outside of China (with the exception of sotorasib).

The Amgen Collaboration Agreement is within the scope of ASC 808, as both parties are active participants and are exposed to the risks and rewards dependent on the commercial success of the activities performed under the agreement. The Company is the principal for product sales to customers in China during the commercialization period and recognizes 100% of net product revenue on these sales. Amounts due to Amgen for its portion of net product sales are recorded as cost of sales. Cost reimbursements due to or from Amgen under the profit share are recognized as incurred and recorded to cost of sales; selling, general and administrative expense; or research and development expense, based on the underlying nature of the related

activity subject to reimbursement. Costs incurred for the Company's portion of the global co-development funding are recorded to research and development expense as incurred.

In connection with the Amgen Collaboration Agreement, a Share Purchase Agreement ("SPA") was entered into by the parties in October 2019. On January 2, 2020, the closing date of the transaction, Amgen purchased 15,895,001 of the Company's ADSs for $174.85 per ADS, representing a 20.5% ownership stake in the Company. Per the SPA, the cash proceeds shall be used as necessary to fund the Company's development obligations under the Amgen Collaboration Agreement. Pursuant to the SPA, Amgen also received the right to designate one member of the Company's board of directors, and Anthony Hooper joined the Company's board of directors as the Amgen designee in January 2020.

In determining the fair value of the common stock at closing, the Company considered the closing price of the common stock on the closing date of the transaction and included a lack of marketability discount because the shares are subject to certain restrictions. The fair value of the shares on the closing date was determined to be $132.74 per ADS, or $2,109,902 in the aggregate. The Company determined that the premium paid by Amgen on the share purchase represents a cost share liability due to the Company's co-development obligations. The fair value of the cost share liability on the closing date was determined to be $601,857 based on the Company's discounted estimated future cash flows related to the pipeline assets. The total cash proceeds of $2,779,241 were allocated based on the relative fair value method, with $2,162,407 recorded to equity and $616,834 recorded as a research and development cost share liability. The cost share liability is being amortized proportionately as the Company contributes cash and development services to its total co-development funding cap.

Amounts recorded related to the Company's portion of the co-development funding on the pipeline assets for the three months ended March 31, 2021 and 2020 were as follows:

	Three Months Ended March 31,	
	2021	2020
	$	$
Research and development expense	27,643	28,366
Amortization of research and development cost share liability	26,930	27,634
Total amount due to Amgen for BeiGene's portion of the development funding	54,573	56,000

	As of March 31, 2021
Remaining portion of development funding cap	964,437

As of March 31, 2021 and December 31, 2020, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Research and development cost share liability, current portion	135,333	127,808
Research and development cost share liability, non-current portion	340,585	375,040
Total research and development cost share liability	475,918	502,848

The total reimbursement due under the commercial profit-sharing agreement for in-line product sales is classified in the income statement for the three months ended March 31, 2021 and 2020 as follows:

	Three Months Ended March 31,	
	2021	2020
	$	$
Cost of sales - product	710	—
Research and development	(259)	—
Selling, general and administrative	(6,699)	—
Total	(6,248)	—

4. Restricted Cash and Investments

Restricted Cash

The Company's restricted cash balance of $8,587 and $8,055 as of March 31, 2021 and December 31, 2020, respectively, primarily consists of RMB-denominated cash deposits held in designated bank accounts for collateral for letters of credit. The Company classifies restricted cash as current or non-current based on the term of the restriction.

Short-Term Investments

Short-term investments as of March 31, 2021 consisted of the following available-for-sale debt securities:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
	$	$	$	$
U.S. treasury securities	2,910,074	398	—	2,910,472
Total	2,910,074	398	—	2,910,472

Short-term investments as of December 31, 2020 consisted of the following available-for-sale debt securities:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Net Carrying Amount)
	$	$	$	$
U.S. treasury securities	3,267,875	850	—	3,268,725
Total	3,267,875	850	—	3,268,725

As of March 31, 2021, the Company's available-for-sale debt securities consisted entirely of short-term U.S. treasury securities, which were determined to have zero risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of March 31, 2021.

Equity Securities with Readily Determinable Fair Values

Leap

In January 2020, the Company purchased $5,000 of Series B mandatorily convertible, non-voting preferred stock of Leap in connection with a strategic collaboration and license agreement the Company entered into with Leap. The Series B shares were subsequently converted into shares of Leap common stock and warrants to purchase additional shares of common stock upon approval of Leap's shareholders in March 2020. As of March 31, 2021, the Company's ownership interest in the outstanding common stock of Leap was 8.1% based on information from Leap. Inclusive of the shares of common stock issuable upon the exercise of the currently exercisable warrants, the Company's interest is approximately 14.9% based on information from Leap. The Company measures the investment in the common stock and warrants at fair value, with changes in fair value recorded to other (expense) income, net. During the three months ended March 31, 2021 and 2020, the Company recorded an unrealized (loss)/gain of $(3,051) and $6,964, respectively, in the consolidated statements of operations. As of March 31, 2021 and December 31, 2020, the fair value of the common stock and warrants was as follows:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Fair value of Leap common stock	9,129	10,810
Fair value of Leap warrants	5,299	6,669

Private Equity Securities without Readily Determinable Fair Values

The Company invests in equity securities of certain companies whose securities are not publicly traded and fair value is not readily determinable and where the Company has concluded it does not have significant influence based on its ownership

percentage and other factors. These investments are recorded at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The Company held investments of $18,702 and $9,705 in equity securities without readily determinable fair values as of March 31, 2021 and December 31, 2020, respectively. There were no adjustments to the carrying values of these securities for the three months ended March 31, 2021.

Equity-Method Investments

MapKure

In June 2019, the Company announced the formation of MapKure, LLC ("MapKure"), an entity jointly owned by the Company and SpringWorks Therapeutics, Inc. ("SpringWorks"). The Company out-licensed to MapKure the Company's product candidate BGB-3245, an oral, selective small molecule inhibitor of monomer and dimer forms of activating B-RAF mutations including V600 BRAF mutations, non-V600 B-RAF mutations, and RAF fusions. The Company received 10,000,000 Series A preferred units of MapKure, or a 71.4% ownership interest in exchange for its contribution of the intellectual property. SpringWorks purchased 3,500,000 Series A preferred units, or a 25% ownership interest, and other investors purchased 250,000 Series A preferred units or 1.8% ownership each. Following the initial closing, the Company consolidated its interests in MapKure under the voting model due to its controlling financial interest.

In June 2020, MapKure held a second closing under the existing terms of the SPA in which it issued additional Series A preferred units to SpringWorks and the other investors that purchased units in the first closing (the "Second Closing"), and the Company's ownership interest decreased to 55.6%. As the requisite Series A voting requirements in MapKure's governing documents require 70% combined voting power for certain actions, the Company determined that it lost its controlling financial interest after the Second Closing. Therefore, the Company deconsolidated MapKure and recognized a gain of $11,307 for the excess of the fair value of its 55.6% ownership interest in MapKure and carrying amount of the prior non-controlling interest over the carrying amount of MapKure's net assets within other income during the year ended December 31, 2020.

Upon deconsolidation, the Company recorded an equity investment of $10,000, which represents the estimated fair value of its 55.6% ownership interest in MapKure. Effective June 8, 2020, the Company is accounting for the investment as an equity-method investment and records its portion of MapKure's earnings or losses within other (expense) income, net. The Company recognized losses of $236 for its portion of MapKure's net loss for the three months ended March 31, 2021. As of March 31, 2021 and December 31, 2020, the carrying amount of the Company's investment in MapKure was $9,273 and $9,509, respectively.

Guangzhou GET Phase I Biomedical Industry Investment Fund Partnership (Limited Partnership)

On July 23, 2020, BeiGene (Guangzhou) invested $11,782 (RMB80,000) in an existing investment fund, Guangzhou GET Phase I Biomedical Industry Investment Fund Partnership (Limited Partnership) (“GET Bio-fund”). The stated purpose of GET Bio-fund is to promote and upgrade the local industrial transformation in Guangzhou and it is committed to invest at least 60% of the total fund in the biotechnology, medical device, and medical information industries.

GET Bio-fund has four limited partners and one general partner, Guangzhou GET Biomedical Industry Investment Fund Management Co., Ltd. (“GET Bio-fund Management”). GET Bio-fund has an agreed duration for seven years, with the first five years as the investment period and the following two years as the projected payback period. The agreed upon duration may be extended for two additional years with the approval of all of the partners. BeiGene Guangzhou, as a limited partner, holds an ownership interest in the fund of 26.3%. The investment committee for the fund has seven members, and requires resolutions to be approved by at least five of the seven members. BeiGene Guangzhou holds one position on the investment committee and GET Bio-fund Management holds three positions. The Company determined that it has the ability to exercise significant influence over the fund due to the Company's ownership interest and involvement on the investment committee, and the investment represents an equity method investment. The Company recognized losses of $134 for its portion of the fund's net loss for the three months ended March 31, 2021. As of March 31, 2021 and December 31, 2020, the carrying amount of the Company's investment in the fund was $12,005 and $12,189, respectively. In addition to the GET Bio-fund Management investment, the Company also plans to enter into a cooperative investment agreement with GET to form a joint venture for the construction of a new research center in Guangzhou.

Other Equity-Method Investments

In addition to the equity-method investments mentioned above, the Company made additional equity-method investments during the year ended December 31, 2020 and the three months ended March 31, 2021 that it does not consider to be individually significant to its financial statements. The Company recognized the equity-method investments at cost and

subsequently adjusted the basis based on the Company's share of the results of operations. The Company records its share of the investees' results of operations within other (expense) income, net.

5. Inventories

The Company’s inventory balance consisted of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Raw materials	26,894	19,330
Work in process	9,504	1,378
Finished goods	36,576	68,585
Total inventories	72,974	89,293

6. Property, plant and equipment

Property, plant and equipment are recorded at cost and consisted of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Laboratory equipment	88,136	78,640
Leasehold improvements	38,357	37,643
Building	131,789	111,527
Manufacturing equipment	105,775	96,669
Software, electronics and office equipment	22,947	20,782
Property, plant and equipment, at cost	387,004	345,261
Less accumulated depreciation	(83,829)	(73,354)
Construction in progress	70,774	85,779
Property, plant and equipment, net	373,949	357,686

As of March 31, 2021 and December 31, 2020, construction in progress ("CIP") of $70,774 and $85,779, respectively, was primarily related to the buildout of additional capacity at the Guangzhou manufacturing facility and expansion of BeiGene (Guangzhou) Co., Ltd.'s ("BGC") research and development activities in Guangzhou, China. Subsequent phases of the Guangzhou factory buildout and BGC research and development expansion will continue to be recorded as CIP until they are placed into service.

Depreciation expense for the three months ended March 31, 2021 and 2020 was $9,444 and $7,467, respectively.

7. Guangzhou Biologics Business

In March 2017, BeiGene HK, a wholly owned subsidiary of the Company, and Guangzhou GET Technology Development Co., Ltd. (now Guangzhou High-tech Zone Technology Holding Group Co., Ltd.) ("GET"), entered into a definitive agreement to establish a commercial scale biologics manufacturing facility in Guangzhou, Guangdong Province, PRC. BeiGene HK and GET entered into an Equity Joint Venture Contract (the “JV Agreement”).

Under the terms of the JV Agreement, BeiGene HK made an initial cash capital contribution of RMB200,000 and a subsequent contribution of one or more biologics assets in exchange for a 95% equity interest in BeiGene Biologics. GET made a cash capital contribution of RMB100,000 to BeiGene Biologics, representing a 5% equity interest in BeiGene Biologics. In addition, on March 7, 2017, BeiGene Biologics entered into a contract with GET, under which GET agreed to provide a RMB900,000 loan (the “Shareholder Loan”) to BeiGene Biologics. In September 2019, BeiGene Biologics completed the first phase of construction of a biologics manufacturing facility in Guangzhou, through a wholly-owned subsidiary, BeiGene Guangzhou Biologics Manufacturing Co., Ltd. ("BeiGene Guangzhou Factory"), to manufacture biologics for the Company and its subsidiaries.

In September 2020, BeiGene HK entered into a share purchase agreement (“JV Share Purchase Agreement”) with GET to acquire GET’s 5% equity interest in BeiGene Biologics for a total purchase price of $28,723 (RMB195,262). The transaction was finalized in November 2020 upon completion of the business registration filing. The share purchase was recorded as an equity transaction. The carrying amount of the noncontrolling interest balance of $9,116 was adjusted to nil to reflect the increase in BeiGene HK’s ownership interest to 100%, and the difference in the fair value of the consideration paid and the carrying amount of the noncontrolling interest of $19,599 was recorded to additional paid in capital. In conjunction with the JV Share Purchase Agreement, BeiGene Biologics repaid the outstanding principal of the shareholder loan of $132,061 (RMB900,000) and accrued interest of $36,558 (RMB249,140).

In connection with the JV share purchase, the Company entered into a loan agreement with China Minsheng Bank for a total loan facility of up to $200,000 ("Senior Loan"), of which $120,000 will be used to fund the JV share repurchase and repayment of the shareholder loan and $80,000 can be used for general working capital purposes. The Company may extend the original maturity date for up to two additional twelve month periods. In October 2020, the Company drew down $80,000 of the working capital facility and $118,320 of the acquisition facility to be used for the JV share repurchase. In addition, the Company entered into a loan agreement with Zhuhai Hillhouse Zhaohui Equity Investment Partnership ("Zhuhai Hillhouse") for a total loan facility of $73,640 (RMB500,000) ("Related Party Loan"), of which $14,728 (RMB100,000) can be used for general corporate purposes and $58,912 (RMB400,000) can only be applied towards the repayment of the Senior Loan facility, including principal, interest and fees. The Company has drawn down $14,728 (RMB100,000) of the Related Party Loan as of March 31, 2021. See Note 11 for further discussion of the loans.

8. Intangible Assets

Intangible assets as of March 31, 2021 and December 31, 2020 are summarized as follows:

	As of					
	March 31, 2021			December 31, 2020		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
	$	$	$	$	$	$
Finite-lived intangible assets:						
Product distribution rights	7,500	(2,687)	4,813	7,500	(2,500)	5,000
Trading license	816	(816)	—	816	(816)	—
Total finite-lived intangible assets	8,316	(3,503)	4,813	8,316	(3,316)	5,000

Product distribution rights consist of distribution rights on the approved cancer therapies licensed from BMS, REVLIMID®, VIDAZA®, and ABRAXANE®, acquired as part of the transaction with BMS (then Celgene) in 2017. The Company is amortizing the product distribution rights over a period of 10 years which is the term of the agreement. The trading license represents the Guangzhou drug distribution license acquired on September 21, 2018. The Company amortized the drug distribution trading license over the remainder of the initial license term through February 2020. The trading license has been renewed through February 2024.

Amortization expense of intangible assets for the three months ended March 31, 2021 and 2020 was $188 and $283, respectively.

As of March 31, 2021, expected amortization expense for the unamortized finite-lived intangible assets is approximately $563 for the remainder of 2021, $750 in 2022, $750 in 2023, $750 in 2024, and $2,000 in 2025 and thereafter.

9. Income Taxes

Income tax benefit was $4,630 for the three months ended March 31, 2021, compared to expense of $1,554 for the three months ended March 31, 2020. The income tax benefit for the three months ended March 31, 2021 was primarily attributable to the deferred tax benefit of U.S. stock-based compensation deductions in excess of tax expense on income reported in certain China subsidiaries as adjusted for certain non-deductible expenses. The income tax expense for the three months ended March 31, 2020 was primarily attributable to tax expense on income reported in certain China subsidiaries as adjusted for certain non-deductible expenses offset by the tax benefit of deferred U.S. stock-based compensation deductions.

On a quarterly basis, the Company evaluates the realizability of deferred tax assets by jurisdiction and assesses the need for a valuation allowance. In assessing the realizability of deferred tax assets, the Company considers historical profitability, evaluation of scheduled reversals of deferred tax liabilities, projected future taxable income and tax-planning strategies. Valuation allowances have been provided on deferred tax assets where, based on all available evidence, it was considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. After consideration of all positive and negative evidence, the Company believes that as of March 31, 2021, it is more likely than not that deferred tax assets will not be realized for the Company's subsidiaries in Australia and Switzerland, for certain subsidiaries in China, and for all U.S. tax credit carryforwards.

As of March 31, 2021, the Company had gross unrecognized tax benefits of $7,727. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly change within the next 12 months. The Company's reserve for uncertain tax positions increased by $604 in the three months ended March 31, 2021 primarily due to U.S. federal and state tax credits and incentives.

The Company has elected to record interest and penalties related to income taxes as a component of income tax expense. As of March 31, 2021 and December 31, 2020, the Company's accrued interest and penalties, where applicable, related to uncertain tax positions were not material.

The Company conducts business in a number of tax jurisdictions and, as such, is required to file income tax returns in multiple jurisdictions globally. As of March 31, 2021, Australia tax matters are open to examination for the years 2013 through 2021, China tax matters are open to examination for the years 2014 through 2021, Switzerland tax matters are open to examination for the years 2017 through 2021, and U.S. federal tax matters are open to examination for years 2015 through 2021. Various U.S. states and other non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2010 through 2021.

10. Supplemental Balance Sheet Information

The roll-forward of the allowance for credit losses related to trade accounts receivable for the three months ended March 31, 2021 and 2020 consists of the following activity:

	Three Months Ended March 31,	
	2021	2020
	$	$
Balance at beginning of the period	112	—
Current period provision for expected credit losses	48	2,022
Amounts written-off	—	—
Exchange rate changes	1	—
Balance at end of the period	161	2,022

Prepaid expenses and other current assets consist of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Prepaid research and development costs	69,382	71,341
Prepaid taxes	30,299	30,392
Payroll tax receivable	6,120	3,580
Non-trade receivable	2,974	4,464
Interest receivable	6,284	6,619
Prepaid insurance	10,459	1,347
Prepaid manufacturing cost	23,238	25,996
Prepayment of facility capacity expansion activities (1)	4,004	—
Income tax receivable	4,540	4,607
Other	14,099	11,666
Total	171,399	160,012

Other non-current assets consist of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Goodwill	109	109
Prepayment of property and equipment	22,584	16,984
Prepayment of facility capacity expansion activities (1)	25,652	29,778
Prepaid VAT	16,781	10,913
Rental deposits and other	6,983	5,962
Long-term investments (Note 4)	55,711	49,344
Total	127,820	113,090

(1) Represents payments for facility expansions under commercial supply agreements. The payments will provide future benefit to the Company through credits on future supply purchases.

Accrued expenses and other payables consist of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Compensation related	49,056	106,765
External research and development activities related	126,228	143,302
Commercial activities	63,219	66,131
Individual income tax and other taxes	19,762	14,373
Sales rebates and returns related	45,665	11,874
Professional fees and other	8,204	3,699
Total	312,134	346,144

Other long-term liabilities consist of the following:

	As of	
	March 31, 2021	December 31, 2020
	$	$
Deferred government grant income	47,528	49,139
Pension liability	7,616	8,113
Other	176	177
Total	55,320	57,429

11. Debt

The following table summarizes the Company's short-term and long-term debt obligations as of March 31, 2021 and December 31, 2020:

Lender	Agreement Date	Line of Credit	Term	Maturity Date	Interest Rate	March 31, 2021		December 31, 2020	
						$	RMB	$	RMB
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	305	2,000	307	2,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	382	2,500	—	—
China Minsheng Bank (the "Senior Loan")	September 24, 2020	$200,000		(3)	5.8 %	198,320	1,299,351	198,320	1,294,010
Zhuhai Hillhouse (the "Related Party Loan")	September 24, 2020	RMB500,000		(4)	5.8 %	15,263	100,000	15,326	100,000
Other short-term debt (5)						190,775	1,249,918	121,062	789,918
Total short-term debt						405,045	2,653,769	335,015	2,185,928
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	88,220	578,000	88,584	578,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	53,039	347,500	53,641	350,000
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(6)	51,758	339,111	41,412	270,206
Total long-term bank loans						193,017	1,264,611	183,637	1,198,206

1. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.9% as of March 31, 2021. The loan is secured by BeiGene Guangzhou Factory's land use right and certain Guangzhou Factory fixed assets in the first phase of the Guangzhou manufacturing facility's build out.

2. On January 22, 2020, BeiGene Guangzhou Factory entered into a nine-year bank loan with China Merchants Bank to borrow up to RMB1,100,000 at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan is secured by Guangzhou Factory's second land use right and fixed assets that will be placed into service upon completion of the second phase of the Guangzhou manufacturing facility's build out. In connection with the Company's short-term loan agreements with China Merchants Bank entered into during the year ended December 31, 2020, the borrowing capacity was reduced from RMB1,100,000 to RMB350,000. The loan interest rate was 4.4% as of March 31, 2021.

3. $120,000 of the Senior Loan was designated to fund the JV share purchase and repayment of the shareholder loan and $80,000 was designated for general working capital purposes. The Senior Loan has an original maturity date of October 8, 2021, which is the first anniversary of the first date of utilization of the loan. The Company may extend the original maturity date for up to two additional 12 month periods.

4. RMB100,000 of the Related Party Loan was designated for general corporate purposes and RMB400,000 was designated for repayment of the Senior Loan, including principal, interest and fees. The loan matures at the earlier of: (i) November 9, 2021, which is one month after the Senior Loan maturity date, if not extended, or (ii) 10 business days after the Senior Loan is fully repaid. Zhuhai Hillhouse is a related party of the Company, as it is an affiliate of Hillhouse Capital. Hillhouse Capital is a shareholder of the Company, and a Hillhouse Capital employee is a member of the Company's board of directors.

5. During the year ended December 31, 2020, the Company entered into additional short-term working capital loans with China Industrial Bank and China Merchants Bank to borrow up to RMB1,480,000 in aggregate, with maturity dates ranging from April 19, 2021 to March 7, 2022. The Company drew down $71,001 (RMB460,000) during the three months ended March 31, 2021. The weighted average interest rate for the short-term working capital loans was approximately 4.4% as of March 31, 2021. One of the short-term working capital loans outstanding in the amount of $24,421 (RMB160,000) is secured by the Company's research and development facility in Beijing and the associated land use right owned by its subsidiary, Beijing Innerway Bio-tech Co., Ltd.

6. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.3% as of March 31, 2021. The Company drew down $10,664 (RMB68,905) during the three months ended March 31, 2021. The loan is secured by fixed assets that will be placed into service upon completion of the third phase of the Guangzhou manufacturing facility's build out.

Interest Expense

Interest expense recognized for the three months ended March 31, 2021 and 2020 was $6,950 and $4,291, respectively, among which, $104 and $66 was capitalized, respectively.

12. Product Revenue

The Company's product revenue is derived from the sale of its internally developed products BRUKINSA® in the United States and China and tislelizumab in China, as well as the sale of REVLIMID®, VIDAZA® and ABRAXANE® in China under a license from BMS and XGEVA® in China under a license from Amgen. On March 25, 2020, the Company announced that the China National Medical Products Administration ("NMPA") suspended the importation, sales and use of ABRAXANE® in China supplied to BeiGene by Celgene, a BMS company, and the drug was subsequently recalled by BMS and is not currently available for sale in China.

The table below presents the Company's net product sales for the three months ended March 31, 2021 and 2020.

	Three Months Ended March 31,	
	2021	2020
	$	$
Product revenue – gross	143,482	53,188
Less: Rebates and sales returns	(37,365)	(1,129)
Product revenue – net	106,117	52,059

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

	Three Months Ended March 31,	
	2021	2020
	$	$
Tislelizumab	48,879	20,526
BRUKINSA®	22,090	717
REVLIMID®	16,629	7,628
VIDAZA®	3,706	6,043
ABRAXANE®	—	17,145
XGEVA®	14,454	—
Other	359	—
Total product revenue – net	106,117	52,059

The following table presents the roll-forward of accrued sales rebates and returns for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	$	$
Balance at beginning of the period	11,874	3,198
Accrual	37,365	1,129
Payments	(3,574)	(313)
Balance at end of the period	45,665	4,014

The rebate accrual at March 31, 2021 includes an accrual of $24.2 million for compensating distributors for products previously sold at the pre-NRDL price, that remained in the distribution channel, due to the first inclusion of tislelizumab, BRUKINSA and XGEVA in the NRDL.

13. Earnings (Loss) Per Share

The following table reconciles the numerator and denominator in the computations of basic and diluted earnings (loss) per share:

	Three Months Ended March 31,	
	2021	2020
	$	$
Numerator:		
Net income (loss)	66,495	(364,939)
Less: Net loss attributable to noncontrolling interest	—	(1,204)
Net income (loss) attributable to BeiGene, Ltd.	66,495	(363,735)
Denominator:		
Weighted average shares outstanding—basic	1,188,943,726	1,005,347,581
Effect of dilutive securities:		
Stock options, restricted stock units and ESPP shares	68,545,945	—
Weighted average shares outstanding—diluted	1,257,489,671	1,005,347,581

For the three months ended March 31, 2021, basic earnings per share was computed using the weighted-average number of ordinary shares outstanding during the period. Diluted earnings per share was computed using the weighted-average number of ordinary shares and the effect of potentially dilutive shares outstanding during the periods. Potentially dilutive shares consist of stock options, restricted stock units and ESPP shares. The dilutive effect of outstanding stock options, restricted stock units and ESPP shares is reflected in diluted net earnings per share by application of the treasury stock method.

For the three months ended March 31, 2020, the computation of basic earnings per share using the two-class method was not applicable as the Company was in a net loss position, and the effects of all share options, restricted shares, restricted share units and ESPP shares were excluded from the calculation of diluted earnings per share, as their effect would have been anti-dilutive.

14. Share-Based Compensation Expense

2016 Share Option and Incentive Plan

In January 2016, in connection with the Company's initial public offering ("IPO") on the NASDAQ Stock Market, the board of directors and shareholders of the Company approved the 2016 Share Option and Incentive Plan (the “2016 Plan”), which became effective in February 2016. The Company initially reserved 65,029,595 ordinary shares for the issuance of awards under the 2016 Plan, plus any shares available under the 2011 Option Plan (the “2011 Plan”), and not subject to any outstanding options as of the effective date of the 2016 Plan, along with underlying share awards under the 2011 Plan that are cancelled or forfeited without issuance of ordinary shares. As of March 31, 2021, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,166,432. In December 2018, the shareholders approved an amended and restated 2016 Plan to increase the number of shares authorized for issuance by 38,553,159 ordinary shares, as well as amend the cap on annual compensation to independent directors and make other changes. In June 2020, the shareholders approved an Amendment No. 1 to the 2016 Plan to increase the number of shares authorized for issuance by 57,200,000 ordinary shares and to extend the term of the plan through April 13, 2030. The number of shares available for issuance under the 2016 Plan is subject to adjustment in the event of a share split, share dividend or other change in the Company’s capitalization.

During the three months ended March 31, 2021, the Company granted options for 229,606 ordinary shares and restricted share units for 2,480,478 ordinary shares under the 2016 Plan. As of March 31, 2021, options and restricted share units for ordinary shares outstanding under the 2016 Plan totaled 60,263,469 and 34,105,032, respectively.

2018 Inducement Equity Plan

In June 2018, the board of directors of the Company approved the 2018 Inducement Equity Plan (the “2018 Plan”) and reserved 12,000,000 ordinary shares to be used exclusively for grants of awards to individuals that were not previously employees of the Company or its subsidiaries, as a material inducement to the individual’s entry into employment with the Company or its subsidiaries within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. The 2018 Plan was approved by the board of directors upon recommendation of the compensation committee, without shareholder approval

pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. The terms and conditions of the 2018 Plan, and the forms of award agreements to be used thereunder, are substantially similar to the 2016 Plan and the forms of award agreements thereunder. In August 2018, in connection with the Hong Kong IPO, the board of directors of the Company approved an amended and restated 2018 Plan to implement changes required by the listing rules of the HKEx.

During the three months ended March 31, 2021, the Company did not grant any options or restricted share units under the 2018 Plan. As of March 31, 2021, options and restricted share units for ordinary shares outstanding under the 2018 Plan totaled 34,996 and 1,244,867, respectively.

2018 Employee Share Purchase Plan

In June 2018, the shareholders of the Company approved the 2018 Employee Share Purchase Plan (the "ESPP"). Initially, 3,500,000 ordinary shares of the Company were reserved for issuance under the ESPP. In December 2018, the board of directors of the Company approved an amended and restated ESPP to increase the number of shares authorized for issuance by 3,855,315 ordinary shares to 7,355,315 ordinary shares. In June 2019, the board of directors adopted an amendment to revise the eligibility criteria for enrollment in the plan. The ESPP allows eligible employees to purchase the Company's ordinary shares (including in the form of ADSs) at the end of each offering period, which will generally be six months, at a 15% discount to the market price of the Company's ADSs at the beginning or the end of each offering period, whichever is lower, using funds deducted from their payroll during the offering period. Eligible employees are able to authorize payroll deductions of up to 10% of their eligible earnings, subject to applicable limitations.

The following tables summarizes the shares issued under the ESPP:

		Market Price[1]		Purchase Price[2]		
Issuance Date	Number of Ordinary Shares Issued	ADS	Ordinary	ADS	Ordinary	Proceeds
February 26, 2021	436,124	$ 236.30	$ 18.18	$ 200.86	$ 15.45	$ 6,738
August 31, 2020	485,069	$ 164.06	$ 12.62	$ 139.45	$ 10.73	$ 5,203
February 28, 2020	425,425	$ 145.54	$ 11.20	$ 123.71	$ 9.52	$ 4,048

[1] The market price is the lower of the closing price on the NASDAQ Stock Market on the issuance date or the offering date, in accordance with the terms of the ESPP.

[2] The purchase price is the price which was discounted from the applicable market price, in accordance with the terms of the ESPP.

The following table summarizes total share-based compensation expense recognized for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	$	$
Research and development	21,889	20,399
Selling, general and administrative	23,944	17,856
Total	45,833	38,255

15. Accumulated Other Comprehensive Income

The movement of accumulated other comprehensive income was as follows:

	Foreign Currency Translation Adjustments	Unrealized Gains on Available-for-Sale Securities	Pension Liability Adjustments	Total
	$	$	$	$
Balance as of December 31, 2020	14,184	871	(8,113)	6,942
Other comprehensive (loss) income before reclassifications	(3,762)	(421)	497	(3,686)
Amounts reclassified from accumulated other comprehensive income (1)	—	(52)	—	(52)
Net-current period other comprehensive (loss) income	(3,762)	(473)	497	(3,738)
Balance as of March 31, 2021	10,422	398	(7,616)	3,204

(1) The amounts reclassified from accumulated other comprehensive income were included in other (expense) income, net in the consolidated statements of operations.

16. Shareholders' Equity

Share Purchase Agreement

In January 2020, the Company sold 15,895,001 ADSs, representing a 20.5% ownership stake in the Company, to Amgen for aggregate cash proceeds of $2,779,241, or $174.85 per ADS, pursuant to the SPA executed in connection with the Amgen Collaboration Agreement.

17. Restricted Net Assets

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

In accordance with the company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the board of directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's PRC subsidiaries were established as domestic enterprises and therefore are subject to the above-mentioned restrictions on distributable profits.

As a result of these PRC laws and regulations, including the requirement to make annual appropriations of at least 10% of after-tax income and set aside as general reserve fund prior to payment of dividends, the Company's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulations in the PRC may further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of dividends, loans and advances. As of March 31, 2021 and December 31, 2020, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to $439,268 and $119,776, respectively.

18. Commitments and Contingencies

Purchase Commitments

As of March 31, 2021, the Company had purchase commitments amounting to $141,159, of which $88,024 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $53,135 related to binding purchase obligations of inventory from BMS and Amgen. The Company does not have any minimum purchase requirements for inventory from BMS or Amgen.

Capital Commitments

The Company had capital commitments amounting to $51,421 for the acquisition of property, plant and equipment as of March 31, 2021, which were mainly for BeiGene Guangzhou Factory's manufacturing facility, expansion of BGC's research and development activities in Guangzhou, China, and research and development operations at the Changping facility in Beijing, China.

Co-Development Funding Commitment

Under the Amgen Collaboration Agreement, the Company is responsible for co-funding global development costs for the Amgen oncology pipeline assets up to a total cap of $1,250,000. The Company is funding its portion of the co-development costs by contributing cash and development services. As of March 31, 2021, the Company's remaining co-development funding commitment was $964,437.

Funding Commitment

The Company had committed capital related to one equity method investment in the amount of $15,000. As of March 31, 2021, the remaining capital commitment was $14,250 and is expected to be paid from time to time over the investment period.

Pension Commitment

The Company maintains a defined benefit pension plan in Switzerland. Funding obligations under the defined benefit pension plan are equivalent to $1,300 per year based on annual funding contributions in effect as of March 31, 2021 to achieve fully funded status where the market value of plan assets equals the projected benefit obligations. Future funding requirements will be subject to change as a result of future changes in staffing and compensation levels, various actuarial assumptions and actual investment returns on plan assets.

Other Business Agreements

The Company enters into agreements in the ordinary course of business with contract research organizations ("CROs") to provide research and development services. These contracts are generally cancelable at any time by us with prior written notice.

The Company also enters into collaboration agreements with institutions and companies to license intellectual property. The Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with its collaboration agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on the Company's balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in the Company's financial statements.

19. Segment and Geographic Information

The Company operates in one segment: pharmaceutical products. Its chief operating decision maker is the Chief Executive Officer, who makes operating decisions, assesses performance and allocates resources on a consolidated basis.

The Company's long-lived assets are substantially located in the PRC.

Net product revenues by geographic area are based upon the location of the customer, and net collaboration revenue is recorded in the jurisdiction in which the related income is expected to be sourced from. Total net revenues by geographic area are presented as follows:

	Three Months Ended March 31,	
	2021	2020
	$	$
PRC	95,982	51,342
United States	359,963	717
Other	149,927	—
Total	605,872	52,059

U.S. revenues for the three months ended March 31, 2021 consisted of $349,828 of collaboration revenue and $10,135 of BRUKINSA® product sales. U.S. revenues for the three months ended March 31, 2020 consisted entirely of BRUKINSA® product sales.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements (unaudited) and related notes included in the section of this Quarterly Report on Form 10-Q (this "Quarterly Report"), titled "Item 1-Financial Statements." This Quarterly Report contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "aim," "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "goal," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. These forward-looking statements, include, but are not limited to, statements regarding: our ability to successfully commercialize our approved medicines and to obtain approvals in additional indications and territories for our medicines; our ability to successfully develop and commercialize our in-licensed medicines and drug candidates and any other medicines and drug candidates we may in-license; our ability to successfully develop and commercialize oncology assets licensed from Amgen in China pursuant to our global strategic oncology collaboration with Amgen; our ability to further develop sales and marketing capabilities and launch and commercialize new medicines, if approved; our ability to maintain and expand regulatory approvals for our medicines and drug candidates, if approved; the pricing and reimbursement of our medicines and drug candidates, if approved; the initiation, timing, progress and results of our preclinical studies and clinical trials and our research and development programs; our ability to advance our drug candidates into, and successfully complete, clinical trials and obtain regulatory approvals; our reliance on the success of our clinical stage drug candidates; our plans, expected milestones and the timing or likelihood of regulatory filings and approvals; our expectations about the successful restoration of supply of ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension) in China; the implementation of our business model, strategic plans for our business, medicines, drug candidates and technology; the scope of protection we (or our licensors) are able to establish and maintain for intellectual property rights covering our medicines, drug candidates and technology; the scope of protection we (or our licensors) are able to establish and maintain for intellectual property rights covering our medicines, drug candidates and technology; our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties; costs associated with enforcing or defending against intellectual property infringement, misappropriation or violation, product liability and other claims; regulatory developments in the United States, the People's Republic of China ("China" or "PRC"), the United Kingdom, the European Union ("EU") and other jurisdictions; the accuracy of our estimates regarding expenses, revenues, capital requirements and our need for additional financing; the potential benefits of strategic collaboration and licensing agreements and our ability to enter into strategic arrangements; our ability to maintain and establish collaborations or licensing agreements; our reliance on third parties to conduct drug development, manufacturing and other services; our ability to manufacture and supply, or have manufactured and supplied, drug candidates for clinical development and medicines for commercial sale; the rate and degree of market access and acceptance and the pricing and reimbursement of our medicines and drug candidates, if approved; developments relating to our competitors and industry, including competing therapies; the size of the potential markets for our medicines and drug candidates and our ability to serve those markets; our ability to effectively manage our growth; our ability to attract and retain qualified employees and key personnel; statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance; the future trading price of our ADSs and ordinary shares, and impact of securities analysts' reports on these prices; the impact of the COVID-19 pandemic on our clinical development, commercial and other operations; and other risks and uncertainties, including those listed under "Part II-Item 1A-Risk Factors" of this Quarterly Report. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described in "Part II-Item 1A-Risk Factors" of this Quarterly Report. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. Unless the context requires otherwise, in this Quarterly Report, the terms "BeiGene," the "Company," "we," "us" and "our" refer to BeiGene, Ltd. and its subsidiaries, on a consolidated basis.

Overview

We are a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and expand access for patients worldwide.

Our research organization has delivered ten molecules into the clinic in our first ten years, including our two lead commercial medicines, BRUKINSA®, a small molecule inhibitor of Bruton's Tyrosine Kinase ("BTK") for the treatment of various blood cancers, and tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and

blood cancers. We are marketing BRUKINSA® in the world's two largest pharmaceutical markets, the United States and China, and tislelizumab in China, with an established, science-based commercial organization. We have built state-of-the-art biologic and small molecule manufacturing facilities in China to support the potential future demand of our medicines, and we also work with high quality contract manufacturing organizations ("CMOs") to manufacture our internally developed clinical and commercial products.

We are a leader in China-inclusive global clinical development, which we believe can facilitate faster and more cost-effective development of innovative medicines. Our internal clinical development capabilities are deep, including a more than 1,600-person global clinical development team that is running more than 100 ongoing or planned clinical trials. This includes more than 25 pivotal or registration-enabling trials for three drug candidates that have enrolled more than 12,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of March 2021. We have over 45 medicines and drug candidates in commercial stage or clinical development, including 7 approved medicines, 5 pending approval, and over 30 in clinical development.

Supported by our development and commercial capabilities, we have entered into collaborations with world-leading biopharmaceutical companies such as Amgen and Novartis to develop and commercialize innovative medicines globally. Since our inception in 2010 in Beijing, we have become a fully integrated global organization of approximately 6,000 employees in 16 countries and regions, including China, the United States, Europe and Australia.

Recent Developments

Recent Business Developments

On April 28, 2021, we announced positive results from a planned interim analysis of the Phase 3 ALPINE trial comparing BRUKINSA® against ibrutinib in adults with relapsed or refractory ("R/R") chronic lymphocytic leukemia ("CLL") or small lymphocytic lymphoma ("SLL"). BRUKINSA® met the primary endpoint of the trial, demonstrating non-inferiority in objective response rate ("ORR") by both investigator and independent review committee (IRC) assessments ($p < 0.0001$). The trial also demonstrated superior ORR with a statistically significant improvement in ORR for BRUKINSA vs. ibrutinib ($p = 0.0006$) by investigator assessment, as well as a numerically higher ORR but not statistically significant improvement by IRC ($p = 0.0121$ compared to the two-sided stringent statistical boundary of $p < 0.0099$ set for the interim analysis). The interim analysis from this fully-enrolled, ongoing trial is based on 415 of 652 patients followed for a minimum of 12 months.

On April 7, 2021, we announced approval from the China National Medical Products Administration ("NMPA") for us to begin manufacturing commercial supply of tislelizumab at our state-of-the-art biologics facility in Guangzhou, China. At over one million square feet (100,000 square meters) and 8,000 liters of biologics capacity approved for commercial supply, this wholly owned facility will immediately begin production of commercial supply of tislelizumab for the China market. An additional phase of construction currently in progress to bring total capacity to 64,000 liters is expected to be completed by the end of 2022.

On March 10, 2021, we announced that the first patient was dosed in a Phase 1 clinical trial of BGB-15025, its investigational hematopoietic progenitor kinase 1 ("HPK1") inhibitor. BGB-15025 is designed to be a potent and highly selective small molecule oral inhibitor of HPK1, a kinase downstream of the T cell receptor ("TCR") signaling pathway that is believed to play a key role in T cell activation.

On March 5, 2021, we announced that a supplemental Biologics License Application ("sBLA") for tislelizumab was accepted by the Center for Drug Evaluation ("CDE") of the NMPA for treatment in the second- or third-line setting of patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") who have progressed on prior platinum-based chemotherapy.

On March 2, 2021, we announced that BRUKINSA® was accepted by Health Canada for the treatment of adult patients with Waldenström's macroglobulinemia ("WM").

On February 26, 2021, we announced the closing of the collaboration and license agreement with Novartis Pharma AG ("Novartis"), previously announced on January 11, 2021, granting Novartis rights to develop, manufacture, and commercialize tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. We have agreed to jointly develop tislelizumab with Novartis in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and we have an option to co-detail the product in North America, funded in part by Novartis.

Components of Operating Results

Revenue

Product Revenue

We began generating product revenue in September 2017 through our in-license agreement with BMS (then Celgene) to distribute the approved cancer therapies REVLIMID®, VIDAZA®, and ABRAXANE® in China. Following approval from the FDA in November 2019, we launched our first internally developed medicine, BRUKINSA®, in the United States. We launched our second internally developed medicine, tislelizumab, in China in March 2020 and in June 2020, we launched BRUKINSA® in China. In July 2020, we began selling XGEVA® under our in-license agreement with Amgen. In December 2020, we announced the inclusion of tislelizumab, BRUKINSA®, and XGEVA® in the updated National Reimbursement Drug List (the "NRDL") by the China National Healthcare Security Administration ("NHSA"), which became effective on March 1, 2021. We received approval for BLINCYTO® in China in December 2020 and plan to launch additional in-licensed products from our collaborations in 2021, and continue to expand our efforts to promote our existing commercial products.

Revenues from product sales are recognized when there is a transfer of control from the Company to the customer. The Company determines transfer of control based on when the product is delivered, and title passes to the customer. Revenues from product sales are recognized net of variable consideration resulting from rebates, chargebacks, trade discounts and allowances, sales returns allowances and other incentives. Provisions for estimated reductions to revenue are provided for in the same period the related sales are recorded and are based on contractual terms, historical experience and trend analysis.

Collaboration Revenue

We recognize collaboration revenues for amounts earned under collaborative and out-licensing arrangements. In January 2021, we entered into a collaboration and license agreement with Novartis, granting Novartis rights to develop, manufacture and commercialize tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan (the "Novartis Territory"). There were two performance obligations identified at the outset of the agreement: (1) the exclusive license to develop, manufacture, and commercialize tislelizumab in the Novartis Territory, transfer of know-how and use of the tislelizumab trademark and (2) conducting and completing ongoing trials of tislelizumab (“R&D services”). Under this agreement, we received an upfront cash payment, which was allocated between the two performance obligations identified in the agreement based on the relative standalone selling prices of the performance obligations. The portion allocated to the license was recognized upon the delivery of the license right and transfer of know-how. The portion of the upfront payment allocated to the R&D services was deferred and is being recognized as collaboration revenue as the R&D services are performed using a percentage of completion method. Estimated costs to complete are reassessed on a periodic basis and any updates to the revenue earned are recognized on a prospective basis.

The potential milestone payments that we are eligible to receive under the Novartis collaboration were excluded from the initial transaction price, as all milestone amounts are variable consideration and were fully constrained due to uncertainty of achievement. Performance-based milestones will be recognized when the milestone event is achieved or when the risk of revenue reversal is remote. Sales-based milestones and royalties will be recognized when the underlying sales occur.

Expenses

Cost of Sales

Cost of sales includes the cost of products purchased from Amgen and BMS and distributed in China and the costs to manufacture our internally developed commercial products. Also included in cost of sales are amounts paid to Amgen for its share of net sales or gross margin earned on sales of products in-licensed from Amgen. Costs to manufacture inventory in preparation for commercial launch of a product incurred prior to regulatory approval are expensed to research and development expense as incurred. Cost of sales for newly launched products will not be recorded until the initial pre-launch inventory is depleted and additional inventory is manufactured. To date, the Company's initial pre-launch inventory for its commercial products has been immaterial, and the consumption of the remaining pre-launch inventory on hand is not expected to have a significant impact on the Company's gross margin.

Research and Development Expenses

Research and development expenses consist of the costs associated with our research and development activities, conducting preclinical studies and clinical trials, and activities related to regulatory filings. Our research and development expenses consist of:

- expenses incurred under agreements with contract research organizations ("CROs"), CMOs, and consultants that conduct and support clinical trials and preclinical studies;
- costs of comparator drugs in certain of our clinical trials;
- manufacturing costs related to pre-commercial activities;
- costs associated with preclinical activities and development activities;
- costs associated with regulatory operations;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- in-process research and development costs expensed as part of collaboration agreements entered into; and
- other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in research and development activities.

Our current research and development activities mainly relate to the clinical advancement of our internally developed medicines and drug candidates:

- BRUKINSA® (zanubrutinib), a small molecule inhibitor of BTK;
- tislelizumab, a humanized monoclonal antibody against PD-1;
- pamiparib, an investigational selective small molecule inhibitor of PARP1 and PARP2;
- BGB-A1217, an investigational humanized monoclonal antibody against TIGIT;
- BGB-15025, an investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor;
- BGB-11417, an investigational small molecular inhibitor of Bcl-2;
- lifirafenib, an investigational novel small molecule inhibitor of both the monomer and dimer forms of BRAF;
- BGB-A333, an investigational humanized monoclonal antibody against PD-L1; and
- BGB-A425, an investigational humanized monoclonal antibody against TIM-3.

Research and development activities also include costs associated with in-licensed drug candidates, including:

- R&D expense related to the co-development of pipeline assets under the Amgen collaboration agreement. Our total cost share obligation to Amgen is split between R&D expense and a reduction to the R&D cost share liability;
- sitravatinib, an investigational, spectrum-selective kinase inhibitor, licensed from Mirati Therapeutics, Inc. ("Mirati");
- zanidatamab (ZW25) and ZW49, two investigational bispecific antibody-based product candidates targeting HER2, licensed from Zymeworks Inc. ("Zymeworks");
- BA3071, an investigational CAB-CTLA-4 antibody, licensed from BioAtla, Inc. ("BioAtla");
- BAT1706, an investigational biosimilar to Avastin® (bevacizumab), licensed from Bio-Thera Solutions, Ltd. ("Bio-Thera"); and
- DXP-593 and DXP-604, investigational anti-COVID-19 antibodies, licensed from Singlomics (Beijing DanXu) Biopharmaceuticals Co., Ltd. ("Singlomics").

We expense research and development costs when we incur them. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us. We expense the manufacturing costs of our internally developed products that are used in clinical trials as they are incurred as research and development expense. We do not allocate employee-related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified as unallocated research and development expenses.

At this time, it is difficult to estimate or know for certain, the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our internally developed medicines and drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our medicines and drug candidates, if approved. This is due to the numerous risks and uncertainties associated with developing such medicines and drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety and efficacy profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing and other required approvals from applicable regulatory authorities;
- successfully launching and commercializing our medicines and drug candidates, if and when approved, whether as monotherapies or in combination with our internally developed medicines and drug candidates or third-party products;
- market acceptance, pricing and reimbursement;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our medicines and drug candidates;
- continued acceptable safety and efficacy profiles of the products following approval;
- sufficient supply of the products following approval;
- competition from competing products; and
- retention of key personnel.

A change in the outcome of any of these variables with respect to the development of any of our medicines and drug candidates would significantly change the costs, timing and viability associated with the commercialization or development of that medicine or drug candidate.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, as we continue to support the clinical trials of our medicines and drug candidates as treatments for various cancers and as we move these medicines and drug candidates into additional clinical trials, including potential pivotal trials. There are numerous factors associated with the successful commercialization of any of our medicines and drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development and commercial programs and plans.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of product promotion costs, distribution costs, salaries and related benefit costs, including share-based compensation for selling, general and administrative personnel. Other selling, general and administrative expenses include professional fees for legal, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, travel costs, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support planned increases in commercialization activities with respect to tislelizumab, BRUKINSA®, XGEVA® and BLINCYTO® and the preparation for potential launch and commercialization of additional in-licensed products from our collaborations and internally developed products, if approved. We also expect selling, general and administrative expenses to increase in future periods to support our research and development efforts, including the continuation of the clinical trials of our treatments for various cancers and the initiation of clinical trials for potential new indications or drug candidates. These cost

increases will likely be due to increased promotional costs, increased headcount, increased share-based compensation expenses, expanded infrastructure and increased costs for insurance. We also incur significant legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company with our ADSs and ordinary shares listed for trading on The NASDAQ Global Select Market and The Hong Kong Stock Exchange, respectively.

Interest (Expense) Income, Net

Interest Income

Interest income consists primarily of interest generated from our cash and short-term investments in money market funds, time deposits, U.S. Treasury securities and U.S. agency securities.

Interest Expense

Interest expense consists primarily of interest on our bank loans, related party loan and shareholder loan.

Other (Expense) Income, Net

Other (expense) income consists primarily of gains recognized related to equity investments, government grants and subsidies received that involve no conditions or continuing performance obligations by us, realized and unrealized gains and losses related to foreign currency exchange rates, unrealized gains and losses on equity securities, and realized gains and losses on the sale of investments.

Results of Operations

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,		Change	
	2021	2020	$	%
	(dollars in thousands)			
Revenues				
Product revenue, net	$ 106,117	$ 52,059	$ 54,058	103.8 %
Collaboration revenue	499,755	—	499,755	NM
Total revenues	605,872	52,059	553,813	1,063.8 %
Expenses				
Cost of sales	32,685	14,149	18,536	131.0 %
Research and development	320,726	304,302	16,424	5.4 %
Selling, general and administrative	182,106	107,081	75,025	70.1 %
Amortization of intangible assets	188	283	(95)	(33.6)%
Total expenses	535,705	425,815	109,890	25.8 %
Income (loss) from operations	70,167	(373,756)	443,923	(118.8)%
Interest (expense) income, net	(4,179)	6,690	(10,869)	(162.5)%
Other (expense) income, net	(4,123)	3,681	(7,804)	(212.0)%
Income (loss) before income taxes	61,865	(363,385)	425,250	(117.0)%
Income tax (benefit) expense	(4,630)	1,554	(6,184)	(397.9)%
Net income (loss)	66,495	(364,939)	431,434	(118.2)%
Less: Net loss attributable to noncontrolling interest	—	(1,204)	1,204	(100.0)%
Net income (loss) attributable to BeiGene, Ltd.	$ 66,495	$ (363,735)	$ 430,230	(118.3)%

Comparison of the Three Months Ended March 31, 2021 and 2020

Revenue

Total revenue increased to $605.9 million for the three months ended March 31, 2021, from $52.1 million for the three months ended March 31, 2020, primarily due to collaboration revenue resulting from the upfront fee allocated to the license rights provided to Novartis, increased sales of our internally developed products, as well as sales of XGEVA®, the first product licensed under our collaboration with Amgen, which commenced sales in China in July 2020. The following table summarizes the components of revenue for the three months ended March 31, 2021 and 2020, respectively:

	Three Months Ended March 31,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
Product revenue	$ 106,117 0	$ 52,059	$ 54,058	103.8 %
Collaboration revenue:				
License revenue	484,646	—	484,646	NM
Research and development service revenue	15,109	—	15,109	NM
Total collaboration revenue	499,755	—	499,755	NM
Total Revenue	$ 605,872	$ 52,059	$ 553,813	1,063.8 %

Net product revenues consisted of the following:

	Three Months Ended March 31,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
Tislelizumab	$ 48,879	$ 20,526	$ 28,353	138.1 %
BRUKINSA®	22,090	717	21,373	2,980.9 %
REVLIMID®	16,629	7,628	9,001	118.0 %
VIDAZA®	3,706	6,043	(2,337)	(38.7)%
ABRAXANE®	—	17,145	(17,145)	(100.0)%
XGEVA®	14,454	—	14,454	NM
Other	359	—	359	NM
Total product revenue	$ 106,117	$ 52,059	$ 54,058	103.8 %

Net product revenue increased 103.8% to $106.1 million for the three months ended March 31, 2021, compared to $52.1 million in the prior year period, primarily due to increased sales of tislelizumab in China and BRUKINSA® in the United States and China, partially offset by decreased sales of the BMS products distributed in China. In addition, product revenues in the first quarter of 2021 were positively impacted by sales of Amgen's XGEVA® in China, which we began distributing in July 2020, and the strengthening of the RMB against the United States dollar in the current quarter compared to the prior year period.

Product revenues in the first quarter of 2021 were negatively impacted by an adjustment of $24.2 million as a result of compensating distributors for products that remained in the distribution channel which were sold during the quarter, prior to applying the lower prices of the NRDL, due to the first inclusion of tislelizumab, BRUKINSA®, and XGEVA® in the updated NRDL by the NHSA, which became effective on March 1, 2021. In the first quarter, the inclusion of tislelizumab, BRUKINSA®, and XGEVA® in the NRDL significantly increased patient demand that more than offset the net effect of price reductions as a result of NRDL inclusion. Overall, we expect sales of our internally-developed products and in-licensed products from Amgen to lead to total product revenue growth in 2021, driven by an increase in sales volume as our launches progress.

We expect product revenue from the in-licensed products from BMS to continue to be impacted by the NMPA's suspension of the importation, sales and use of ABRAXANE® in China in March 2020 and the subsequent voluntary recall of ABRAXANE® by BMS, as well as increased competition from generic products for REVLIMID® and the loss of volume-based procurement ("VBP") bidding for VIDAZA®. Although the impact of COVID-19 on commercial activities in China lessened in the second half of 2020, there is continued uncertainty regarding the future potential impact of the pandemic both in China and the United States, as well as globally. We do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified drug is manufactured and available for sale in China. We do not know when the NMPA suspension of ABRAXANE® will be lifted and when we will be able to re-commence sales of ABRAXANE®.

Collaboration revenue totaled $499.8 million for the three months ended March 31, 2021. $484.7 million was recognized upon delivery of the license right and transfer of know-how to Novartis under our collaboration and license agreement with Novartis, and $15.1 million was recognized from deferred revenue for R&D services performed during the three months ended March 31, 2021 (see Footnote 3). We did not have any collaboration revenue during the three months ended March 31, 2020.

Cost of Sales

Cost of sales increased to $32.7 million for the three months ended March 31, 2021 from $14.1 million for the three months ended March 31, 2020, primarily due to increased product sales of tislelizumab, BRUKINSA®, and XGEVA®, and were partially offset by lower sales of BMS in-licensed products.

Gross Margin

Gross margin on product sales increased to $73.4 million for the three months ended March 31, 2021, compared to $37.9 million in the prior year period, primarily due to increased product revenue in the current year period. Gross margin as a percentage of product sales decreased to 69% for the three months ended March 31, 2021, from 73% in the comparable period of the prior year. The decrease is primarily due to the impact of the accrued compensation to customers for sales of tislelizumab, BRUKINSA®, and XGEVA® that remained in the channel and were sold at the pre-NRDL price. We expect gross

margin to normalize in the remainder of 2021 and be consistent with the prior year, as the sales mix evolves toward our higher margin internally developed products. We anticipate that the effect to gross margin for significant reductions in listing prices effective March 1, 2021 as a result of inclusion in the NRDL for tislelizumab, BRUKINSA and XGEVA will be partially mitigated by adjustments to the Company's patient assistance programs. Pre-launch inventory carried at zero or low cost consumed during the three months ended March 31, 2021 and March 31, 2020 was immaterial and did not have a significant impact on our gross margin.

Research and Development Expense

Research and development expense increased by $16.4 million, or 5.4%, to $320.7 million for the three months ended March 31, 2021 from $304.3 million for the three months ended March 31, 2020. The following table summarizes external clinical, external non-clinical and internal research and development expense for the three months ended March 31, 2021 and 2020, respectively:

	Three Months Ended March 31,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 122,946	$ 111,734	$ 11,212	10.0 %
Upfront license fees	8,500	43,000	(34,500)	(80.2)%
Amgen co-development expense[1]	27,643	28,366	(723)	(2.5)%
Total external research and development expenses	159,089	183,100	(24,011)	(13.1)%
Internal research and development expenses	161,637	121,202	40,435	33.4 %
Total research and development expenses	$ 320,726	$ 304,302	$ 16,424	5.4 %

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended March 31, 2021 totaled $54.6 million, of which $27.6 million was recorded as R&D expense. The remaining $26.9 million was recorded as a reduction of the R&D cost share liability.

The decrease in external research and development expenses in the first quarter was primarily attributable to:

- a decrease of $34.5 million related to license fees under collaboration agreements; and
- a decrease of $0.7 million related to expense recognized on co-development fees to Amgen.

The overall decrease in external research and development expense was partially offset in the period by increases in external spending for tislelizumab, ociperlimab, and other clinical programs.

Internal research and development expense increased $40.4 million and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, and included the following:

- $24.6 million increase of employee salary and benefits, primarily attributable to hiring more research and development personnel to support our expanding research and development activities;
- $5.0 million increase of materials and reagent expenses, primarily in connection with the in-house manufacturing of drug candidates used for clinical purposes;
- $4.6 million increase of consulting fees, which was mainly attributable to increased travel and meeting expense related to scientific, regulatory and development consulting activities, in connection with the advancement of our drug candidates;
- $1.5 million increase of share-based compensation expense, primarily attributable to our increased headcount of research and development employees, resulting in more awards being expensed related to the growing research and development employee population; and
- $4.8 million increase of facilities, depreciation, office expense, rental fees, and other expenses to support the growth of our organization.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $75.0 million, or 70.1%, to $182.1 million for the three months ended March 31, 2021, from $107.1 million for the three months ended March 31, 2020. The increase was primarily attributable to the following:

- $34.7 million increase of employee salary and benefits, which was primarily attributable to the expansion of our commercial organizations in China, the United States, Canada, Europe and other emerging markets, and the hiring of more personnel to support our growing business;
- $27.5 million increase in external commercial-related expenses, including market research, sales and marketing, consulting and conference related expenses, related to the growth of our global commercial organization, as we continue to build our worldwide footprint and capabilities;
- $6.7 million increase of professional fees, consulting, recruiting, information technology, tax, accounting and audit services, and facility expenses, rental fees, office expenses, and other administrative expenses, primarily attributable to the global expansion of our business, including the expansion of our commercial operations in China and the United States; and
- $6.1 million increase of share-based compensation expense, primarily attributable to our increased headcount of sales and administrative employees, resulting in more awards being expensed related to the growing sales and administrative employee population.

Interest (Expense) Income, Net

Interest (expense) income, net decreased by $10.9 million, or 162.5%, to $4.2 million of net interest expense for the three months ended March 31, 2021, from $6.7 million of net interest income for three months ended March 31, 2020. The decrease in interest income, net, was primarily attributable to decreased interest income, compared to the prior year period.

Other (Expense) Income, Net

Other (expense) income, net decreased to $4.1 million of net other expense for the three months ended March 31, 2021, from $3.7 million of net other income for the three months ended March 31, 2020. The decrease was mainly attributable to unrealized losses on equity investments in the current period.

Income Tax (Benefit) Expense

Income tax benefit was $4.6 million for the three months ended March 31, 2021, as compared to $1.6 million of income tax expense for the three months ended March 31, 2020. The income tax benefit for three months ended March 31, 2021 was primarily attributable to the deferred tax benefit of U.S. stock-based compensation deductions in excess of tax expense on income reported in certain China subsidiaries as adjusted for certain non-deductible expenses. The income tax expense for the three months ended March 31, 2020 was primarily attributable to tax expense on income reported in certain China subsidiaries offset by the tax benefit of deferred U.S. stock-based compensation deductions.

Liquidity and Capital Resources

The following table represents our cash, short-term investments, and debt balances as of March 31, 2021 and December 31, 2020:

	As of	
	March 31, 2021	December 31, 2020
	(dollars in thousands)	
Cash, cash equivalents and restricted cash	$ 1,910,406	$ 1,390,005
Short-term investments	$ 2,910,472	$ 3,268,725
Total debt	$ 598,062	$ 518,652

With the exception of upfront payments from out-licensing rights to tislelizumab to Novartis, and prior to that BMS, we have incurred net losses and negative cash flows from operations since inception, resulting from the funding of our research and development programs and selling, general and administrative expenses associated with our operations, as well as to support the commercialization of our products globally. We recognized net income of $66.5 million and a net loss of $364.9 million for the

three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of $3.5 billion.

To date, we have financed our operations principally through proceeds from public and private offerings of our securities and proceeds from our collaborations, together with product sales since September 2017. Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of March 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months after the date that the financial statements included in this report are issued.

In January 2021, the Shanghai Stock Exchange (the "SSE") accepted our listing application for a proposed public offering of our ordinary shares and listing of such shares on the Science and Technology Innovation Board (the “STAR Market”) of the SSE (the “STAR Offering”). The STAR Offering will be conducted within the PRC, and such shares will be issued to and subscribed for by investors in Renminbi (“RMB”) in the PRC and listed and traded on the STAR Market in RMB (the “RMB Shares”). The number of RMB Shares (including the over-allotment option) to be issued will not exceed 132,313,549 ordinary shares, representing no more than 10% of the sum of the total number of our issued ordinary shares as of January 7, 2021 and the total number of RMB Shares to be issued in the STAR Offering. The STAR Offering is subject to, among other things, market conditions, the approval of our shareholders, and applicable regulatory approvals.

In January 2021, we entered into a collaboration and license agreement with Novartis Pharma AG ("Novartis"), granting Novartis rights to develop, manufacture and commercialize tislelizumab in North America, Europe, and Japan. Under the agreement, we received an upfront cash payment of $650 million from Novartis subsequent to closing of the transaction on February 26, 2021.

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

	Three Months Ended March 31,	
	2021	2020
	(dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 1,390,005	$ 620,775
Net cash provided by (used in) operating activities	125,095	(341,944)
Net cash provided by (used in) investing activities	291,948	(1,114,969)
Net cash provided by financing activities	107,419	2,802,168
Net effect of foreign exchange rate changes	(4,061)	(6,212)
Net increase in cash, cash equivalents, and restricted cash	520,401	1,339,043
Cash, cash equivalents and restricted cash at end of period	$ 1,910,406	$ 1,959,818

Operating Activities

Cash flows from operating activities is net income adjusted for certain non-cash items and changes in assets and liabilities.

Operating activities provided $125.1 million of cash in the three months ended March 31, 2021, which resulted principally from our net income of $66.5 million, non-cash charges of $33.4 million and a decrease in our net operating assets and liabilities of $25.2 million. The non-cash charges were primarily driven by share-based compensation expense, offset by amortization of the research and development cost share liability. The decrease in working capital was driven largely by an increase in deferred revenue, resulting from the upfront payment from Novartis, as well as a decrease in inventory, partially offset by decreases in accounts payable and accrued expenses, and increases in accounts receivable and prepaid expenses.

Operating activities used $341.9 million of cash in the three months ended March 31, 2020, which resulted principally from our net loss of $364.9 million and an increase in our net operating assets and liabilities of $34.7 million, partially offset by non-cash charges of $57.7 million. The non-cash charges were primarily driven by share-based compensation expense, offset by amortization of the research and development cost share liability. The increase in working capital was driven primarily by an increase in prepaid expenses and other current assets, as well as a decrease in accounts payable, offset by a decrease in accrued expenses and other liabilities.

Investing Activities

Cash flows from investing activities consist primarily of capital expenditures, investment purchases, sales, maturities, and disposals, and upfront payments related to our collaboration agreements.

Investing activities provided $291.9 million of cash in the three months ended March 31, 2021, consisting sales and maturities of investment securities of $1.1 billion, offset by $764.2 million in purchases of investment securities, capital expenditures of $42.4 million, and $8.5 million of acquired in-process research and development.

Investing activities used $1.1 billion of cash in the three months ended March 31, 2020, consisting of $1.3 billion in purchases of investment securities, $43.0 million of acquired in-process research and development, capital expenditures of $21.5 million, all of which were offset by sales and maturities of investment securities of $256.7 million.

Financing Activities

Cash flows from financing activities consist primarily of sale of ordinary shares and ADSs through equity offerings, issuance and repayment of short-term and long-term debt, and proceeds from the sale of ordinary shares and ADSs through employee equity compensation plans.

Financing activities provided $107.4 million of cash in the three months ended March 31, 2021, consisting primarily of $71.0 million from proceeds of short-term bank loans, $25.8 million from the exercise of employee share options and proceeds from the issuance of shares through our employee share purchase plan, and $10.7 million from proceeds of long-term bank loans.

Financing activities provided $2.8 billion of cash in the three months ended March 31, 2020, consisting primarily of $2.8 billion received from our collaboration with Amgen, of which $2.2 billion was recorded as equity, and $0.6 billion was recorded as a research and development cost share liability. Additionally, we received $11.6 million from the exercise of employee share options and proceeds issuance of shares through our employee share purchase plan, and $11.3 million from proceeds of a short-term bank loan.

Effects of Exchange Rates on Cash

We have substantial operations in the PRC, which generate a significant amount of RMB-denominated cash from product sales and require a significant amount of RMB-denominated cash to pay our obligations. Since the reporting currency of the Company is the U.S. dollar, periods of volatility in exchange rates may have a significant impact on our consolidated cash balances.

Operating Capital Requirements

We expect to continue to incur losses for the foreseeable future and expect these losses to increase in the near term, as we continue to develop and seek regulatory approvals for our product candidates, expand our research and manufacturing facilities and activities, and commercialize both our internally developed and in-licensed products. The size of our future net losses will depend, in part, on the number and scope of our development programs and the associated costs of those programs, our ability to generate product revenue, and the timing and amount of payments we make or receive from arrangements with third parties. If any of our medicines and drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our future capital requirements will depend on many factors, including:

- our ability to successfully commercialize our internally developed and in-licensed medicines and drug candidates, if approved;
- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our drug candidates to progress through clinical development successfully;
- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- the number and characteristics of the medicines and drug candidates we pursue;
- the costs of establishing or expanding commercial manufacturing capabilities or securing necessary supplies from third-party manufacturers;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- the costs of establishing and expanding our commercial operations and the success of those operations;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to establish and maintain collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we may be required to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, strategic alliances, licensing arrangements, government grants, and other available sources. Under the rules of the SEC, we currently qualify as a "well-known seasoned issuer," which allows us to file shelf registration statements to register an unspecified amount of securities that are effective upon filing. In May 2020, we filed such a shelf registration statement with the SEC for the issuance of an unspecified amount of ordinary shares (including in the form of ADSs), preferred shares, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement was effective upon filing and will remain in effect for up to three years from filing, prior to which time we may file another shelf registration statement that will be effective for up to three years from filing.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs or ordinary shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaboration agreements, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our medicines or drug candidates, future revenue streams or research programs, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings, collaborations or other sources when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our significant contractual obligations as of the payment due date by period at March 31, 2021:

	Payments Due by Period				
	Total	Less Than 1 Year	1–3 Years	3–5 Years	More Than 5 Years
	(dollars in thousands)				
Contractual obligations					
Operating lease commitments	$ 44,437	$ 16,065	$ 22,366	$ 5,879	$ 127
Purchase commitments	141,159	62,517	33,613	31,173	13,856
Debt obligations	598,062	405,045	19,264	66,859	106,894
Interest on debt	59,077	21,056	17,260	13,301	7,460
Co-development funding commitment	964,437	274,250	580,750	109,437	—
Funding commitment	14,250	4,750	4,750	4,750	—
Pension plan	7,616	956	2,548	2,548	1,564
Capital commitments	51,421	51,421	—	—	—
Total	$ 1,880,459	$ 836,060	$ 680,551	$ 233,947	$ 129,901

Operating Lease Commitments

We lease office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou in China; office facilities in California, Massachusetts, Maryland, and New Jersey in the United States; and in Basel, Switzerland under non-cancelable operating leases expiring on various dates. Payments under operating leases are expensed on a straight-line basis over the respective lease terms. The aggregate future minimum payments under these non-cancelable operating leases are summarized in the table above.

Purchase Commitments

As of March 31, 2021, purchase commitments amounted to $141.2 million, of which $88.0 million related to minimum purchase requirements for supply purchased from CMOs and $53.1 million related to binding purchase obligations of inventory from BMS and Amgen. We do not have any minimum purchase requirements for inventory from BMS or Amgen.

Debt Obligations

The following table summarizes our short-term debt and long-term bank loans as of March 31, 2021 (amounts in thousands, except for percentage data):

Lender	Agreement Date	Line of Credit	Term	Maturity Date	Interest Rate	March 31, 2021	
						$	RMB
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	305	2,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	382	2,500
China Minsheng Bank (the "Senior Loan")	September 24, 2020	$200,000		(3)	5.8 %	198,320	1,299,351
Zhuhai Hillhouse (the "Related Party Loan")	September 24, 2020	RMB500,000		(4)	5.8 %	15,263	100,000
Other short-term debt (5)						190,775	1,249,918
Total short-term debt						405,045	2,653,769
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	88,220	578,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	53,039	347,500
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(6)	51,758	339,111
Total long-term bank loans						193,017	1,264,611

1. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.9% as of March 31, 2021. The loan is secured by BeiGene Guangzhou Factory's land use right and certain Guangzhou Factory fixed assets in the first phase of the Guangzhou manufacturing facility's build out.

2. On January 22, 2020, BeiGene Guangzhou Factory entered into a nine-year bank loan with China Merchants Bank to borrow up to RMB1,100,000 at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan is secured by Guangzhou Factory's second land use right and fixed assets that will be placed into service upon completion of the second phase of the Guangzhou manufacturing facility's build out. In connection with the Company's short-term loan agreements with China Merchants Bank entered into during the year ended December 31, 2020, the borrowing capacity was reduced from RMB1,100,000 to RMB350,000. The loan interest rate was 4.4% as of March 31, 2021.

3. $120,000 of the Senior Loan was designated to fund the JV share purchase and repayment of the shareholder loan and $80,000 was designated for general working capital purposes. The Senior Loan has an original maturity date of October 8, 2021, which is the first anniversary of the first date of utilization of the loan. The Company may extend the original maturity date for up to two additional 12 month periods.

4. RMB100,000 of the Related Party Loan was designated for general corporate purposes and RMB400,000 was designated for repayment of the Senior Loan, including principal, interest and fees. The loan matures at the earlier of: (i) November 9, 2021, which is one month after the Senior Loan maturity date, if not extended, or (ii) 10 business days after the Senior Loan is fully repaid. Zhuhai Hillhouse is a related party of the Company, as it is an affiliate of Hillhouse Capital. Hillhouse Capital is a shareholder of the Company, and a Hillhouse Capital employee is a member of the Company's board of directors.

5. During the year ended December 31, 2020, the Company entered into additional short-term working capital loans with China Industrial Bank and China Merchants Bank to borrow up to RMB1,480,000 in aggregate, with maturity dates ranging from April 19, 2021 to March 7, 2022. The Company drew down $71,001 (RMB460,000) during the three months ended March 31, 2021. The weighted average interest rate for the short-term working capital loans was approximately 4.4% as of March 31, 2021. One of the short-term working capital loans outstanding in the amount of $24,421 (RMB160,000) is secured by the Company's research and development facility in Beijing and the associated land use right owned by its subsidiary, Beijing Innerway Bio-tech Co., Ltd.

6. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.3% as of March 31, 2021. The Company drew down $10,664 (RMB68,905) during the three months ended March 31, 2021. The loan is secured by fixed assets that will be placed into service upon completion of the third phase of the Guangzhou manufacturing facility's build out.

Interest on Debt

Interest on bank loans and the Related Party Loan is paid quarterly until the respective loans are fully settled. For the purpose of contractual obligations calculation, current interest rates on floating rate obligations were used for the remainder contractual life of the outstanding borrowings.

Co-Development Funding Commitment

Under the Amgen collaboration, we are responsible for co-funding global development costs for the licensed Amgen oncology pipeline assets up to a total cap of $1.25 billion. We are funding our portion of the co-development costs by contributing cash and development services. As of March 31, 2021, our remaining co-development funding commitment was $0.96 billion.

Funding commitment

Funding commitment represents our committed capital related to one of our equity method investments in the amount of $15.0 million. As of March 31, 2021, our remaining capital commitment was $14.3 million and is expected to be paid from time to time over the investment period.

Pension Plan

We maintain a defined benefit pension plan in Switzerland. Funding obligations under the defined benefit pension plan are equivalent to $1.3 million per year based on annual funding contributions in effect as of March 31, 2021 to achieve fully funded status where the market value of plan assets equals the projected benefit obligations. Future funding requirements will be subject to change as a result of future changes in staffing and compensation levels, various actuarial assumptions and actual investment returns on plan assets.

Capital Commitments

We had capital commitments amounting to $51.4 million for the acquisition of property, plant and equipment as of March 31, 2021, which was primarily for BeiGene Guangzhou Factory’s manufacturing facility, expansion of BGC's research and development activities in Guangzhou, China, and research and development operations at our Changping facility in Beijing, China.

Other Business Agreements

We enter into agreements in the ordinary course of business with CROs to provide research and development services. These contracts are generally cancelable at any time by us with prior written notice.

We also enter into collaboration agreements with institutions and companies to license intellectual property. We may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with these agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on our balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in our financial statements.

Off-Balance Sheet Arrangements

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. These include, but are not limited to, estimating the useful lives of long-lived assets, estimating variable consideration in product sales and collaboration revenue arrangements, estimating the incremental borrowing rate for operating lease liabilities, identifying separate accounting units and the standalone selling price of each performance obligation in the Company's revenue arrangements, assessing the impairment of long-lived assets, valuation and recognition of share-based compensation expenses, realizability of deferred tax assets and the fair value of financial instruments. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be 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. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies as of and for the three months ended March 31, 2021, as compared to those described in the section titled "Part I—Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020.

For new accounting policies adopted during the three months ended March 31, 2021 , see "Part I—Item 1. Financial Statements—Notes to the Condensed Consolidated Financial Statements—1. Description of Business, Basis of Presentation and Consolidation and Significant Accounting Policies—Significant accounting policies" in this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

See Note 1 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for information regarding recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest and Credit Risk

Financial instruments that are potentially subject to credit risk consist of cash, cash equivalents, restricted cash and short-term investments. The carrying amounts of cash, cash equivalents, restricted cash and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $1.9 billion and $1.4 billion, restricted cash of $8.6 million and $8.1 million, and short-term investments of $2.9 billion and $3.3 billion at March 31, 2021 and December 31, 2020, respectively. At March 31, 2021, the majority of our cash and cash equivalents is held in U.S. treasury securities and U.S. money market funds. We also have cash and cash equivalent deposits with various major reputable financial institutions located both within and outside the PRC. The deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. We believe that these financial institutions are of high credit quality, and we continually monitor the credit worthiness of these financial institutions. Restricted cash represents secured deposits held in designated bank accounts for issuance of letters of credit. At March 31, 2021, our short-term investments consisted of U.S. treasury securities. We believe that the U.S. treasury securities are of high credit quality and continually monitor the credit worthiness of these institutions.

The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significant increasing risk. Our primary exposure to market risk relates to fluctuations in the interest rates, which are affected by changes in the general level of PRC and U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We estimate that a hypothetical 100-basis point increase or decrease in market interest rates would result in a decrease of $16.9 million or an increase of $3.5 million, respectively, as of March 31, 2021.

We do not believe that our cash, cash equivalents and short-term investments have significant risk of default or illiquidity. While we believe our cash, cash equivalents, and short-term investments do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

Foreign Currency Exchange Rate Risk

We are exposed to foreign exchange risk arising from various currency exposures. Our reporting currency is the U.S. dollar, but a portion of our operating transactions and assets and liabilities are in other currencies, such as RMB, Euro, and Australian dollar. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge exposure to such risk.

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange prices. Since 2005, the RMB has been permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. The RMB compared to the U.S. dollar depreciated approximately 0.4% in the three months ended March 31, 2021 and appreciated approximately 6.3% in the year ended December 31, 2020, respectively. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for capital expenditures, working capital and other business purposes, appreciation of RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of the U.S. dollar against RMB would have a negative effect on the U.S. dollar amount available to us.

In addition, a significant depreciation of the RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our foreign cash balances and trade receivables. Further, volatility in exchange rate fluctuations may have a significant impact on the foreign currency translation adjustments recorded in other comprehensive income (loss). We have not used derivative financial instruments to hedge exposure to foreign exchange risk.

Currency Convertibility Risk

A significant portion of our expenses, assets, and liabilities are denominated in RMB. In 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China (the "PBOC"). However, the unification of exchange rates does not imply that the RMB may be readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the three months ended March 31, 2021.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Based on their evaluation, required by paragraph (b) of Rules 13a-15 or 15d-15, promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act are effective, at a reasonable assurance level, as of March 31, 2021, to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in U.S. Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

On June 26, 2020, following the suspension and recall of ABRAXANE® in China supplied to us by Celgene Logistics Sàrl, a Bristol Myers Squibb company (referred to elsewhere in this report as BMS, but for this paragraph only, "Celgene"), we initiated an arbitration proceeding at the International Chamber of Commerce (the "ICC") against Celgene asserting that it had breached and continues to breach the terms and conditions of the License and Supply Agreement entered into by BeiGene and Celgene in July 2017 and a related quality agreement (collectively, the "Celgene License"). Under the Celgene License, we allege that Celgene is obligated, among other things, to ensure the continuity and adequacy of its supply of ABRAXANE® to us. In the arbitration proceeding, we are seeking a declaration that Celgene is in breach of the Celgene License, an award of damages as a result of the breach in an amount to be determined, and such other relief as the ICC deems appropriate. Celgene responded in part by submitting a counterclaim against us seeking to recover approximately $17 million in costs that it incurred as part of the ABRAXANE® recall. We believe that the allegations contained in the counterclaim are without merit and intend to defend the counterclaim vigorously. A hearing is scheduled in the matter for June 2022.

Item 1A. Risk Factors.

The following section includes the most significant factors that we believe may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Quarterly Report, including our financial statements and the related notes and "Part I—Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our ADSs or ordinary shares. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our ADSs and ordinary shares could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

The risk factors denoted with a "", if any, are newly added or have been materially updated from our Annual Report on Form 10-K for the year ended December 31, 2020.*

Risks Related to Commercialization of Our Medicines and Drug Candidates

Our medicines may fail to achieve and maintain the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

Our medicines may fail to achieve and maintain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our medicines. In addition, physicians, patients and third-party payors may prefer other novel or generic products to ours. If our medicines do not achieve and maintain an adequate level of acceptance, the sales of our medicines may be limited and we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our medicines will depend on a number of factors, including:

- the clinical indications for which our medicines are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our medicines as safe and effective treatments;
- government agencies, professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations, and organizations publishing guidelines and recommendations recommending our medicines and reimbursement;
- the potential and perceived advantages of our medicines over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;

- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our medicines as well as competitive medicines;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any medicines that we commercialize fail to achieve and maintain market acceptance among physicians, patients, hospitals, third-party payors, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our medicines achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our medicines, are more cost effective or render our medicines obsolete.

We have limited experience in launching and marketing our internally developed and in-licensed medicines. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our medicines, we may not be able to generate substantial product sales revenue.

We first became a commercial-stage company in 2017, when we entered into a license and supply agreement with Celgene Logistics Sàrl, now a Bristol Myers Squibb company ("BMS"), to commercialize BMS's approved cancer therapies, REVLIMID®, VIDAZA® and ABRAXANE® in the People's Republic of China ("PRC" or "China"), excluding Hong Kong, Macau and Taiwan, and acquired BMS's commercial operations in China, excluding certain functions.

In October 2019, we entered into a strategic collaboration with Amgen for its commercial-stage oncology products XGEVA®, BLINCYTO®, KYPROLIS®, and a portfolio of clinical- and late-preclinical-stage oncology pipeline products, which became effective on January 2, 2020. XGEVA® was approved in China in 2019, while BLINCYTO® was approved in China in December 2020.

We received the first new drug approval for one of our internally developed medicines in November 2019, for our BTK inhibitor BRUKINSA® (zanubrutinib), in the United States for the treatment of certain patients with mantle cell lymphoma ("MCL"). We have since received approvals for BRUKINSA® in China for the treatment of certain patients with MCL, chronic lymphocytic leukemia ("CLL") or small lymphocytic lymphoma ("SLL") (June 2020); and for tislelizumab in China for the treatment of certain patients with classical Hodgkin's Lymphoma ("cHL") (December 2019), urothelial carcinoma ("UC"), a form of bladder cancer (April 2020), and squamous non-small cell lung cancer ("NSCLC") (January 2021).

We continue to build our salesforce in the United States and China to commercialize our internally developed and in-licensed medicines and any additional medicines or drug candidates that we may develop or in-license, which will require significant capital expenditures, management resources and time.

We have limited experience in commercializing our internally developed and in-licensed medicines. We have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our medicines. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, our ability to successfully commercialize our medicines may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in launching medicines.

We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for any or all of our medicines in any country or region, we will likely pursue collaborative arrangements regarding the sales and marketing of our medicines. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our medicines ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our medicines.

There can be no assurance that we will be able to further develop and successfully maintain internal sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any medicine, and as a result, we may not be able to generate substantial product sales revenue.

We face substantial competition, which may result in others discovering, developing, or commercializing competing medicines before or more successfully than we do.

The development and commercialization of new medicines is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of medicines for the treatment of cancer for which we are commercializing our medicines or developing our drug candidates. For example, both BRUKINSA® and tislelizumab face substantial competition, and some of our products face or are expected to face competition from generic therapies. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our medicines. Our competitors also may obtain approval from the FDA, China National Medical Products Administration ("NMPA"), European Medicines Agency ("EMA") or other comparable regulatory authorities for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and or slow our regulatory approval.

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

The market opportunities for our medicines may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

In markets with approved therapies, we have and expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those medicines that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first-line therapy, but there is no guarantee that our medicines and drug candidates, even if approved, would be approved for second-line or first-line therapy.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive later stage therapy and who have the potential to benefit from treatment with our medicines and drug candidates, are based on our beliefs and estimates and may prove to be inaccurate or based on imprecise data. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our medicines and drug candidates may be limited or may not be amenable to treatment with our medicines and drug candidates. Even if we obtain significant market share for our medicines and drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first- or second-line therapy.

If we are not able to continue to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our medicines and drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the drug candidate is safe and effective, or the biologic drug candidate is safe, pure, and potent, for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the new drug application ("NDA") or biologics license application ("BLA") must include significant information regarding the chemistry, manufacturing and controls ("CMC") for the drug candidate. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA or BLA

to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that a submission will be accepted for filing and review by the FDA.

We have limited experience in obtaining regulatory approvals for our drug candidates. For example, we have limited experience in preparing the required materials for regulatory submission and navigating the regulatory approval process. As a result, our ability to successfully submit an NDA or BLA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in obtaining regulatory approvals.

Regulatory authorities outside of the United States, such as the NMPA and EMA, also have requirements for approval of medicines for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals outside of the United States could require additional nonclinical studies or clinical trials, which could be costly and time consuming. The regulatory approval process outside of the United States may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly in the United States, China, Europe and other regions, and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the medicine, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed.

We have limited manufacturing capability and must rely on third-party manufacturers to manufacture some of our commercial products and clinical supplies, and if they fail to meet their obligations, the development and commercialization of our medicines and drug candidates could be adversely affected.

We have limited manufacturing capabilities and experience. Our medicines and drug candidates are composed of multiple components and require specialized formulations for which scale-up and manufacturing can be difficult. We have limited experience in such scale-up and manufacturing, requiring us to depend on a limited number of third parties, who may not be able to deliver in a timely manner, or at all. In order to develop medicines and drug candidates, apply for regulatory approvals, and commercialize our medicines and drug candidates, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our contract manufacturers to meet our delivery time requirements or provide adequate amounts of material to meet our needs.

Although we are manufacturing commercial supply of tislelizumab and zanubrutinib at our own manufacturing facilities in China, we continue to rely on third-party manufacturers to produce some of the commercial quantities of the internally developed and in-licensed medicines we are marketing. In addition, if any of our other drug candidates or in-licensed medicines or drug candidates becomes approved for commercial sale, we will need to expand our internal capacity or establish additional third-party manufacturing capacity. Manufacturing partner requirements may require us to fund capital improvements, perhaps on behalf of third parties, to support the scale-up of manufacturing and related activities. We may not be able to establish scaled manufacturing capacity for an approved medicine in a timely or economic manner, if at all. If we or our third-party manufacturers are unable to provide commercial quantities of such an approved medicine, we will have to successfully transfer manufacturing technology to a different manufacturer. Engaging a new manufacturer or modifying manufacturing processes and procedures for such an approved medicine could require us to conduct comparative studies or utilize other means to determine bioequivalence of the new and prior manufacturers' products or of products manufactured by the old and new processes and procedures, which could delay or prevent our ability to commercialize such an approved medicine. If we or any of these manufacturers is unable or unwilling to increase its manufacturing capacity or if we are unable to establish alternative arrangements on a timely basis or on acceptable terms, the development and commercialization of such an approved medicine may be delayed or there may be a shortage in supply. Any inability to manufacture our medicines, drug candidates, in-licensed medicines and drug candidates or future approved medicines in sufficient quantities when needed could seriously harm our business and our financial results.

Manufacturers of our medicines must comply with good manufacturing practice ("GMP") requirements enforced by the FDA, NMPA, EMA and other comparable foreign health authorities through facilities inspection programs. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our approved medicines may be unable to comply with these GMP requirements and with other FDA, NMPA, EMA, state, and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to a manufacturer's failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our medicines, which would seriously harm our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of ABRAXANE® in China. As a result, there has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at its current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration ("NHSA") removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®. We do not know when the NMPA suspension of ABRAXANE® will be lifted and we will be able to re-commence sales of ABRAXANE®. As such, we do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified medicine is manufactured and available for sale in China.

If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate level of reimbursement, our commercial success and business operations could be adversely affected.

Our ability or the ability of any third parties with which we collaborate to commercialize our medicines successfully will depend in part on the extent to which reimbursement for these medicines is available on adequate terms, or at all, from government health administration authorities, private health insurers and other organizations. In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Sales of our medicines will depend substantially, both domestically and abroad, on the extent to which the costs of our medicines will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Without third-party payor reimbursement, patients may not be able to obtain or afford prescribed medications. Third-party payors also are seeking to encourage the use of generic or biosimilar products or entering into sole source contracts with healthcare providers, which could effectively limit the coverage and level of reimbursement for our medicines and have an adverse impact on the market access or acceptance of our medicines. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our medicines on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare and Medicaid Services (the "CMS"). They decide whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

Coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable regulatory authorities in other countries. Even if we obtain coverage for a given medicine, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our medicines. Patients are unlikely to use our medicines unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the medicine. Because some of our medicines and drug candidates have a higher cost of goods than conventional therapies and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs.

In China, drug prices are typically lower than in the United States and Europe, and until recently, the market has been dominated by generic drugs. Government authorities regularly review the inclusion or removal of medicines from China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List (the "NRDL"), or provincial or local medical insurance catalogues for the National Medical Insurance Program, and the tier under which a medicine will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those medicines. There can be no assurance that our medicines and any approved drug candidates will be included in the NRDL or provincial reimbursements lists, or if they are, that they will be included at a price that allows us to be commercially successful. Products included in the NRDL have typically been generic and essential drugs. Innovative drugs similar to our medicines and drug candidates have historically been more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance, although this has been changing in recent years. For example, BRUKINSA®, tislelizumab and XGEVA® were included in the NRDL, which became effective from March 1, 2021. While we expect that the demand for these medicines will increase with inclusion in the NDRL, there can be no assurance that demand will increase or, to the extent that demand increases, that such increases will be sufficient to offset the reduction in the prices and our margins, which could have a material adverse effect on our business, financial condition and results of operations.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any medicine which we commercialize. Obtaining or maintaining reimbursement for our medicines may be particularly difficult because of the higher prices often associated with medicines administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any medicine and drug candidate that we in-license or successfully develop.

There may be significant delays in obtaining reimbursement for approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by regulatory authorities. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on payments allowed for lower cost medicines that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for our medicines and any new medicines that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

We intend to seek approval to market our medicines and drug candidates in the United States, China, Europe and in other jurisdictions. In some countries, such as those in the EU, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of our medicines will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our medicines and may be affected by existing and future health care reform measures.

We may be subject to anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the United States and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished sales.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act ("FCA"), and physician payment sunshine

laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

Additionally, we are subject to state equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any third-party payor, not just governmental payors, but also private insurers. These laws are enforced by various state agencies and through private actions. Some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or other voluntary industry codes of conduct that restrict the payments made to healthcare providers and other potential referral sources. Several states and local laws also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and require the registration of pharmaceutical sales representatives. State laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal FCA as well as under the false claims laws of several states. Neither the U.S. government nor the U.S. courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, individual imprisonment, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws.

In addition, the approval, commercialization, and other activities for our medicines and drug candidates outside the United States subjects us to non-U.S. equivalents of the healthcare laws such as those mentioned above, among other non-U.S. laws. As with the state equivalents mentioned above, some of these non-U.S. laws may be broader in scope. Data privacy and security laws and regulations in non-U.S. jurisdictions may also be more stringent than those in the United States, such as the General Data Protection Regulation, or GDPR.

If any of the physicians or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may adversely affect our business.

We have operations in the United States, China, Europe and Australia and plan to expand in these and new markets on our own or with collaborators, which exposes us to risks of conducting business in international markets.

We are currently developing and commercializing or plan to commercialize our products in international markets, including China, Europe and other markets outside of the United States, either on or own or with third party collaborators or distributors. Our international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management’s attention from the acquisition or development of drug candidates;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potential third-party patent rights or potentially reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements, including the loss of normal trade status between China and the United States;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act and other anti-bribery and corruption laws; and
- business interruptions resulting from geo-political actions, including trade disputes, war and terrorism, disease or public health pandemics, such as COVID-19, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue in international markets.

The illegal distribution and sale by third parties of counterfeit versions of our medicines or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our medicines, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit medicine may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit medicines sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants or while in- transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Risks Related to Clinical Development and Regulatory Approval of Our Medicines and Drug Candidates

We depend substantially on the success of the clinical development of our medicines and drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals and commercialize our medicines and drug candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business depends on the successful development, regulatory approval and commercialization of our medicines and other drug candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development of our medicines and drug candidates. The success of our medicines and drug candidates depends on several factors, including:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- the performance by contract research organizations ("CROs") or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring that we do not infringe, misappropriate or otherwise violate the valid patent, trade secret or other intellectual property rights of third parties;
- successfully launching our medicines and drug candidates, if and when approved;
- obtaining favorable reimbursement from third-party payors for our medicines and drug candidates, if and when approved;
- competition with other products;

- continued acceptable safety profile following regulatory approval; and
- manufacturing or obtaining sufficient supplies of our medicines, drug candidates and any competitor drug products that may be necessary for use in clinical trials for evaluation of our drug candidates and commercialization of our medicines.

If we do not achieve and maintain one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to obtain additional regulatory approvals for and/or to successfully commercialize our medicines and drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries involved in such trials. A number of companies in our industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

Even if our future clinical trial results show favorable efficacy and durability of anti-tumor responses, not all patients may benefit. For certain drugs, including checkpoint inhibitors, and in certain indications, it is likely that the majority of patients may not respond to the agents at all, some responders may relapse after a period of response, and certain tumor types may appear particularly resistant.

If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to: regulators, institutional review boards ("IRBs"), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; our inability to reach agreements on acceptable terms with CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; manufacturing issues, including problems with manufacturing, supply quality, compliance with GMP, or obtaining sufficient quantities of a drug candidate for use in a clinical trial or for commercialization; clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate; our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including noncompliance with regulatory requirements; the cost of clinical trials of our drug candidates may be greater than we anticipate; and the supply or quality of our medicines and drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates or commercialization of our medicines may be insufficient or inadequate.

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

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to warning labels or restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Significant clinical trial, manufacturing or regulatory delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We have and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol, competition from competing companies, and natural disasters or public health epidemics, such as the COVID-19 pandemic.

Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Risks Related to Extensive Government Regulation

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, and we may face difficulties in complying with or be unable to comply with such regulations, which could have a material adverse effect on our business.

All jurisdictions in which we conduct or intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We are currently focusing our activities in the major markets of the United States, China, Europe, and other select countries. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes-some minor, some significant-that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in each of these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. The failure to comply with these regulations could have a material adverse effect on our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension was based on inspection findings at BMS’s contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of ABRAXANE® in China. As a result, there has been a disruption in

ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the NHSA removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®. Additionally, although we have obtained regulatory approvals of our medicines, regulatory authorities could suspend or withdraw these approvals. In order to market approved products in any given jurisdiction, we must comply with numerous and varying regulatory requirements of such jurisdiction regarding safety, efficacy and quality. In any event, the receipt of regulatory approval does not assure the success of our commercialization efforts for our medicines.

The approval processes of regulatory authorities in the United States, China, Europe and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the NMPA, the EMA, and other comparable regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

Our drug candidates could be delayed or fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or that a biologic candidate is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- reporting or data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- failure to satisfy regulatory conditions regarding endpoints, patient population, available therapies and other requirements for our clinical trials in order to support marketing approval on an accelerated basis or at all;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The FDA, NMPA, EMA or a comparable regulatory authority may require more information, including additional preclinical, CMC, and/or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product revenues from that drug candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug development and approval process, and jeopardize our ability to commence product sales and generate revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

Our development activities and regulatory filings also could be harmed or delayed by a shutdown of the U.S. government, including the FDA, or other governments and regulatory authorities. As of June 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. In July 2020, FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. Since 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

Our medicines and any future approved drug candidates will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our medicines and drug candidates.

Our medicines and any additional drug candidates that are approved will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-marketing information, including both federal and state requirements in the United States and requirements of comparable regulatory authorities in China, Europe and other regions. As such, we and our collaborators will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. Additionally, to the extent we want to make certain changes to the approved medicines, product labeling, or manufacturing processes, we will need to submit new applications or supplements to regulatory authorities for approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, EMA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to GMP regulations. As such, we and our contract manufacturers are and will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA or BLA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The failure to comply with these requirements could have a material adverse effect on our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE® in China. As a result, there has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply.

The regulatory approvals for our medicines and any approvals that we receive for our drug candidates are and may be subject to limitations on the approved indicated uses for which the medicine may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug or drug candidate. The FDA, NMPA, EMA or comparable regulatory authorities may also require a REMS program or comparable program as a condition of approval of our drug candidates or following approval, as is the case with REVLIMID®. In addition, if the FDA, NMPA, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, establishment registration, as well as continued compliance with GMP and good clinical practice ("GCP") for any clinical trials that we conduct post-approval.

The FDA, NMPA, EMA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if compliance with regulatory requirements is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our medicines or drug candidates or with our drug's manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our medicines, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA, NMPA, EMA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;

- product seizure or detention, or refusal to permit the import or export of our medicines and drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA, NMPA, EMA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, NMPA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA, NMPA, EMA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, particularly in China, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we obtain accelerated approval or conditional approval of any of our drug candidates, as we have done with the initial approval of BRUKINSA® in the United States and China and certain approvals of tislelizumab in China, we will be required to conduct a confirmatory study to verify the predicted clinical benefit and may also be required to conduct post-marketing safety studies. Other comparable regulatory authorities may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which could result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

Even if we are able to commercialize our medicines and any approved drug candidates, the medicines may become subject to unfavorable pricing regulations or third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. The EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact our revenues and results of operations.

Our ability to commercialize our medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available on adequate terms, or at all, from government health administration authorities, private health insurers and other organizations. See "— Risks Related to Commercialization of Our Medicines and Drug Candidates — If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate level of reimbursement, our commercial success and business operations could be adversely affected."

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as ASP and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Furthermore, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries, proposed bills or announced plans intended to, among other things, bring more transparency to drug pricing, set patient spending caps, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer's patient programs, reform government program reimbursement methodologies for drug products, allow import of lower-priced drugs from other countries, and set prices based on international reference pricing in other countries. While some proposed measures may require additional authorization to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We cannot be sure whether additional changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be.

In China, the government launched a national program for volume-based, centralized drug procurement with minimum quantity commitments in an attempt to negotiate lower prices from drug manufacturers and reduce the price of drugs. Under the program, one of the key determining factors for a successful bid is the price. The government will award a contract to the lowest bidders who are able to satisfy the quality and quantity requirements. The successful bidders will be guaranteed a sale volume for at least a year. A volume guarantee gives the winner an opportunity to gain or increase market share. The volume guarantee is intended to make manufacturers more willing to cut their prices to win a bid. It may also enable manufacturers to lower their distribution and commercial costs. Many types of drugs are covered under the program, including drugs made by international pharmaceutical companies and generics made by domestic Chinese manufacturers. For example, in January 2020, ABRAXANE® and its generic forms were included in the program. We won the bid and became one of the three companies who were awarded a government contract, with a price for sales of ABRAXANE® under the government contract that would have been significantly lower than the price that we had been charging. On March 25, 2020, the NHSA removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®, which has adversely impacted our business and results of operations. In August 2020, VIDAZA® and its generic forms were included for bidding in the program. We did not win the bid for VIDAZA®, which has resulted in the drug being restricted from use in public hospitals, which account for a large portion of the market, and a decline in sales revenue. Moreover, the program may change how generic drugs are priced and procured in China and is likely to accelerate the replacement of originator drugs with generics. We cannot be sure whether there will be any changes to the program in the future. The implementation of the program may negatively impact our existing commercial operations in China as well as our strategies on how to commercialize our drugs in China, which could have a material adverse effect on our business, financial condition and results of operations.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any medicine which we commercialize. Obtaining or maintaining reimbursement for our medicines may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug and drug candidate that we in-license or successfully develop.

We intend to seek approval to market our drug candidates in the United States, China, Europe and in other jurisdictions. In some non-U.S. countries, for example those in the EU, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of our medicines will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs and may be affected by existing and future health care reform measures.

Although China recently adopted changes to its patent law to include patent term extension and an early resolution mechanism for pharmaceutical patent disputes starting in June 2021, key provisions of the law remain unclear and/or subject to implementing regulations. The absence of effective regulatory exclusivity for pharmaceutical products in China could further increase the risk of early generic or biosimilar competition with our medicines in China.

In the United States, a law commonly referred to as "Hatch-Waxman" provides the opportunity for patent-term restoration of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. The Hatch-Waxman law also provides for patent linkage, pursuant to which FDA will stay approval of certain follow-on new drug applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, for a period of up to 30 months. Finally, the Hatch-Waxman law provides for regulatory exclusivity that can prevent submission or approval of certain follow-on marketing applications. For example, U.S. law provides a five-year period of exclusivity to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical trials to obtain approval for the modification. Similarly, the Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases.

These provisions, which are designed to promote innovation, can prevent competing products from entering the market for a certain period of time after marketing approval for the innovative product.

In China, however, laws on patent term extension, patent linkage, and data exclusivity (referred to as regulatory data protection) are still developing. Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. The Economic and Trade Agreement Between the United States of America and the People's Republic of China announced in January 2020 (the "Trade Agreement") also provides for a mechanism for early resolution of patent disputes and patent term extension systems. To be implemented, this framework will require adoption of legislation and regulations. In October 2020, China adopted amendments to its Patent Law (the “Amended PRC Patent Law”), which will become effective on June 1, 2021. The Amended PRC Patent Law contains both patent term extension and a mechanism for early resolution of patent disputes, which may be comparable to patent linkage in the United States. However, the provisions for patent term extension and an early resolution mechanism are unclear and/or remain subject to the approval of implementing regulations that are still in draft form or have not yet been proposed, leading to uncertainty about their scope and implementation.

Until the relevant implementing regulations for patent term extension and an early resolution mechanism in the Amended PRC Patent Law are implemented, and until data exclusivity is adopted and implemented, we may be subject to earlier generic or biosimilar competition in China than in the United States and other jurisdictions with stronger regulatory data protection for pharmaceutical products.

The manufacturing facilities for our medicines and drug candidates are subject to rigorous regulations and failure to obtain or maintain regulatory approvals or operate in line with established GMPs and international best practices could delay or impair our ability to commercialize our medicines or drug candidates.

We and the third-party manufacturers of our medicines and drug candidates are subject to applicable GMPs prescribed by the FDA and other rules and regulations prescribed by the NMPA, EMA and other regulatory authorities. To obtain FDA, NMPA and EMA approval for our drug candidates in the United States, China and Europe, we need to undergo strict pre-approval inspections of our or our third-party manufacturing facilities located in China and elsewhere. Historically, some manufacturing facilities in China have had difficulty meeting the FDA’s, NMPA's or EMA's standards. When inspecting our or our contractors' manufacturing facilities, the FDA, NMPA or EMA might cite GMP deficiencies, both minor and significant, which we may not be required to disclose. Remediating deficiencies can be laborious and costly and consume significant periods of time. Moreover, if the FDA, NMPA or EMA notes deficiencies as a result of its inspection, it will generally reinspect the facility to determine if the deficiency has been remediated to its satisfaction. The FDA, NMPA or EMA may note further deficiencies as a result of its reinspection, either related to the previously identified deficiency or otherwise. If we or the manufacturers of our drug candidates cannot satisfy the FDA, NMPA and EMA as to compliance with GMP in a timely basis, marketing approval for our drug candidates could be seriously delayed, which in turn would delay commercialization of our drug candidates.

Undesirable adverse events caused by our medicines and drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events ("AEs") caused by our medicines and drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval, or could result in limitations or withdrawal following approvals. If the conduct or results of our trials or patient experience following approval reveal a high and unacceptable severity or prevalence of AEs, our trials could be suspended or terminated and regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates or require us to cease commercialization following approval.

As is typical in the development of pharmaceutical products, drug-related AEs and serious AEs ("SAEs") have been reported in our clinical trials. Some of these events have led to patient deaths. Drug-related AEs or SAEs could affect patient recruitment or the ability of enrolled subjects to complete the trial and could result in product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In our periodic and current reports filed with the SEC and our press releases and scientific and medical presentations released from time to time we disclose clinical results for our drug candidates, including the occurrence of AEs and SAEs. Each such disclosure speaks only as of the date of the data cutoff used in such report, and we undertake no duty to update such information unless required by applicable law. Also, a number of immune-related adverse events ("IRAEs") have been associated with treatment with checkpoint inhibitors such as tislelizumab, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and renal dysfunction, skin adverse reactions, and encephalitis. These IRAEs may be more common in certain patient

populations (potentially including elderly patients) and may be exacerbated when checkpoint inhibitors are combined with other therapies.

Additionally, undesirable side effects caused by our medicines and drug candidates, or caused by our medicines and drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including:

- regulatory authorities could delay or halt pending clinical trials;
- we may suspend, delay or alter development of the drug candidate or marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label;
- we may be required to implement a Risk Evaluation Mitigation Strategy ("REMS") for the drug, as is the case with REVLIMID®, or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a regulatory authority;
- we may be required to conduct post-marketing studies; and
- we could be sued and held liable for harm caused to subjects or patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug or drug candidate, and could significantly harm our business, results of operations, financial condition, and prospects.

If safety, efficacy, or other issues arise with any medical product that is used in combination with our medicines, we may be unable to market such medicine or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our medicines and drug candidates for use as a combination therapy. If a regulatory authority revokes its approval of the other therapeutic that we use in combination with our medicines or drug candidates, we will not be able to market our medicines or drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our medicines and drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination medicines or drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline or at all, or we may experience disruptions in the commercialization of our approved medicines. For example, we have in-licensed drug candidates from third parties to conduct clinical trials in combination with our drug candidates. We may rely on those third parties to manufacture the in-licensed drug candidates and may not have control over their manufacturing process. If these third parties encounter any manufacturing difficulties, disruptions or delays and are not able to supply sufficient quantities of drug candidates, our drug combination study program may be delayed.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our medicines and drug candidates and affect the prices we may obtain.

In the United States, China, the EU and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our medicines and any drug candidates for which we obtain regulatory approval. We expect that healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved medicine. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our medicines and drug candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether any regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our medicines and drug candidates may be.

For example, in the United States, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act (the “ACA”), and we expect there will be additional challenges and amendments

to the ACA in the future. The United States Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 ("Tax Act") includes a provision that decreased the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the “individual mandate,” to nil, effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. Pending a decision, the ACA remains in effect, but it is unclear at this time what effect these developments will have on the status of the ACA.

Further, on January 20, 2017, former President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, former President Trump signed another Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The former Trump administration concluded that cost-sharing reduction ("CSR") payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings will have on our business, especially given the new administration.

In addition, CMS published a final rule that would give states greater flexibility as of 2020 in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may not become profitable.

Investment in pharmaceutical drug development is highly capital-intensive and speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we have incurred losses in each period since our inception, except in the third quarter of 2017 and the first quarter of 2021, when we were profitable due to revenue recognized from an up-front license fee from collaboration agreements. As of March 31, 2021 and December 31, 2020, we had an accumulated deficit of $3.5 billion and $3.6 billion, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative expenses associated with our operations.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase in the near term as we continue and expand our development of, and seek regulatory approvals for, our drug candidates, and our manufacturing facilities, commercialize our medicines and launch new medicines, if approved, maintain and expand regulatory approvals, contribute up to $1.25 billion to the global development of a portfolio of Amgen pipeline assets under our collaboration agreement, and commercialize the medicines that we have licensed from Amgen, BMS and other parties and any other medicines that we may successfully develop or license. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company. We will also incur costs in support of our growth as a commercial-stage global biotechnology company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of our manufacturing activities, the cost of commercializing our approved products,

our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with arrangements with third parties. If we fail to achieve market acceptance for our medicines or any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research, development, manufacturing and commercialization efforts, expand our business or continue our operations.

We have limited experience in obtaining regulatory approvals and commercializing pharmaceutical products, which may make it difficult to evaluate our current business and predict our future performance.

We have limited experience in completing large-scale, pivotal or registrational clinical trials and obtaining, maintaining or expanding regulatory approvals for our medicines and drug candidates. Additionally, we have limited experience in manufacturing, sales, marketing or distribution of pharmaceutical products. We became a commercial-stage company in 2017, with the in-license of medicines in China from BMS, and received the first approvals for our internally developed drug candidates in late 2019 in the United States and in 2020 in China. Our limited experience operating as a commercial-stage company may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development of our drug candidates or achieve profitability.

Our portfolio of drug candidates will require the completion of clinical development, regulatory review, scale up and availability of manufacturing resources, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Additionally, we are investing in the manufacturing and commercialization of our approved medicines. Our operations have consumed substantial amounts of cash since inception. Our operating activities used $1.3 billion and $750.3 million of net cash during the years ended December 31, 2020 and 2019, respectively, and provided $125.1 million and used $341.9 million of net cash during the three months ended March 31, 2021 and 2020, respectively. We recorded negative net cash flows from operating activities in 2020 and 2019 primarily due to our net losses of $1.6 billion and $950.6 million, respectively. Although we recorded positive net cash flows from operating activities in 2017, primarily due to the upfront fees received from the BMS collaboration, we cannot assure you that we will be able to generate positive cash flows from operating activities in the future. In January 2020, we received approximately $2.8 billion from the sale of our shares to Amgen, and in July 2020, we received approximately $2.1 billion from the sale of our shares to eight existing investors, including entities associated with Hillhouse Capital and Baker Bros. Advisors LP, as well as Amgen. In February 2021, we received $650 million upfront cash payment from our strategic collaboration with Novartis Pharma AG ("Novartis").

Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise financing by issuing further equity securities your interest in our company may be diluted. If we have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, contributing to the global development of a portfolio of Amgen pipeline assets, developing our manufacturing capabilities and securing drug supply, and launching and commercializing our and our collaborators' medicines and any additional drug candidates for which we receive regulatory approval, including building and maintaining a commercial organization to address markets in China, the United States and other countries.

Since September 2017, we have generated revenues from the sale of medicines in China licensed from BMS, and since the fourth quarter of 2019, we have generated revenues from our internally developed medicines. These revenues are not sufficient to support our operations. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that we have sufficient cash, cash equivalents and short-term investments to meet our projected operating requirements for at least the next 12 months. However, we believe that our existing cash, cash equivalents and short-term investments may not be sufficient to enable us to complete all global development or launch all of our current medicines and drug candidates for the currently anticipated indications and to invest in additional programs. Accordingly, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward- looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including

the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- our ability to successfully market our approved medicines;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the number and characteristics of medicines and drug candidates that we may in-license and develop;
- the amount and timing of the development, milestone and royalty payments we receive from our collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our medicines and any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions, licensing and/or the development of other medicines and drug candidates;
- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities; and
- our headcount growth and associated costs.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

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

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

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially reduce the value of your investment.

We incur portions of our expenses, and derive revenues, in currencies other than the U.S. dollar or Hong Kong dollar, in particular, the RMB, the Euro, and Australian dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We do not regularly engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we operate could have a negative impact on our results of operations. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations, and cash flows.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy proposed or adopted by the PRC, Australia and other governments. It is difficult to predict how market forces or PRC, Australia, other governments outside the U.S. and U.S.

government policies may impact the exchange rate of RMB and the U.S. dollar or any other currencies in the future. There remains significant international pressure on the China to adopt a more flexible currency policy, including from the U.S. government, which has threatened to label China as a "currency manipulator," which could result in greater fluctuation of the RMB against the U.S. dollar.

Substantially all of our revenues are denominated in U.S. dollars and RMB, our costs are denominated in U.S. dollars, Australian dollars and RMB, and a large portion of our financial assets and a significant portion of our debt is denominated in U.S. dollars and RMB. To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount we would receive.

In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to obtain the Chinese government approval before converting significant sums of foreign currencies into RMB. All of these factors could materially and adversely affect our business, financial condition, results of operations, and prospects, and could reduce the value of, and any dividends payable on, our shares in foreign currency terms.

Our business, profitability and liquidity may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers, and an impairment in the carrying value of our short-term investments could negatively affect our consolidated results of operations.

We are exposed to the risk that our distributors and customers may default on their obligations to us as a result of bankruptcy, lack of liquidity, operational failure or other reasons. As we continue to expand our business, the amount and duration of our credit exposure will be expected to increase, as will the breadth of the entities to which we have credit exposure. Although we regularly review our credit exposure to specific distributors and customers that we believe may present credit concerns, default risks may arise from events or circumstances that are difficult to detect or foresee.

Also, the carrying amounts of cash and cash equivalents, restricted cash and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of $1.9 billion, $1.4 billion and $618.0 million, restricted cash of $8.6 million, $8.1 million and $2.8 million and short-term investments of $2.9 billion, $3.3 billion and $364.7 million as of March 31, 2021, December 31, 2020 and 2019, respectively, most of which are deposited in financial institutions outside of China. Although our cash and cash equivalents in China are deposited with various major reputable financial institutions, the deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. As of March 31, 2021 and December 31, 2020, our short-term investments consisted of U.S. Treasury securities.

Although we believe that the U.S. Treasury securities are of high credit quality and continually monitor the credit worthiness of these institutions, concerns about, or a default by, one institution in the U.S. market, could lead to significant liquidity problems, losses or defaults by other institutions, which in turn could adversely affect us.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to protect our medicines, drug candidates and proprietary technology from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the medicines, drug candidates and technology that we consider commercially important by filing patent applications in the United States, the PRC, the EU and other territories, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and/or patent applications at a reasonable cost or in a timely manner. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent applications or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and any other third parties, any of these parties may breach such

agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, the PRC and the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the National Intellectual Property Administration, or NIPA, for security examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

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

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

Furthermore, although various extensions may be available, the life of a patent and the protection it affords, is limited. For example, the approved cancer therapies we have licensed from BMS in China face competition from generic medications, and we may face similar competition for our approved medicines even if we successfully obtain patent protection. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our medicines and drug candidates are expected to expire on various dates as described in “Part I-Item 1-Business-Intellectual Property” of our Annual Report. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with or licensed from third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners or the licensors of our patents in order to enforce such patents against third parties, and such cooperation

may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We may not be able to protect our intellectual property rights throughout the world. If we fail to adequately protect our intellectual property rights, our competitive position could be impaired and our business could be materially harmed.

Filing, prosecuting, maintaining and defending patents on drugs or drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than in the United States. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as U.S. laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drugs made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the United States. These drugs may compete with our medicines and drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing. In addition, we may not be able to enforce patents that we in-license from third parties, who may delay or decline to enforce patents in the licensed territory.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our medicines and drug candidates could be found invalid or unenforceable if challenged in court or before government patent authorities.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us challenging the validity or enforceability of our patents or alleging that we infringe their intellectual property rights.

Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our medicines or drug candidates. The outcome following legal

assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our medicines or drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our medicines or drug candidates.

Our commercial success depends in part on our avoiding infringement of the valid patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields of our medicines and drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our medicines and drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our medicines and drug candidates. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing medicines and drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our medicines or drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our medicines and drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

We are aware of patents in the U.S. and some other jurisdictions with claims covering certain antibodies that are relevant to tislelizumab for which patents are expected to expire in 2023 or 2024; complexes of irreversible BTK inhibitors that are relevant to BRUKINSA® for which the patent is expected to expire in 2027; and the use of PARP inhibitors to treat certain cancers that are relevant to pamiparib for which patents are expected to expire between 2027 and 2031. We are also aware of issued patents in Europe and China relevant to pamiparib. Although we believe that the relevant claims of these patents would likely be held invalid, we can provide no assurance that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims of one or more of these patents were to be upheld upon a validity challenge, and our related medicine was approved for sale in the United States before the expiration of the relevant patents, we would need a license to commercialize the medicine in the United States before the expiration of the relevant patents. In addition, depending upon the circumstances, we may need licenses for jurisdictions outside of the United States where we wish to commercialize a particular medicine before the expiration of corresponding patents covering that medicine. In such cases, we can provide no assurance that we would be able to obtain a license or licenses on commercially reasonable terms or at all, which could materially and adversely affect our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more

effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. The USPTO and other patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If we do not obtain patent term extension and regulatory exclusivity for our medicines, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our medicines and drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman law. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, although China has amended its patent law, effective on June 1, 2021, to include patent term extension, the patent term extension provision of the law is unclear and/or remains subject to the approval of implementing regulations that are still in draft form or have not yet been proposed, leading to uncertainty about its scope and implementation. As a result, the patents we have in the PRC are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our medicines or drug candidates.

The laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our medicines and drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time- consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and in some cases non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or

disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications. These license agreements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any medicine or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements.

Risks Related to Our Reliance on Third Parties

If we fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.

We rely on third-party distributors to distribute our approved medicines. For example, we rely on sole third-party distributors to distribute Amgen's and BMS's approved cancer therapies in China and multiple third-party distributors for the distribution of our internally developed medicines. We also expect to rely on third-party distributors to distribute our other internally developed and in-licensed medicines, if approved. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our medicines. However, we have relatively limited control over our distributors, who may fail to distribute our medicines in the manner we contemplate. For example, while we have long-standing business relationship with our sole distributor for the in-licensed products from BMS, the agreement we entered into with our sole distributor can be terminated by either party upon six months' written notice. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our medicines to hospitals, medical institutions and sub-distributors, they may terminate their relationship with us. While we believe alternative distributors are readily available, there is a risk that, if the distribution of our medicines is interrupted, our sales volumes and business prospects could be adversely affected.

****We rely on third parties to manufacture some of our commercial and clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.***

Although we currently have manufacturing facilities that are used for clinical-scale and commercial-scale manufacturing and processing, we continue to rely on outside vendors to manufacture supplies and process some of our medicines and drug candidates. For example, we have entered into a commercial supply agreement for tislelizumab with Boehringer Ingelheim Biopharmaceuticals (China) Ltd. ("Boehringer Ingelheim") and entered into a commercial supply agreement for BRUKINSA® with Catalent Pharma Solutions, LLC ("Catalent"). In addition, we rely on BMS and its third-party manufacturers for supply of REVLIMID®, VIDAZA® and ABRAXANE® in China. We rely on Amgen for the supply of XGEVA® and BLINCYTO® and will be dependent on Amgen for the supply of other drugs that we plan to develop and commercialize in China under the collaboration with Amgen. We have limited experience in manufacturing or processing our medicines and drug candidates on a commercial scale. Additionally, we have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

Although we intend to use our own manufacturing facilities, we also intend to use third parties as part of our manufacturing process and for the clinical and commercial supply of our medicines and drug candidates. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our medicines and drug candidates. This evaluation would require new testing and GMP-compliance inspections by regulatory authorities;
- our manufacturers may have little or no experience with manufacturing our medicines and drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our medicines and drug candidates;
- our third-party manufacturers might be unable to timely manufacture our medicines and drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any. For example, we encountered supply disruptions of ABRAXANE® in 2019, and in 2020 the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS, as further described below;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with GMPs and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements. For example, in 2020, based on inspection findings at BMS's contract manufacturing facility in the United States, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS, as further described below;
- we may not own, or may have to share, the intellectual property rights to some of the technology used and improvements made by our third-party manufacturers in the manufacturing process for our medicines and drug candidates;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and drug component suppliers may be subject to disruptions in their business, including unexpected demand for or shortage of raw materials or components, cyber-attacks on supplier systems, labor disputes or shortage and inclement weather, as well as natural or man-made disasters or pandemics.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact development of our drug candidates or commercialization of our medicines. In addition, we will rely on third parties to perform certain specification tests on our medicines and drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE® in China. There has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the NHSA removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®. Additionally, there are risks that our supplemental import drug application for ABRAXANE®, which was accepted by the NMPA in May 2019, as well as our clinical study evaluating tislelizumab in combination with ABRAXANE®, may be adversely affected. Until the corrective actions are implemented and accepted by the NMPA or the approval of an alternative manufacturing site is granted, the NMPA may refuse to grant approval of applications for ABRAXANE® and/or refuse to grant import certificates for ABRAXANE®. We do not know when the NMPA suspension of ABRAXANE® will be lifted and we will be able to re-commence sales of ABRAXANE®. As such, we do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified drug is manufactured and available for sale in China.

Currently, the raw materials for our manufacturing activities are supplied by multiple source suppliers, although portions of our supply chain may rely on sole source suppliers. We have agreements for the supply of drug materials with manufacturers or

suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business. Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and/or commercial medicines, which could lead to delays in these trials and/or issues with our commercial supply. Throughout the COVID-19 pandemic, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our business and results of operations could be materially impacted. If we or our third party manufacturers experience a shortage in supply of active ingredients or other raw materials, we may not be able to continue to supply adequate levels of our medicines to our customers, which would have a negative impact on our business and results of operations.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in the supply of our medicines and drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our medicines and drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our medicines for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.

Before a third party can begin commercial manufacture of our medicines, they are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture drug and biological products, any potential third-party manufacturer may be unable to initially pass regulatory inspections in a timely or cost-effective manner in order for us to obtain regulatory approval. If contract manufacturers do not pass their inspections by the relevant regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates or disruption in sales. In addition, drug and biological manufacturing facilities are continuously subject to inspection by regulatory authorities, before and after drug approval, and must comply with GMPs. Our or our collaborators' contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we or our collaborators' contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE® in China. As a result, there has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the NHSA removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®. In addition to any possible sanctions, we do not expect to recognize revenue from sales of ABRAXANE® in China until the suspension on the importation, sales and use of ABRAXANE® in China is lifted by

the NMPA and qualified drug is manufactured and available for sale in China, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, could require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. This review may be costly and time consuming and could delay or prevent the launch of a product or impact commercialization or continuous supply of approved drugs. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay. For example, we are working with BMS to restore supply of ABRAXANE® as soon as possible, including through BMS's application to qualify an alternative manufacturing site for China supply, which requires prior review and approval by the NMPA and is subject to various requirements described above.

We have entered into licensing and collaboration arrangements and may enter into additional collaborations, licensing arrangements, or strategic alliances in the future, and we may not realize the benefits of such arrangements.

We have entered into licensing and collaboration agreements and may enter into additional collaboration, licensing arrangements, or strategic alliances with third parties that we believe will complement or augment our research, development and commercialization efforts. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

In August 2017, we acquired Celgene's commercial operations in China and an exclusive license to Celgene's (now BMS's) commercial cancer portfolio in China, REVLIMID®, VIDAZA® and ABRAXANE® (the "BMS China License"). In 2019, we entered into a strategic collaboration with Amgen with respect to its commercial-stage oncology products XGEVA®, BLINCYTO® and KYPROLIS® and a portfolio of clinical- and late-preclinical-stage oncology pipeline products. In 2021, we entered into a collaboration and license agreement with Novartis, granting Novartis rights to develop, manufacture and commercialize our anti-PD-1 antibody tislelizumab in North America, Japan, the EU, and six other European countries.

Our strategic collaborations with Amgen, Novartis and BMS involve numerous risks. For our collaboration with Amgen, we cannot be certain that we will achieve the financial and other benefits that led us to enter into the collaboration. Moreover, we may not achieve the revenue and cost synergies expected from our collaborations with Amgen or BMS for their commercial products in China, and our management's attention may be diverted from our drug discovery and development business. For our collaboration with Novartis, we cannot be certain that we will achieve potential benefits that led us to enter into the collaboration. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Lastly, strategic collaborations can be terminated for various reasons. For example, our strategic collaboration with Celgene for the development and commercialization of tislelizumab, which we entered into in connection with the BMS China License in 2017, was terminated in June 2019 in advance of the acquisition of Celgene by BMS, and we received a $150.0 million payment and regained global rights to tislelizumab. The termination of the collaboration agreement for tislelizumab did not impact the BMS China License, which remains in effect.

Additionally, from time to time, we may enter into joint ventures with other companies. Establishment of a joint venture involves significant risks and uncertainties, including (i) our ability to cooperate with our strategic partner, (ii) our strategic partner having economic, business, or legal interests or goals that are inconsistent with ours, and (iii) the potential that our strategic partner may be unable to meet its economic or other obligations, which may require us to fulfill those obligations alone.

We face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic collaboration or other alternative arrangements for our medicines and drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our medicines and drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a medicine or drug candidate, we can expect to relinquish some or all of the control over the future success of that medicine or drug candidate to the third party. For any medicines or drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biotechnology companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

Collaborations involving our medicines and drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates and medicines or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our medicines or drug candidates;
- a collaborator with marketing and distribution rights to one or more medicines may not commit sufficient resources to their marketing and distribution or may set prices that reduce the profitability of the medicines;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; for example, the China patents for KYPROLIS® (carfilzomib) are in an invalidation proceeding brought by another company and if such patents are not successfully defended we could face generic competition in China sooner than expected, which would have a material adverse effect on any potential sales of KYPROLIS® in China, once approved;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our medicines and drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable medicines and drug candidates; and
- collaborators may own or co-own intellectual property covering our medicines and drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations, licensing arrangements or strategic alliances for our medicines and drug candidates if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will be able to fulfill all of our contractual obligations in a timely manner or achieve the revenue, specific net income or other goals that justify such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our medicines and drug candidates or bring them to market and generate product revenue, which would harm our business prospects, financial condition and results of operations.

If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize.

We have a collaboration agreement with Amgen pursuant to which we and Amgen have agreed to collaborate on the commercialization of Amgen's oncology products XGEVA®, BLINCYTO® and KYPROLIS® in China, and the global development and commercialization in China of a portfolio of Amgen's clinical- and late-preclinical-stage pipeline products. Amgen has paused or stopped development of some of the pipeline assets due to portfolio prioritization, and the parties expect that the development plan for the pipeline assets will continue to evolve over time. Additionally, Amgen has advised us that its applications to the Human Genetic Resources Administration of China ("HGRAC") to obtain approval to conduct clinical

studies in China for the pipeline assets, including its application for sotorasib (AMG 510), a first-in-class investigational KRAS G12C inhibitor, are currently delayed. Approval from the HGRAC is required for the initiation of clinical trials involving the collection of human genetic materials in China. We do not expect this to affect the conduct of the clinical trials in China for our drug candidates, other than assets that are part of the collaboration. The Amgen collaboration involves numerous risks, including unanticipated costs and diversion of our management's attention from our other drug discovery and development business. There can be no assurance that we will be able to successfully develop and commercialize Amgen's oncology products in China, which could disrupt our business and harm our financial results.

Moreover, we may not achieve the revenue and cost synergies expected from the Amgen transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from the Amgen transaction may be offset by increases in other expenses, operating losses or problems in our business unrelated to the Amgen transaction. As a result, there can be no assurance that such synergies will be achieved.

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by regulatory authorities for all of our drug candidates in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCPs and other regulatory requirements, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with drug product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We could also be subject to government investigations and enforcement actions.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

Risks Related to Our Industry, Business and Operations

****We have significantly increased and expect to continue to increase our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.***

At the beginning of 2020, we had approximately 3,400 employees, and we ended the year with approximately 5,100 employees, an increase of 50%. As of March 31, 2021, we had approximately 5,400 employees. We expect to continue our growth. Most of our employees are full-time. As our research, development, manufacturing and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, drug development, clinical, regulatory affairs, manufacturing, sales, marketing, financial and other personnel in the United States, China, Europe and other regions. Our recent growth and any anticipated future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;

- managing the growth in our research, clinical operations, commercial, and supporting functions;
- managing our internal development efforts effectively, including the clinical and regulatory review process for our drug candidates, while complying with our contractual obligations to third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop and commercialize our medicines and drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our medicines and drug candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals.

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

We are highly dependent on Xiaodong Wang, Ph.D., our Co-Founder, Chairman of our scientific advisory board, and director; John V. Oyler, our Co-Founder, Chief Executive Officer and Chairman of the board of directors; Xiaobin Wu, Ph.D., our President, Chief Operating Officer and General Manager of China; and the other principal members of our management and scientific teams. Although we have employment agreements or offer letters with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided share option, restricted share unit and restricted share grants that vest over time or based on performance conditions. The value to employees of these equity grants that may be significantly affected by movements in our share price that are beyond our control and may be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements or offer letters with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating and executing our discovery, clinical development, manufacturing and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development, manufacturing and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executives, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our business is subject to complex and evolving industry-specific laws and regulations regarding the collection and transfer of personal data. These laws and regulations can be complex and stringent, and many are subject to change and uncertain interpretation, which could result in claims, changes to our data and other business practices, significant penalties, increased cost of operations, or otherwise adversely impact our business.

Regulatory authorities around the world have implemented industry-specific laws and regulations that affect the collection and transfer of personal data. For example, in China, the Regulation on the Administration of Human Genetic Resources promulgated by the State Council (the "HGR Regulation"), which became effective in 2019, applies to activities that involve sampling, biobanking, use of HGR materials and associated data, in China, and provision of such to foreign parties. The HGR Regulation prohibits both onshore or offshore entities established or actually controlled by foreign entities and individuals from sampling or biobanking any China HGR in China and require approval for the sampling of certain HGR and biobanking of all HGR by Chinese parties. Approval for any export or cross-border transfer of the HGR material is required, and transfer of China HGR data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data to the HGR administration for record. The HGR Regulation also requires that foreign parties ensure the full participation of Chinese parties in international collaborations and all records and data must be shared with the Chinese parties. For information about applications under the HGR Regulation for clinical studies in China that are part of the Amgen- BeiGene Collaboration, see the risk factor entitled "If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize."

If the Chinese parties fail to comply with data protection laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, it could result in a loss of our confidential information and subject us to litigation and government enforcement actions. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our or our collaborators' practices, potentially resulting in suspension of relevant ongoing clinical trials or the initiation of new trials, confiscation of HGR samples and associated data and administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further HGR projects and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in China. So far, the HGR administration has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain HGR materials to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGR administration to take rectification measures and at the same time banned from submitting any HGR applications until the HGR administration was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, a public hospital was found to have illegally transferred certain HGR data to a university in Europe, and that hospital was eventually subject to the same ban.

To further tighten the control of China HGR, the government adopted amendments to the criminal code, which became effective on March 1, 2021, which criminalize the illegal collection of China HGR, the illegal transfer of China HGR materials outside of China, and the transfer of China HGR data to foreign parties or entities established or actually controlled by them without going through security review and assessment. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to 7 years, and/or a criminal fine. On April 15, 2021, the Biosecurity Law became effective. The Biosecurity Law establishes an integrated system to regulate biosecurity-related activities in China, including the security regulation of HGR and biological resources. The Biosecurity Law for the first time expressly declares that China has sovereignty over its HGR and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese HGR by foreign entities in China. Although the Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulatory authority of HGR, i.e., the Ministry of Science and Technology, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for Chinese HGR will evolve and become even more rigorous. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

We expect that these areas will receive greater and continued attention and scrutiny from regulators and the public going forward, which could increase our compliance costs and subject us to heightened risks and challenges associated with data security and protection. If we are unable to manage these risks, we could become subject to significant penalties, including fines, suspension of business and revocation of required licenses, and our reputation and results of operations could be materially and adversely affected.

We manufacture some of our medicines and intend to manufacture some of our drug candidates, if approved. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

We currently have manufacturing facilities in Beijing, Guangzhou, and Suzhou, China. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction or expansion, regulatory evaluation and/or approval of our facilities are delayed, we may not be able to manufacture sufficient quantities of our medicines and drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources.

In addition to the similar manufacturing risks described in "Risks Related to Our Reliance on Third Parties," our manufacturing facilities are subject to inspection in connection with clinical development and new drug approvals and ongoing, periodic inspection by the FDA, NMPA, EMA or other comparable regulatory agencies to ensure compliance with GMP and other regulatory requirements. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our medicines. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, NMPA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with GMP regulations and other requirements of the FDA, NMPA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of drug candidates or medicines, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete.

To supply commercial quantities for our marketed products, produce our medicines in the quantities that we believe will be required to meet anticipated market demand, and to supply clinical drug material to support the continued growth of our clinical programs, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production, which will require substantial additional expenditures and various regulatory approvals and permits. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our medicines in a sufficient quantity to meet future demand.

In addition to the similar manufacturing risks described in "Risks Related to Our Reliance on Third Parties," if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any medicines manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates or medicines in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property, plant and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates and medicines if there were a catastrophic event or interruption or failure of our manufacturing facilities or processes.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance requirements, including establishing and maintaining internal controls over financial reporting. We may be exposed to potential risks if we are unable to comply with these requirements.

As a public company in the United States and Hong Kong, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the listing rules of the Nasdaq Stock Market ("Nasdaq") and The Stock Exchange of Hong Kong Limited (the "HKEx"), and incur significant legal, accounting and other expenses to comply with applicable requirements. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

For example, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Such compliance may require that we incur substantial accounting expenses and expend significant management efforts. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, the market price of our shares could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC, HKEx or other applicable regulatory authorities, and our business could be harmed.

If we engage in acquisitions or strategic collaborations, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or strategic collaborations, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For example, in connection with the Amgen transaction, we issued to Amgen a total of 206,635,013 ordinary shares in the form of ADSs, representing 20.5% of the issued share capital of the Company after giving effect to the share issuance, which resulted in Amgen becoming our largest shareholder and the ownership of our existing shareholders being diluted.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (the "M&A Rules"), and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the Ministry of Commerce of the PRC (the "MOFCOM") be notified in advance of any change-of-control transaction in which a foreign investor takes

control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of the PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (the "Prior Notification Rules") issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the State Administration of Market Regulation (the "SAMR") when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Measures for Security Review of Foreign Investment jointly issued by the National Development and Reform Commission and MOFCOM and the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (the "Security Review Rules") issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements.

We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (the "CFIUS") and other agencies, including the Foreign Investment Risk Review Modernization Act (the "FIRRMA"),which became effective in February 2020.

In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from CFIUS, the SAMR, the MOFCOM or other agencies may delay or inhibit our ability to complete such transactions. It is unclear whether those complementary businesses we may acquire in the future would be deemed to be in an industry that raises “national defense and security” or “national security” concerns.

However, CFIUS, MOFCOM or other government agencies may publish explanations in the future determining that certain of the complementary business is in an industry subject to the security review, in which case our future acquisitions in the United States and the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

If we fail to comply with the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the Foreign Corrupt Practices Act (the "FCPA"). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery and corruption laws of other jurisdictions, particularly China. The anti-bribery laws in China generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. As our business has expanded, the applicability of the FCPA and other anti-bribery and corruption laws to our operations has increased.

We do not fully control the interactions our employees, distributors and third-party promoters have with hospitals, medical institutions and doctors, and they may try to increase sales volumes of our products through means that constitute violations of United States, PRC or other countries’ anti-corruption and related laws. If our employees, distributors or third-party promoters engage in corrupt or other improper conduct that results in violation of applicable anti-corruption laws, our reputation could be harmed. Furthermore, we could be held liable for actions taken by our employees, distributors or third-party promoters, which could expose us to regulatory investigations and penalties.

Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti- bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Our procedures and controls to monitor anti-bribery and corruption compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery and corruption laws, our reputation could be harmed and we could incur criminal or civil penalties, including but not limited to imprisonment, criminal and civil fines, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs, other sanctions and/or significant expenses, which could have a material adverse effect on our business.

If we or our CROs or contract manufacturing organizations ("CMOs") fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and third parties, such as our CROs or CMOs, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and waste. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health and safety have been completed. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our insurance coverage. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses that we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, manufacturing or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our information technology systems, or those used by our contractors or collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization efforts.

Despite the implementation of security measures, our information technology systems and those of our contractors and collaborators, are vulnerable to damage from internal or external events, such as computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures, which can compromise the confidentiality, integrity and availability of the systems. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research, development, manufacturing, regulatory and commercialization efforts and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could cause loss of data, damage to systems and data and leave us unable to utilize key business systems or access important data needed to operate our business. Our contractors and collaborators have and in the future may face similar risks, and service disruptions or security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we and our third-party vendors have on occasion experienced, and will continue to experience, threats to our or their data and systems, including malicious codes and viruses, phishing, business email compromise attacks, ransomware, or other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or

those of our vendors occurs, we could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have processes to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our contractors and collaborators, as well as our and their efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruptions, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, ransomware, industrial espionage attack or insider threat attack that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

In the United States, we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels. Numerous laws and regulations, including security breach notification laws, health information privacy laws, and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/679 ("GDPR"), which became effective in 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including requirements relating to having legal bases for processing personal information, including personal health data, relating to identifiable individuals and transferring such information outside the European Economic Area, providing information to those individuals regarding the data processing of their personal information, implementing safeguards to keep personal information secure and confidential, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, and recordkeeping. The GDPR imposes strict rules on the transfer of personal data to countries outside the European Economic Area, and also imposes restrictions on cross-border data transfers. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20 million or up to 4% of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. We face uncertainty as to the interpretation of these requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the law. Despite our best efforts to comply, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. National laws of member states of the EU are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

China has implemented rules and is considering a number of additional proposals concerning data protection. The Cyber Security Law of the PRC, which became effective in 2017, created China's first national-level data protection for "network operators," which may include all organizations in China that provide services over the internet or another information network. Numerous related laws, regulations, guidelines and other measures are expected to be adopted, such as draft Data Security Law and draft Personal Information Protection Law, which may, upon enactment, require security review before transferring human health-related data out of China. Additionally, the Measures for the Management of Scientific Data provides a broad definition of scientific data and relevant rules for the management of scientific data in China and requires that enterprises in China must seek regulatory approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal.

We expect that these data protection and transfer laws and regulations will receive greater attention and focus from regulators going forward, and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under European, Chinese and other data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant administrative, civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information or scientific data (such as the results of our preclinical studies or clinical trials conducted within China), result in the suspension of research and development of drug candidates, ongoing clinical trials or ban on initiation of new trials, require us to change our business practices, increase our costs, or materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business, results of operations, and financial condition.

If we or parties on whom we rely fail to maintain the necessary licenses for the development, manufacture, sale and distribution of our products, our ability to conduct our business could be materially impaired.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, manufacture, promote and sell our products. Third parties, such as distributors, third-party promoters and third-party manufacturers, on whom we may rely to develop, manufacture, promote, sell and distribute our products may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations and those of our third-party contractors and collaborators could be subject to natural or man-made disasters, public health epidemics or other business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by such business interruptions, government shutdowns or withdrawn funding. The occurrence of any of these business interruptions could seriously harm our operations and financial condition and increase our costs and expenses. We partially rely on third-party manufacturers to produce and process our medicines and drug candidates. Our ability to obtain supplies of our medicines and drug candidates could be disrupted if the operations of these suppliers are affected by man-made or natural disasters, public health epidemics or other business interruptions. Damage or extended periods of interruption to our or our vendors' corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, public health epidemics or other events could cause us to delay or cease development or commercialization of some or all of our medicines and drug candidates. Although we maintain insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be

seriously harmed by such delays and interruption. For example, the COVID-19 pandemic has impacted and could continue to negatively impact our business and our financial performance. Our clinical development and commercial efforts could be delayed or otherwise negatively impacted, as patients may be reluctant to go to the hospitals to receive treatment, or our regulatory filings and approvals could be delayed. We have already experienced delays in clinical trial recruitment. Additionally, the commercial or clinical supply of our medicines and drug candidates could be negatively impacted due to reduced operations or a shutdown of our or our third-party manufacturing facilities, distribution channels and transportation systems, or shortages of raw materials and drug product.

Our business and results of operations could be adversely affected by public health crises and natural catastrophes or other disasters outside of our control in the locations in which we and our contractors and collaborators operate.

Our global operations expose us to risks associated with public health crises, such as epidemics and pandemics, natural catastrophes, such as earthquakes, hurricanes, typhoons, or floods, or other disasters such as fires, explosions and terrorist activity or wars that are outside of our control, including government reactions due to such events. Our business operations and those of our contractors and collaborators may potentially suffer interruptions caused by any of these events.

In December 2019, the COVID-19 outbreak began to impact the population in China and since January 2020, the COVID-19 outbreak has spread around the world. The continued spread of COVID-19 has negatively impacted our business and results of operations, including commercial sales, regulatory interactions, inspections, and filings, and clinical trial recruitment, participation and data read outs. In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring many employees to work remotely. We have suspended or limited non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism or employee turnover, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our business, results of operations, and financial condition.

The extent to which the COVID-19 pandemic may continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the United States, China, Europe and other geographies where we or our third-party contractors and collaborators operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions and any new wave of COVID-19 cases could have a widespread impact on our business and results of operations depending on where infection rates are the highest. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operations, and financial condition.

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

We face an inherent risk of product liability as a result of the commercialization of our medicines in China and the United States and the clinical testing and any future commercialization of our drug candidates globally. For example, we may be sued if our medicines or drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the medicine, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our medicines and drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our medicines; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of our management’s time and resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any medicine or drug candidate; and a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our medicines and drug candidates. Although we currently hold product liability coverage which we believe to be sufficient in light of our current products and clinical programs, the amount of such insurance coverage may not be adequate, and we may be unable to maintain such insurance at a reasonable cost

or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We are subject to the risks and challenges of doing business globally, which may adversely affect our business operations.

Because we operate in China, Europe and other regions outside of the United States, our business is subject to risks and challenges associated with doing business globally. Accordingly, our business and financial results could be adversely affected due to a variety of factors, including: changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; challenges in replicating or adapting our company policies and procedures to operating environments different from that of the United States; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain countries; enforcement of anti-corruption and anti-bribery laws, such as the FCPA; trade-protection measures or disputes, import or export licensing requirements, and fines, penalties or suspension or revocation of export privileges; laws and regulations on foreign investment in the United States under the jurisdiction of the CFIUS and other agencies; the effects of applicable local tax regimes and potentially adverse tax consequences; the impact of public health epidemics on employees, our operations and the global economy; restrictions on international travel and commerce; and significant adverse changes in local currency exchange rates. For example, the withdrawal of the United Kingdom from the EU effective on January 31, 2020, commonly referred to as "Brexit," may cause increased economic volatility, affecting our operations and business. In addition, in 2017 the United Kingdom Financial Conduct Authority, which regulates the London Interbank Offered Rate ("LIBOR"), announced that it will no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator after 2021, and it is anticipated that LIBOR will be phased out and replaced by 2022. While various replacement reference rates have been proposed, an alternative reference rate to LIBOR has not yet been widely adopted. As such, the replacement of LIBOR could have an adverse effect on the market for, or value of, LIBOR-linked financial instruments. Failure to manage these risks and challenges could negatively affect our ability to expand our businesses and operations as well as materially and adversely affect our business, financial condition and results of operations.

Future operating results could be negatively affected by changes in tax rates, the adoption of new tax legislation in the jurisdictions in which we operate, or exposure to additional tax liabilities.

The nature of our international operations subjects us to local, state, regional and national tax laws in jurisdictions around the world. Our future tax expense could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities or changes in tax laws or their interpretation. Additionally, tax rules governing cross-border activities are continually subject to modification as a result of both coordinated actions by governments and unilateral measures designed by individual countries, both intended to address concerns over base erosion and profit shifting (BEPS) and perceived international tax avoidance techniques. For example, the Cayman Islands has enacted the International Tax Co-operation (Economic Substance) Law (2020 Revision) (the "Economic Substance Law"), which originally took effect on January 1, 2019, and which is accompanied by Guidance on Economic Substance for Geographically Mobile Activities (Version 2.0; April 30, 2019) published by the Cayman Islands Tax Information Authority. The Economic Substance Law embraces a global initiative to combat BEPS and demonstrates the continued commitment of the Cayman Islands to international best practice. The Economic Substance Law provides that relevant entities that existed before January 1, 2019 and that had been conducting relevant activities by that date must comply with the economic substance requirements from July 1, 2019, and relevant entities that are established from January 1, 2019 onwards must comply with the requirements from the date they commence the relevant activity. Although we believe that we currently are not obliged to meet the economic substance requirements under the Economic Substance Law, we cannot predict any changes to the legislation or its interpretation in the future. If we are obliged to meet certain economic substance requirements in the future, our business and results of operations could be negatively impacted if we are required to make changes to our business in order to gain compliance or if we fail to comply.

We have received tax rulings from various governments that have jurisdictional authority over our operations. If we are unable to meet the requirements of such agreements, or if they expire or are renewed on less favorable terms, the result could negatively impact our future earnings. Additionally, the European Commission has opened formal investigations into specific tax rulings granted by several countries to specific taxpayers. While we believe that our rulings are consistent with accepted tax ruling practices, the ultimate resolution of such activities cannot be predicted and could also have an adverse impact on future operating results.

Risks Related to Our Doing Business in the PRC

Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments may materially and adversely affect our business, financial condition, and results of operations and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC or changes in government relations between China and the United States or other governments. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate, our business in China and United States may also be adversely affected.

The audit report included in our Annual Report on Form 10-K filed with the SEC is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board (the "PCAOB"), and as such, investors are deprived of the benefits of such inspection.

Our auditor, Ernst & Young Hua Ming LLP, is required to undergo regular inspections by the PCAOB as an auditor of companies that are publicly traded in the United States and a firm registered with the PCAOB. However, because we have substantial operations within the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our auditor and its audit work that is carried out in the PRC is not currently able to be inspected independently and fully by the PCAOB.

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

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of U.S. lawmakers introduced bills that would require the SEC to maintain a list of issuers for which the PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted. Furthermore, the U.S. government has considered limiting or restricting China-based companies from accessing U.S. capital markets. In addition, the Holding Foreign Companies Accountable Act (the "HFCA Act") became law in December 2020. The HFCA Act includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction. The HFCA Act also requires that, to the extent that the PCAOB has been unable to inspect an issuer's auditor for three consecutive years since 2021, the SEC shall prohibit its securities registered in the United States from being traded on any national securities exchange or over-the-counter markets in the United States.

On March 24, 2021, the SEC adopted an interim final rule to implement the HFCA Act. The interim final rule will apply to registrants that the SEC identifies as having filed an annual report with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction that the PCAOB is unable to inspect or investigate completely because of a position taken by an authority in that jurisdiction. Consistent with the HFCA Act, the interim final rule requires the submission of documentation to the SEC establishing that such a registrant is not owned or controlled by a government entity in that foreign

jurisdiction and also requires disclosure in a foreign issuer's annual report regarding the audit arrangements of, and government influence on, such registrants. The interim final rule is effective on May 5, 2021.

As a result, our securities may be prohibited from trading on Nasdaq or another U.S. stock exchange if our auditor is not inspected by the PCAOB for three consecutive years as specified in the HFCA Act, and this ultimately could result in our ADSs being delisted. While there has been dialogue among the China Securities Regulatory Commission (the "CSRC"), the SEC and the PCAOB regarding the inspection of PCAOB-registered accounting firms in China, there can be no assurance that our auditor or us will be able to comply with requirements imposed by U.S. regulators. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares, which are listed for trading on the Hong Kong Stock Exchange. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong, or may have to incur increased costs or suffer losses in order to do so. The market price of our ADSs could be adversely affected as a result of anticipated negative impacts of these actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these actions are implemented and regardless of our actual operating performance.

As our global business has expanded, we have built substantial organizational capabilities outside of China. We are evaluating, designing, and implementing additional business processes and control changes to meet the requirements of the HFCA Act, which we believe will enable us to engage an independent registered public accounting firm that satisfies the PCAOB inspection requirements for the audit of our consolidated financial statements, subject to compliance with SEC and other requirements. However, these efforts may not be sufficient, or may take time for us to implement and ultimately may not be successful. We may also be subject to enforcement under the HFCA Act, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act. If we failed to comply with those rules, it is possible that our ADSs will be delisted. The risk and uncertainty associated with a potential delisting would have a negative impact on the price of our ADSs and ordinary shares. Failure to adopt effective contingency plans may also have a material adverse impact on our business and the price of our ADSs and ordinary shares.

Proceedings instituted by the SEC against five PRC-based accounting firms, including our independent registered public accounting firm, could result in our inability to find a registered public accounting firm to audit and issue an opinion on our financial statements, which could result in us not being in compliance with the requirements of the Exchange Act.

In 2012, the SEC brought administrative proceedings against five accounting firms in China, including our independent registered public accounting firm, alleging that they had refused to produce audit work papers and other documents related to certain other PRC-based companies under investigation by the SEC. In 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. In 2015, each of the four PRC-based accounting firms agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC. These firms' ability to continue to serve their clients was not affected by the settlement. The settlement required these firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC. If these firms do not follow these procedures, the SEC could impose penalties such as suspensions, or it could restart the administrative proceedings. Our audit committee is aware of the policy restriction and communicates with our independent registered public accounting firm to ensure compliance. If additional remedial measures are imposed on the China-based accounting firms, including our independent registered public accounting firm, in administrative proceedings brought by the SEC alleging the firms' failure to meet specific criteria set by the SEC with respect to requests for the production of documents, we could be unable to timely file future financial statements in compliance with the requirements of the Exchange Act. The settlement did not require these firms to admit to any violation of law and preserves these firms' legal defenses in the event the administrative proceeding is restarted. In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, U.S.-listed companies and the market price of the ADSs and/or ordinary shares may be adversely affected.

If our independent registered public accounting firm is denied, even temporarily, the ability to practice before the SEC and we are unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined to be not in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to deregistration from the SEC, which would substantially reduce or effectively terminate the trading of our ADSs in the United States. Moreover, any negative news about the proceedings against these audit firms may

adversely affect investor confidence in companies with substantial mainland China-based operations listed in the United States. All these would materially and adversely affect the market price of the ADSs and substantially reduce or effectively terminate the trading of our ADSs in the United States, and the market price of our ordinary shares may be adversely affected.

There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations.

A large portion of our operations are conducted in China through our Chinese subsidiaries. Our Chinese subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. The Chinese legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the Chinese government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

China's Foreign Investment Law and its implementing rule came into force in January 2020. The Foreign Investment Law and its implementing rules embody an expected regulatory trend to rationalize China’s foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the legal requirements for both foreign and domestic investments. There are still uncertainties with respect to the interpretation and implementation of the Foreign Investment Law and its implementing rules. For example, the Foreign Investment Law and its implementing rules provide that foreign invested entities established according to the previous laws regulating foreign investment prior to the implementation of the new law may maintain their structure and corporate governance for a five-year transition period. It is uncertain whether governmental authorities may require us to adjust the structure and corporate governance of certain of our Chinese subsidiaries in such transition period. Failure to take timely and appropriate measures to meet any of these or similar regulatory requirements could materially affect our current corporate governance practices and business operations and our compliance costs may increase significantly. In addition, the Measures for the Security Review of Foreign Investment (the “New Measures”), effective from January 18, 2021, embody China's continued efforts to provide a legal regime for national security review comparable to similar procedures in other jurisdictions, such as CFIUS review in the United States. There are still uncertainties with respect to the interpretation, implementation and enforcement of the New Measures. For example, national security remains undefined and there is no clear guidance on whether the biotechnology industry requires security review and what factors the regulatory authority may consider in determining whether there are security concerns. It is difficult to evaluate the impact of the New Measures on our existing investments or potential investments in China.

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

It may be difficult for overseas regulators to conduct investigations or collect evidence within China. In China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigations initiated outside China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of a mutual and practical cooperation mechanism. According to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the PRC territory. While detailed interpretation of or implementation rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigations or evidence collection activities within China may further increase the difficulties you face in protecting your interests. For risks associated with investing in us as a Cayman Islands company, see also “—Risks Related to Our American Depositary Shares and Ordinary Shares—We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under Hong Kong law or U.S. law, our shareholders may have fewer shareholder rights than they would have under Hong Kong law or U.S. law and may face difficulties in protecting their interests.”

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered and could materially and adversely affect our business, financial condition and results of operations.

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

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign- owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each operating subsidiary. As of March 31, 2021 and December 31, 2020, these restricted assets totaled $439.3 million and $119.8 million, respectively.

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

In response to the persistent capital outflow in the PRC and RMB’s depreciation against the U.S. dollar in the fourth quarter of 2016, the People’s Bank of China ("PBOC") and China's State Administration of Foreign Currency ("SAFE") promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments.

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

The PRC Enterprise Income Tax Law (the "EIT Law") and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries may be subject to PRC withholding tax at a rate of 10%.

Pursuant to an arrangement between Mainland China and the Hong Kong Special Administrative Region (the "Hong Kong Tax Treaty"), BeiGene HK, the shareholder of some of our PRC subsidiaries, may be subject to a withholding tax at a rate of 5% on dividends received from our PRC operating subsidiaries as a Hong Kong tax resident. Pursuant to the Hong Kong Tax Treaty, subject to certain conditions, this reduced withholding tax rate will be available for dividends from PRC entities provided that the recipient can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. The government adopted regulations in 2018 which stipulate that in determining whether a non-resident enterprise has the status as a beneficial owner, comprehensive analysis shall be conducted based on the factors listed therein and the actual circumstances of the specific case shall be taken into consideration. Specifically, it expressly excludes an agent or a designated payee from being considered as a “beneficial owner.” BeiGene HK currently does not hold a Hong Kong tax resident certificate from the Inland Revenue Department of Hong Kong, and there is no assurance that the reduced withholding tax rate will be available.

We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and we may therefore be subject to PRC income tax on our worldwide taxable income. Dividends payable to foreign investors and gains on the sale of our ADSs or ordinary shares by our foreign investors may become subject to PRC tax.

Under the EIT Law, an enterprise established outside the PRC with "de facto management bodies" within the PRC is considered a "resident enterprise," meaning that it is treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. The implementing rules of the EIT Law define "de facto management bodies" as "management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties" of the enterprise. In addition, PRC regulations specify that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders' meetings; and (iv) half or more of senior management or directors having voting rights.

Although BeiGene, Ltd. does not have a PRC enterprise or enterprise group as its primary controlling shareholder and is therefore not a Chinese-controlled offshore incorporated enterprise within the meaning of these regulations, in the absence of guidance specifically applicable to us, we have applied the guidance set forth in the regulations to evaluate the tax residence status of BeiGene, Ltd. and its subsidiaries organized outside of the PRC.

We are not aware of any offshore holding company with a corporate structure similar to ours that has been deemed a PRC "resident enterprise" by the PRC tax authorities. Accordingly, we do not believe that our company or any of our overseas subsidiaries should be treated as a PRC resident enterprise. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow and we may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. If we are deemed a PRC resident enterprise, dividends paid on our shares and any gain realized from the transfer of our ordinary shares may be treated as income derived from sources within the PRC. As a result, dividends paid to non-PRC resident enterprise ADS holders or shareholders may be subject to PRC withholding tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprises ADS holders or shareholders from the transfer of our ordinary shares or ADSs may be subject to PRC tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders).

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company, or other assets attributable to a PRC establishment of a non-PRC company.

Pursuant to Chinese regulations, an "indirect transfer" of "PRC taxable assets," including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a "reasonable commercial purpose" of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in the PRC or if its income mainly derives from the PRC; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be reported on with the enterprise income tax filing of the PRC establishment or place of business being transferred and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC enterprise income tax at the rate of 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC enterprise income tax where such shares were acquired in a transaction through a public stock exchange. As such, the sale of the ADSs or ordinary shares on a public stock exchange will not be subject to PRC enterprise income tax. However, the sale of our ordinary shares or ADSs by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under these regulations.

There are uncertainties as to the application of these regulations, which may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with these regulations or to establish that we and our non-resident enterprises should not be taxed under these regulations, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under these regulations, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the conversion of RMB into foreign currencies and, in certain cases, the remittance of currency out of the PRC. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our ordinary shares and the ADSs. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities or designated banks. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

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

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

Any failure to comply with PRC regulations regarding our employee equity plans and investments in offshore companies by PRC residents may subject the PRC plan participants and PRC-resident beneficial owners or us to fines and other legal or administrative sanctions.

We and our directors, executive officers and other employees who are PRC residents have participated in our employee equity plans. We are an overseas listed company, and therefore, we and our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted share units, restricted shares, options or other forms of equity incentives or rights to acquire equity are subject to the PRC regulations, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in the PRC for a continuous period of not less than one year, subject to limited exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law. Moreover, failure to comply with the various foreign exchange registration requirements could result in liability under PRC law for circumventing applicable foreign exchange restrictions.

The pharmaceutical industry in China is highly regulated, and such regulations are subject to change, which may affect approval and commercialization of our medicines and drug candidates.

A large portion of our business is conducted in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new medicines. In recent years, the regulatory framework in China for pharmaceutical companies has undergone significant changes, which we expect will continue. While we believe our strategies regarding research, development, manufacturing and commercialization in China are aligned with the Chinese government's policies, they may in the future diverge, requiring a change in our strategies. Any such change may result in increased compliance costs on our business or cause delays in or prevent the successful research, development, manufacturing or commercialization of our drug candidates or medicines in China and reduce the current benefits we believe are available to us from developing and manufacturing medicines in China.

Chinese authorities have become increasingly vigilant in enforcing laws affecting the pharmaceutical industry. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. Reports of what have come to be viewed as significant quality-control failures by Chinese vaccine manufacturers have led to enforcement actions against officials responsible for implementing national reforms favorable to innovative drugs (such as ours). While not directly affecting us, this macro-industry event could cause state or private resources to be diverted away from fostering innovation and be redirected toward regulatory enforcement, which could adversely affect our research, development, manufacturing and commercialization activities and increase our compliance costs.

Risks Related to Our American Depositary Shares and Ordinary Shares

The trading prices of our ordinary shares and/or ADSs can be volatile, which could result in substantial losses to you.

The trading price of our ordinary shares and/or ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with significant business operations in China that have listed their securities in Hong Kong or the United States may affect the volatility in the price of and trading volumes for our ordinary shares and/or ADSs. Some of these companies have experienced significant volatility. The trading performances of these companies' securities may affect the overall investor sentiment towards other companies with significant operations in China that are listed in Hong Kong or the United States and consequently may impact the trading performance of our ordinary shares and/or ADSs.

In addition to market and industry factors, the price and trading volume for our ordinary shares and/or ADSs may be highly volatile for various reasons, including: announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process; announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors; adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities; any adverse changes to our relationship with manufacturers or suppliers; the results of our testing and clinical trials; the results of our efforts to acquire or license additional medicines or drug candidates; variations in the level of expenses related to our existing medicines and drug candidates or preclinical, clinical development and commercialization programs; any intellectual property infringement actions in which we may become involved; announcements concerning our competitors or the pharmaceutical industry in general; fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages; variations in our results of operations; announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations; publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts; changes in financial estimates by securities research analysts; media reports, whether or not true, about our business, our competitors or our industry; additions to or departures of our management; fluctuations of exchange rates between the RMB, the U.S. dollar and Hong Kong dollar; release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; sales or perceived potential sales of additional ordinary shares or ADSs by us, our executive officers and directors or our shareholders; general economic and market conditions and overall fluctuations in the United States or Hong Kong equity markets; changes in accounting principles; trade disputes or U.S.-China government relations; and changes or developments in the United States, PRC, EU or global regulatory environment.

In addition, the stock market, in general, and pharmaceutical and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ordinary shares and/or ADSs,

regardless of our actual operating performance. Further, the current volatility in the financial markets and related factors beyond our control may cause the ordinary share and/or ADS price to decline rapidly and unexpectedly.

The characteristics of the U.S. capital markets and the Hong Kong capital markets are different.

The Nasdaq and the HKEx have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our ordinary shares and the ADSs representing them might not be the same, even allowing for currency differences. Fluctuations in the price of our ADSs due to circumstances peculiar to its home capital market could materially and adversely affect the price of the ordinary shares, and vice versa. Because of the different characteristics of the U.S. and Hong Kong equity markets, the historic market prices of our ADSs and ordinary shares may not be indicative of the performance of our securities going forward.

We may be subject to securities litigation, which is expensive and could divert management attention.

Companies that have experienced volatility in the volume and market price of their shares have been subject to an increased incidence of securities class action litigation, particularly in our industry in recent years. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, and, if adversely determined, could have a material adverse effect on our business, financial condition and results of operations.

****Future sales of our ordinary shares and/or ADSs in the public market could cause the ordinary shares and/or ADS price to fall.***

The price of our ordinary shares and/or ADSs could decline as a result of sales of a large number of the ordinary shares and/or ADSs or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of April 30, 2021, 1,197,609,020 ordinary shares, par value $0.0001 per share, were outstanding, of which 973,810,305 ordinary shares were held in the form of 74,908,485 ADSs, each representing 13 ordinary shares.

We filed a registration statement on Form S-3 with the SEC on behalf of certain shareholders on May 11, 2020, registering 300,197,772 ordinary shares, including 224,861,338 ordinary shares in the form of 17,297,026 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. Furthermore, we have registered or plan to register the offer and sale of all securities that we have issued and may issue in the future under our equity compensation plans, including upon the exercise of share options and vesting of restricted share units and under our employee share purchase plan. If these additional securities are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares and/or ADSs could decline. Amgen also has specified registration rights upon expiration of a lock-up period.

In addition, in the future, we may issue additional ordinary shares, ADSs or other equity or debt securities convertible into ordinary shares or ADSs in connection with a financing, acquisition, license, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the ordinary share and/or ADS price to decline.

We have filed to conduct a public offering and to list our shares on the Science and Technology Innovation Board (the "STAR Market"), which if completed, will result in increased regulatory scrutiny and compliance costs and may increase fluctuations in the prices of our ADSs listed on the Nasdaq and ordinary shares listed on the HKEx.

In January 2021, we filed an initial listing application for a proposed public offering and listing of our ordinary shares on the STAR Market of the Shanghai Stock Exchange (the "SSE"). The proposed offering and listing of our ordinary shares, which will be denominated in RMB (the "RMB shares"), is currently expected to be completed in 2021, subject to, among other things, market conditions, approval of our shareholders, and necessary regulatory approvals, including approvals or decisions made by relevant regulatory authorities and governmental departments of the PRC, Hong Kong and other applicable jurisdictions. There is no assurance as to when the proposed offering and listing on the STAR Market will be completed, if at all. If we complete a public offering and listing on the STAR Market, we will become subject to the applicable laws, rules and regulations governing public companies listed on the STAR Market in addition to the various laws, rules and regulations that we are subject to in the United States and Hong Kong. The listing and trading of our equity securities in multiple jurisdictions and multiple markets will lead to increased compliance obligations and costs for us, and we may face the risk of significant intervention by regulatory authorities in these jurisdictions and markets. In addition, if we complete a public offering and listing

on the STAR Market, we may be subject to securities litigations filed with the courts in China by the investors with respect to the RMB Shares traded on the STAR Market in the future.

In addition, under current PRC laws and regulations, our ADSs and ordinary shares will not be interchangeable or fungible with our RMB-denominated ordinary shares traded on the STAR Market, and there is no trading or settlement between either the Nasdaq or the HKEx and the SSE. Furthermore, the Nasdaq, HKEx and SSE have different trading characteristics and investor bases, including different levels of retail and institutional participation. As a result of these differences, the trading prices of our ADSs and ordinary shares, accounting for the ADS to ordinary share ratio, may not be the same as the trading prices of equity securities we may decide to offer and/or list on the STAR Market. The fluctuations in the trading price of our RMB-denominated ordinary shares may also lead to increased volatility in, and may otherwise materially decrease, the prices of our ADSs listed on the Nasdaq and ordinary shares listed on the HKEx.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares and/or ADSs for return on your investment.

We intend to retain most, if not all, of our available funds and earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in the ordinary shares and/or ADSs as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual and regulatory restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in the ordinary shares and/or ADSs will likely depend entirely upon any future price appreciation of the ordinary shares and/or ADSs. There is no guarantee that the ordinary shares and/or ADSs will appreciate in value or even maintain the price at which you purchased the ordinary shares and/or ADSs. You may not realize a return on your investment in the ordinary shares and/or ADSs and you may even lose your entire investment in the ordinary shares and/or ADSs.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, the market price for the ordinary shares and/or ADSs and trading volume could decline.

The trading market for the ordinary shares and ADSs relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades the ordinary shares and/or ADSs or publishes inaccurate or unfavorable research about our business, the market price for the ordinary shares and/or ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for the ordinary shares and/or ADSs to decline significantly.

We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under Hong Kong law or U.S. law, our shareholders may have fewer shareholder rights than they would have under Hong Kong law or U.S. law and may face difficulties in protecting their interests.

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our amended and restated memorandum and articles of association (as may be further amended from time to time), the Companies Law (as amended) of the Cayman Islands, and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on courts in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in Hong Kong and the United States. In particular, the Cayman Islands has a less developed body of securities law than Hong Kong or the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders, with the exception that shareholders may request a copy of the current amended and restated memorandum and articles of association. Our directors have discretion under our amended and restated articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it

more difficult for shareholders to obtain the information needed to establish facts necessary for a shareholder action or to solicit proxies from other shareholders in connection with a proxy contest. As a Cayman Islands company, we may not have standing to initiate a derivative action in a Hong Kong or U.S. federal court. As a result, shareholders may be limited in their ability to protect their interests if they are harmed in a manner that would otherwise enable them to sue in a United States federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in Hong Kong or U.S. federal courts.

Some of our directors and executive officers reside outside of Hong Kong and the United States and a substantial portion of their assets are located outside of Hong Kong and the United States. As a result, it may be difficult or impossible for shareholders to bring an action against us or against these individuals in Hong Kong or in the United States in the event that shareholders believe that their rights have been infringed under the securities laws of Hong Kong, the United States or otherwise. To the extent our directors and executive officers reside outside of China or their assets are located outside of China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if shareholders are successful in bringing an action, the laws of the Cayman Islands and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, Hong Kong or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

As a result of the above, shareholders may have more difficulty protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as shareholders of a Hong Kong company or a U.S. company.

Voting rights of our ADS holders are limited by the terms of the deposit agreement. The depositary for the ADSs will give us a discretionary proxy to vote our ordinary shares underlying our ADS holders ADSs if they do not vote at shareholders' meetings, except in limited circumstances, which could adversely affect their interests.

Holders of our ADSs may exercise their voting rights with respect to the ordinary shares underlying their ADSs only in accordance with the provisions of the deposit agreement. Upon receipt of voting instructions from ADS holders in the manner set forth in the deposit agreement, the depositary for the ADSs will endeavor to vote the holder's underlying ordinary shares in accordance with these instructions. Under our articles of association, the minimum notice period required for convening an annual general meeting is 21 calendar days and the minimum notice period required for convening an extraordinary general meeting is 14 calendar days. When a general meeting is convened, ADS holders may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their ordinary shares to allow them to cast your vote with respect to any specific matter at the meeting. In addition, the depositary and its agents may not be able to send voting instructions to ADS holders or carry out their voting instructions in a timely manner. We will make reasonable efforts to cause the depositary to extend voting rights to our ADS holders in a timely manner, but they may not receive the voting materials in time to ensure that they can instruct the depositary to vote your shares.

Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, ADS holders may not be able to exercise their right to vote and they may lack recourse if the ordinary shares underlying their ADSs are not voted as they requested.

Under the deposit agreement for the ADSs, the depositary will give us a discretionary proxy to vote the ordinary shares underlying ADS holders' ADSs at shareholders' meetings if such holders do not give voting instructions to the depositary, unless:

- we have failed to timely provide the depositary with our notice of meeting and related voting materials;
- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that, if ADS holders fail to give voting instructions to the depositary, they cannot prevent the ordinary shares underlying their ADSs from being voted, absent the situations described above, and it may make it more difficult for such ADS holders to influence our management. Holders of our ordinary shares are not subject to this discretionary proxy.

Anti-takeover provisions in our constitutional documents may discourage our acquisition by a third party, which could limit our shareholders' opportunity to sell their shares at a premium.

Our amended and restated memorandum and articles of association include provisions that could limit the ability of others to acquire control of our company, could modify our structure or could cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares, at a premium over prevailing market prices by discouraging third parties from seeking to obtain control in a tender offer or similar transaction.

For example, our board of directors has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix the powers and rights of these shares, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares. Preferred shares could thus be issued quickly with terms calculated to delay or prevent a change in control or make removal of management more difficult. In addition, if our board of directors authorizes the issuance of preferred shares, the market price of the ordinary shares and/or ADSs may fall and the voting and other rights of the holders of our ordinary shares and/or ADSs may be materially and adversely affected.

Furthermore, our amended and restated articles of association permit our directors to vary all or any of the rights attaching to any class of shares in issue without the consent of shareholders but only if such variation is considered by the directors not to have a material adverse effect upon such holders. The amended and restated articles of association provide that the holders must consent to any such material adverse changes in the manner set out therein.

Because our directors are divided into three classes with staggered terms of three years each, shareholders can only elect or remove a limited number of our directors in any given year. The length of these terms could present an obstacle to certain actions, such as a merger or other change of control, which could be in the interest of our shareholders.

Our amended and restated memorandum and articles of association designate specific courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated memorandum and articles of association provide that, unless we consent in writing to the selection of an alternative forum, the courts of Cayman Islands will be the sole and exclusive forum for any derivative action or proceeding brought on behalf of us, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of us to us or our shareholders, any action asserting a claim arising pursuant to any provision of the Companies Law of the Cayman Islands as amended from time to time, or the amended and restated memorandum and articles of association, or any action asserting a claim governed by the internal affairs doctrine (as such concept is recognized under the U.S. laws). In connection with our proposed offering and listing on the STAR Market, and subject to shareholder approval, we plan to adopt a further amended and restated memorandum and articles of association, which will provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"). In addition, the further amended and restated memorandum and articles of association will provide that any person or entity purchasing or otherwise acquiring any interest in any of our securities is deemed to have notice of and consented to these provisions; provided, however, that shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and rules and regulations thereunder.

These provisions may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find these provisions of our amended and restated memorandum and articles of association inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions.

Our amended and restated memorandum and articles of association provide that any shareholder bringing an unsuccessful action against us may be obligated to reimburse us for any costs we have incurred in connection with such unsuccessful action.

Our amended and restated memorandum and articles of association provide that under certain circumstances the fees, costs, and expenses that we incur in connection with actions or proceedings brought by any person or entity, which we refer to as claiming parties, may be shifted to such person or entity. If a claiming party asserts any claim; initiates any proceeding; or joins, offers substantial assistance to, or has a direct financial interest in any claim or proceeding against us, and such claiming party or the third party that received substantial assistance from the claiming party or in whole claim the claiming party had a direct financial interest is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails, then such claiming party shall (to the fullest extent permitted by law) be obligated to reimburse us for all fees, costs, and expenses, including but

not limited to all reasonable attorneys' fees and other litigation expenses, that we may incur in connection with such claim or proceeding.

Fee-shifting articles are relatively new and untested in the Cayman Islands, the United States and Hong Kong. The case law and potential legislative action on fee-shifting articles are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such articles. The application of our fee-shifting article in connection with claims under the Cayman Islands, the United States or Hong Kong securities laws, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting article in any particular dispute. Consistent with our directors' fiduciary duties to act in the best interests of the Company, the directors may in their sole discretion from time to time decide whether or not to enforce this article. In addition, given the unsettled state of the law related to fee-shifting articles, such as ours, we may incur significant additional costs associated with resolving disputes with respect to such articles, which could adversely affect our business and financial condition.

If a shareholder that brings any such claim or proceeding is unable to obtain the judgment sought, the attorneys' fees and other litigation expenses that might be shifted to a claiming party may be significant. This fee-shifting article, therefore, may dissuade or discourage current or former shareholders (and their attorneys) from initiating lawsuits or claims against us. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our shareholders or otherwise discourage plaintiffs' attorneys from representing our shareholders at all. As a result, this article may limit the ability of shareholders to affect the management and direction of our company, particularly through litigation or the threat of litigation.

Holders of ADSs may be subject to limitations on transfer of their ADSs.

ADSs are transferable only on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, as amended, or for any other reason, subject to ADS holders' right to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares.

In addition, holders of ADSs may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

The depositary for the ADSs is entitled to charge holders fees for various services, including annual service fees.

The depositary for the ADSs is entitled to charge holders fees for various services, including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. In the case of ADSs issued by the depositary into The Depository Trust Company ("DTC"), the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time.

Dealings in ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty. There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of the ADSs.

In connection with our Hong Kong public offering in 2018, we established a branch register of members in Hong Kong (the "Hong Kong share register"). Our ordinary shares that are traded on the HKEx, including those that may be converted from ADSs, are registered on the Hong Kong share register, and the trading of these ordinary shares on the HKEx are subject to Hong Kong stamp duty. To facilitate ADS to ordinary share conversion and trading between the Nasdaq and the HKEx, we moved a portion of our issued ordinary shares from our Cayman share register to our Hong Kong share register.

Under the Hong Kong Stamp Duty Ordinance, any person who effects a sale or purchase of Hong Kong stock, defined as stock the transfer of which is required to be registered in Hong Kong, is required to pay Hong Kong stamp duty. The stamp duty is currently set at a total rate of 0.2% of the greater of the consideration for, or the value of, shares transferred, with 0.1% payable by each of the buyer and the seller.

To the best of our knowledge, Hong Kong stamp duty has not been levied in practice on the trading or conversion of ADSs of companies that are listed in both the United States and Hong Kong and that have maintained all or a portion of their ordinary shares, including ordinary shares underlying ADSs, in their Hong Kong share registers. However, it is unclear whether, as a matter of Hong Kong law, the trading or conversion of ADSs of these dual-listed companies constitutes a sale or purchase of the underlying Hong Kong registered ordinary shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. If Hong Kong stamp duty is determined by the competent authority to apply to the trading or conversion of the ADSs, the trading price and the value of your investment in our ADSs or ordinary shares may be affected.

Holders of ADSs may not receive distributions on our ordinary shares or any value for them if it is illegal or impractical to make them available.

The depositary of the ADSs has agreed to ADS holders the cash dividends or other distributions it or the custodian for the ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. ADS holders will receive these distributions in proportion to the number of our ordinary shares that their ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by the depositary. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that holders of ADSs may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to such holders. These restrictions may materially reduce the value of our ADSs.

Holders of ADSs may not be able to participate in rights offerings and may experience dilution of their holdings.

From time to time, we may distribute rights to our shareholders, including rights to acquire securities. Under the deposit agreement, the depositary will not distribute rights to holders of ADSs unless the distribution and sale of rights and the securities to which these rights relate are either exempt from registration under the Securities Act with respect to all holders of ADSs or are registered under the Securities Act. The depositary may, but is not required to, attempt to sell these undistributed rights to third parties and may allow the rights to lapse. We may be unable to establish an exemption from registration under the Securities Act, and we are under no obligation to file a registration statement with respect to these rights or underlying securities or to try to have a registration statement declared effective. Accordingly, holders of ADSs may be unable to participate in our rights offerings and may experience dilution of their holdings as a result.

Our corporate actions are substantially controlled by our directors, executive officers and other principal shareholders, who can exert significant influence over important corporate matters, which may reduce the price of our ordinary shares and/or ADSs and deprive shareholders of an opportunity to receive a premium for their ordinary shares and/or ADSs.

Our directors, executive officers and principal shareholders beneficially owned approximately 66% of our outstanding ordinary shares as of April 19, 2021. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and reducing the price of our ordinary shares and/or ADSs. These actions may be taken even if they are opposed by our other shareholders. In addition, these persons could divert business opportunities away from us to themselves or others.

We may be a passive foreign investment company in future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders.

A non-U.S. corporation will be classified as a “passive foreign investment company” (“PFIC”) for any taxable year if either (1) 75% or more of its gross income consists of certain types of passive income or (2) 50% or more of the average quarterly value of its assets during such year produce or are held for the production of passive income. Based upon the current and expected composition of our income and assets (taking into account the proceeds from the registered direct offering completed in July 2020), we do not presently expect to be a PFIC for the current taxable year. Nevertheless, because our PFIC status must be determined annually with respect to each taxable year and will depend on the composition and character of our assets and income, including our use of proceeds from any equity offerings, and the value of our assets (which may be determined, in part, by reference to the market value of our ADSs and ordinary shares, which may be volatile) over the course of such taxable year, we may be a PFIC in any taxable year. The determination of whether we will be or become a PFIC may also depend, in part, on how, and how quickly, we use our liquid assets and the cash raised in equity offerings. If we determine not to deploy significant amounts of cash for active purposes, our risk of being a PFIC may substantially increase. Because there are uncertainties in the

application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for the current taxable year or any future taxable year. In addition, it is possible that the Internal Revenue Service may challenge our classification of certain income and assets as non-passive, which may result in our being or becoming a PFIC in the current or subsequent years. We believe that we were not a PFIC for the taxable year ended December 31, 2020.

If we are a PFIC for any taxable year during a U.S. shareholder's holding period of the ordinary shares or ADSs, then such U.S. shareholder may incur significantly increased United States income tax on gain recognized on the sale or other disposition of the ordinary shares or ADSs and on the receipt of distributions on the ordinary shares or ADSs to the extent such distribution is treated as an "excess distribution" under the United States federal income tax rules. In addition, such holders may be subject to burdensome reporting requirements.

Further, if we are classified as a PFIC for any year during which a U.S. shareholder holds our ordinary shares or ADSs, we generally will continue to be treated as a PFIC for all succeeding years during which such U.S. shareholder holds such ordinary shares or ADSs. Each U.S. shareholder should consult its tax advisor regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the ordinary shares and ADSs.

If you are a "Ten Percent Shareholder," you may be subject to adverse U.S. federal income tax consequences if we are classified as a Controlled Foreign Corporation.

Each "Ten Percent Shareholder" (as defined below) in a non-U.S. corporation that is classified as a "controlled foreign corporation" ("CFC"), for U.S. federal income tax purposes is generally required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's "Subpart F income" and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Each Ten Percent Shareholder is also required to include in gross income its "global intangible low-taxed income," which is determined by reference to the income of CFCs of which such Ten Percent Shareholder is a Ten Percent Shareholder. Ten Percent Shareholders that are corporations may be entitled to a deduction equal to the foreign portion of any dividend when a dividend is paid. A non-U.S. corporation will generally be classified as a CFC for U.S federal income tax purposes if Ten Percent Shareholders own in the aggregate, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A "Ten Percent Shareholder" is a U.S. person (as defined by the Internal Revenue Code of 1986, as amended), who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote of such corporation or 10% of the value of all classes of stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain.

Although we believe we are not a CFC now, we may become one or own interests in one in the future. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

See the Exhibit Index below for a list of the exhibits filed as part of, or incorporated by reference into, this Quarterly Report, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Exhibit Description	Filed/Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.1#	Collaboration and License Agreement, dated January 11, 2021, by and between BeiGene Switzerland GmbH and Novartis Pharma AG	X			
10.2†	Consulting Agreement, dated February 24, 2021, by and between the Registrant and Xiaodong Wang		10-K (Exhibit 10.20)	2/25/2021	001-37686
10.3†	Independent Director Compensation Policy, as amended		8-K (Exhibit 10.1)	4/8/2021	001-37686
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350	X			
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)	X			

† Indicates a management contract or any compensatory plan, contract or arrangement.

Certain portions of the exhibit have been omitted by means of redacting a portion of the text and replacing it with "[...***...]". BeiGene, Ltd. (the Registrant) has determined that the omitted information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

*Furnished herewith.

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.

BEIGENE, LTD.

Date: May 6, 2021

By: /s/ John V. Oyler
John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: May 6, 2021

By: /s/ Howard Liang
Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN INFORMATION (INDICATED BY "[…*…]") AND SCHEDULES HAVE BEEN EXCLUDED FROM THIS AGREEMENT BECAUSE SUCH INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.**

COLLABORATION AND LICENSE AGREEMENT

by and between

BEIGENE SWITZERLAND GMBH

and

NOVARTIS PHARMA AG

dated as of January 11, 2021

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COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this "Agreement") is entered into as of January 11, 2021 (the "Execution Date") by and between BeiGene Switzerland GmbH, a Swiss corporation ("BeiGene"), and Novartis Pharma AG, a Swiss corporation ("Novartis"). BeiGene and Novartis are each referred to herein by name, or as a "Party" or, collectively, as the "Parties."

RECITALS

WHEREAS, BeiGene Controls the BeiGene IP (each, as defined below);

WHEREAS, Novartis has experience in the development and commercialization of pharmaceutical products in the Novartis Territory (as defined below); and

WHEREAS, the Parties desire to enter into this Agreement pursuant to which, among other things, BeiGene will grant to Novartis certain rights and licenses with respect to the development, manufacture and commercialization of the Licensed Compound and Licensed Products in the Novartis Territory for use in the Field, on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below.

1.1 "Accounting Standards" means United States Generally Accepted Accounting Principles ("GAAP") or, to the extent that a party uses or adopts International Financial Reporting Standards ("IFRS"), then "Accounting Standards" means IFRS, in either case, consistently applied throughout the applicable party's organization.

1.2 "Acquiring Person" means the Person referenced in the definition of Change of Control 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 (including such Person's Affiliates).

1.3 "Additional Global Development Plan" means the global development plan for any Global Monotherapy Trial(s) that the Parties agree to undertake pursuant to this Agreement, to be prepared and approved by the JDC, including a budget (the "Additional Global Development Budget") as such plan may be amended from time to time in accordance with this Agreement.

1.4 "Affiliate" means any Person which, directly or indirectly through one (1) or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this definition only, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means: (a) direct or indirect ownership of fifty percent (50%) or more of the voting securities or other voting interest of any Person (including attribution from related parties); or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management and policies of such Person, whether through ownership of voting securities, by contract, as a general partner, as a manager, or otherwise.

1.5 "Annual Net Sales" means, the aggregate Net Sales by Novartis, its Affiliates, and its Sublicensees in the Novartis Territory of the Licensed Product in a particular Calendar Year, calculated in accordance with Accounting Standards.

1.6 "Applicable Law" means all applicable laws, statutes, rules, regulations, orders, judgments, or ordinances having the effect of law of any national, multinational, federal, state, provincial, county, city, or other political subdivision, including, to the extent applicable, GCP, GLP, and GMP, as well as all applicable data protection and privacy laws, rules, and regulations, including, to the extent applicable, the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act and the EU Data Protection Directive (Council Directive 95/46/EC), applicable laws implementing the EU Data Protection Directive and the General Data Protection Regulation (2016/679) and applicable laws, rules and regulations of HGRAC, as well as all applicable laws, regulations, orders, judicial decisions, conventions, and international financial institution rules regarding corruption, bribery, ethical business conduct, money laundering, political contributions, gifts and gratuities, or lawful expenses to public officials, healthcare professionals, and private persons, agency relationships, commissions, lobbying, books and records, and financial controls, including the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1 et seq.), that, in each case, govern or otherwise apply to the applicable Person.

1.7 "Assist" means providing, directly or indirectly, a Third Party with (a) any analysis of any of the BeiGene Patents or any portion thereof; (b) prior art or analysis of any prior art to any of the BeiGene Patents; (c) any documents in Novartis's possession, custody, or control relating to any of the BeiGene Patents, in whole or in part, or to any prior art to any of the BeiGene Patents; or (d) financial or technical support, in each case, in connection with a Challenge of any of the BeiGene Patents or any portion thereof.

1.8 "Average Sale Price" or "ASP" means for any Calendar Quarter and for a given product, the "average sales price" of such product as defined in 42 U.S.C. § 1395w-3a(c) and 42 C.F.R. § 414.804, that has last been submitted to the Centers for Medicare and Medicaid Services prior to such Calendar Quarter to be used by the United States federal government as the basis for claims reimbursement for such product.

1.9 "BeiGene Anti-PD-L1" means the proprietary PD-L1 inhibitor of BeiGene described on Schedule 1.9 attached hereto.

1.10 "BeiGene Component" means, with respect to BeiGene, (a) any active pharmaceutical ingredient of a Combination Regimen or Finished Dosage Combination Product that is not the Licensed Compound or the Licensed Product or (b) any active pharmaceutical ingredient that is otherwise administered in a clinical trial of the Licensed Product (in accordance with the protocol for such clinical trial) that is not the Licensed Compound or the Licensed Product, in each case ((a) or (b)), that is (i) proprietary to BeiGene (or its Affiliates) or (ii) otherwise Controlled by BeiGene (or its Affiliates), but in all cases excluding all compounds or other active pharmaceutical ingredients that are (a) proprietary to Novartis (or its Affiliates) or (b) proprietary to a Third Party and Controlled by Novartis (or its Affiliates).

1.11 "BeiGene Copyright" means any copyright Controlled by BeiGene or any of its Affiliates as of the Execution Date or thereafter during the Term that relates to the Licensed Compound and/or the Licensed Product.

1.12 "BeiGene FTE Cost" means, (i) with respect to Detailing, **[…***…]** and (ii) with respect to RMM Promotion **[…***…]**.

1.13 "BeiGene Invention" means any Invention that relates to the Licensed Compound and/or Licensed Product and that is conceived or first reduced to practice by employees of, or consultants to, BeiGene, alone or jointly with any Third Party, without the use in any material respect of any Novartis IP or Joint IP.

1.14 "BeiGene IP" means, collectively, the BeiGene Patents, the BeiGene Know-How and the BeiGene Inventions.

1.15 "BeiGene Know-How" means any Know-How Controlled by BeiGene or any of its Affiliates as of the Execution Date or thereafter during the Term which (a) relates to the Licensed Compound and/or the Licensed Product (including its Manufacture or its formulation or a method of its delivery or of its use) and (b) is necessary or reasonably useful for the Development, Manufacture, conduct of Medical Affairs Activities or Commercialization of the Licensed Compound and/or the Licensed Product in the Field in the Novartis Territory. For clarity, BeiGene Know-How **[…***…]**.

1.16 "BeiGene Manufacturer" means Boehringer Ingelheim Biopharmaceuticals GmbH and its applicable affiliates.

1.17 "BeiGene Ongoing Clinical Trials" means the Clinical Trials sponsored or supported by BeiGene that are ongoing as of the Effective Date, including those Clinical Trials set forth on Schedule 1.17.

1.18 "BeiGene Patents" means any and all Patents Controlled by BeiGene or any of its Affiliates as of the Execution Date or at any time during the Term, excluding any and all Joint Patents, which (a) contain one or more claims that Cover the Licensed Compound and/or Licensed Product (including its Manufacture or its formulation or a method of its delivery or of its use) and (b) are necessary or reasonably useful for the Development, Manufacture, or Commercialization of or the conduct of Medical Affairs Activities with respect to, the Licensed

Compound and/or Licensed Product in the Field in the Novartis Territory. Schedule 1.18 sets forth a complete and accurate list of all BeiGene Patents as of the Execution Date. **[…***…]**..

1.19 "BeiGene Territory" means all countries of the world other than the countries included in the Novartis Territory.

1.20 "BeiGene **[…***…]**" means BeiGene's **[…***…]** designated by BeiGene as **[…***…]**.

1.21 "BeiGene Trademarks" means the trademarks and domain names Controlled by BeiGene listed on Schedule 1.21 attached hereto.

1.22 "BeiGene Upstream License Agreements" means any contract or agreement between BeiGene (or any of its Affiliates, as applicable) and any Third Party pursuant to which BeiGene has Control of any BeiGene IP for purposes of this Agreement. For clarity, the BeiGene Upstream License Agreements shall include **[…***…]**.

1.23 "BeiGene Supply Agreements" means **[…***…]**.

1.24 "Biosimilar Product" means, with respect to a product in a given country, (a) a Third Party biologic product that (i) contains the same or a "highly similar" (as such term is used in 42 U.S.C. § 262(i)(2) or analogous laws and regulations outside the United States) active ingredient as such product and (ii) that is approved or licensed by a Regulatory Authority pursuant to Applicable Law or (b) a Third Party biologic product that is interchangeable for such product insofar as it meets the requirements for interchangeability pursuant to Section 351(k) of the Public Health Service Act (42 U.S.C. § 262(k)) or any subsequent or superseding law, statute or regulation or analogous laws and regulations outside the United States. For purposes of clarity, a biologic product will be deemed to be a Biosimilar Product with respect to a product for purposes of this definition if such product is used as the reference product in the application or submission made with respect to such biologic product under Applicable Law.

1.25 "BLA" means a Biologics License Application filed with the FDA in the United States with respect to a Licensed Product, as defined in Title 21 of the U.S. Code of Federal Regulations, Section 601.2 et seq., or a comparable filing for Regulatory Approval in a jurisdiction other than the United States.

1.26 "Bridging Study" means any clinical trial conducted in a country to provide clinical data on safety, efficacy, dosage, and dose regimen to permit the extrapolation of foreign clinical data to the population in such country or in relation to Regulatory Approvals or secondary manufacturing approvals in such country.

1.27 "Business Day" means a day on which banking institutions in New York City, New York, Basel, Switzerland, or Beijing, China, are open for business, excluding any Saturday or Sunday.

1.28 "Calendar Quarter" means each of the three (3) month periods ending March 31, June 30, September 30, and December 31; provided, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall end on the last day of the Term.

1.29 "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) consecutive calendar months beginning on January 1 and ending on December 31; provided, that, the final Calendar Year of the Term shall end on the last day of the Term.

1.30 "Challenge" means to contest or Assist in the contest of the validity or enforceability of any of the BeiGene Patents, in whole or in part, in any court, arbitration proceeding or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. For the avoidance of doubt, the term "contest" includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any BeiGene Patents; (b) citation to the United States Patent and Trademark Office pursuant to 35 U.S.C. § 301 of prior art patents or printed publications or statements of the patent owner concerning the scope of any of the BeiGene Patents; (c) filing a request under 35 U.S.C. § 302 for re-examination of any of the BeiGene Patents; (d) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any BeiGene Patents or any portion thereof; (e) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of the BeiGene Patents or any portion thereof; (f) becoming a party to an interference with an application for any of the BeiGene Patents pursuant to 35 U.S.C. § 135; (f) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against any of the BeiGene Patents in any country; or (g) any foreign equivalents of subsection (a) through (e) applicable in any country.

1.31 "Change of Control" means, with respect to a Party (an "Acquired Party"), the occurrence of any of the following events from and after the Execution Date: (a) any Person or group of Persons becomes the beneficial owner (directly or indirectly) of more than fifty percent (50%) of the voting shares of such Acquired Party; or (b) such Acquired Party consolidates with or merges into or with another Person pursuant to a transaction in which more than fifty percent (50%) of the voting shares of the acquiring or resulting entity outstanding immediately after such consolidation or merger are not held by the holders of the outstanding voting shares of such Acquired Party immediately preceding such consolidation or merger; or (c) that Acquired Party sells or transfers to another Person all or substantially all of its assets to which this Agreement relates.

1.32 "Clinical Data" means any and all raw 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 pursuant to this Agreement.

1.33 "Clinical Trial" means any human clinical trial of the Licensed Product, including any Phase 1 clinical trial, Phase 2 clinical trial, Phase 3 clinical trial, Registrational Clinical

Trial, Bridging Study and any post-marketing clinical trial commenced after Regulatory Approval of the Licensed Product.

1.34 "Combination Regimen" means, with respect to the Licensed Product for a given Indication, the use of such Licensed Product for such Indication together with one or more other pharmaceutical products (each, an "Other Product") as two or more entities of active ingredients in a combination therapy, including concomitant or sequential therapy, either (a) in a Clinical Trial for such Licensed Product for such Indication as set forth in the protocol for such Clinical Trial or (b) for commercial sale for such Indication as set forth in the approved label for such Licensed Product; provided, that, approved chemotherapy treatments shall not constitute Other Products for purposes of this definition. For clarity, an Other Product could be a product that is proprietary to a Party, a product that is proprietary to Third Parties, or that is a generic or biosimilar.

1.35 "Commercialization" means activities directed to the commercialization of a product, including selling, offering for sale, pricing, marketing, detailing, promoting, distributing, order processing, handling returns and recalls, booking sales, importing, exporting, and transporting such product for commercial sale, and seeking Pricing Approval of a product (if applicable), as well all regulatory compliance with respect to the foregoing. For clarity, "Commercialization" does not include Manufacturing. When used as a verb, "Commercialize" means to engage in Commercialization.

1.36 "Commercialization Plan" means, with respect to the Licensed Product, the plan for the Commercialization of such Licensed Product in the Novartis Territory in a given Calendar Year (or in the case of the initial Commercialization Plan, the period through First Commercial Sale and for the twelve (12) month period thereafter), as such plan may be amended from time to time in accordance with this Agreement, which Commercialization Plan shall be comprised of **[…***…]**.

1.37 "Commercially Reasonable Efforts" means, (i) with respect to Novartis in relation to an obligation under this Agreement applicable to the Licensed Product, such efforts that are consistent with the efforts and resources normally used by Novartis and its Affiliates (which in any event shall not be less than the efforts used by a reasonable international biopharmaceutical company or pharmaceutical company, in each case, that is of comparable size and has comparable resources to Novartis) and (ii) with respect to BeiGene in relation to an obligation under this Agreement applicable to the Licensed Compound or the Licensed Product, such efforts that are consistent with the efforts and resources normally used by BeiGene and its Affiliates (which in any event shall not be less than the efforts used by a reasonable international biopharmaceutical company or pharmaceutical company), in each case, that is of comparable size and has comparable resources to BeiGene, in the performance of a corresponding activity for a similar pharmaceutical compound or product, as applicable, at a similar stage in its research, development, or commercial life as the Licensed Product, and that has commercial and market potential similar to the Licensed Product, taking into account, in each case, **[…***…]**.

1.38 "Committee" means the JSC, the JDC, the JMAC, the JCC and any subcommittees formed pursuant to Section 2.9 (together, the "Committees").

1.39 "Competing Product" means any product, other than the Licensed Product, which contains, as its active ingredient, a PD-1 Antagonist or a PD-L1 Antagonist. For purposes of this definition, "PD-1 Antagonist" means any **[…***…]** inhibit the receptor known as Programmed Cell Death protein 1 ("PD-1") and "PD-L1 Antagonist" means any **[…***…]** inhibit the ligand known as Programmed Cell Death ligand 1 ("PD-L1"). For clarity, "Competing Product" shall not include **[…***…]**.

1.40 "Completion of the BeiGene Ongoing Clinical Trial" means the date on which a clinical study report for each of the BeiGene Ongoing Clinical Trials becomes available to BeiGene or its Affiliates.

1.41 "Confidential Information" means, with respect to a Disclosing Party, all confidential and proprietary information, including chemical or biological materials, chemical structures, commercialization plans, correspondence, customer lists, data, development plans, formulae, improvements, Inventions, Know-How, processes, regulatory filings, reports, strategies, techniques, or other information, in each case, that are disclosed by or on behalf of such Disclosing Party to the Receiving Party pursuant to this Agreement, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other Party by or on behalf of the disclosing Party in oral, written, visual, graphic, or electronic form. For purposes of clarity, unless excluded pursuant to Section 12.2, (a) all Clinical Data generated in the conduct of the BeiGene Ongoing Clinical Trial and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan shall be deemed Confidential Information of BeiGene, subject to the rights of Novartis to use and reference such Clinical Data, without additional consideration, in accordance with this Agreement; (b) all Inventions shall be deemed the Confidential Information of the owning Party as set forth in Article 10; (c) any scientific, technical, manufacturing or financial information, including (except as set forth in (a) 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; and (d) the terms of this Agreement shall be deemed Confidential Information of both Parties.

1.42 "Control," "Controls," or "Controlled" means, with respect to any Patent, Know-How or Confidential Information, the ability of a Party or its Affiliates, as applicable (whether through ownership or license (other than a license granted in this Agreement)) to grant to the other Party the licenses or sublicenses to such Patent or Know-How as provided herein, or to otherwise disclose such Confidential Information to the other Party, without violating the terms of any then-existing agreement with any Third Party at the time such Party or its Affiliates, as applicable. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Patent, Know-How or Confidential Information that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such Acquired Party after the Effective Date as a result of such Change of Control unless (a) prior to the consummation of such Change of Control, such Acquired Party or any of its Affiliates also Controlled such Patent, Know-How or Confidential Information, or (b) the Know-How, Patents or Confidential Information owned or in-licensed by such Third Party were not used in the performance of activities under this Agreement prior to the consummation of such

Change of Control, but after the consummation of such Change of Control, the Acquired Party or any of its Affiliates determines to use or uses any such Patents, Know-How or Confidential Information in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases (a) and (b), such Patents, Know-How or Confidential Information will be "Controlled" by such Party for purposes of this Agreement.

1.43 "Cover" means, with reference to a Patent claim, that the making, using, offering to sell, selling, importing, or exporting, as applicable, of the Licensed Product would infringe such Patent claim in the country in which such activity occurs without a license thereto (or ownership thereof).

1.44 "CPI" means the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items 1982-84=100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index), in the United States.

1.45 "Critical Matters" means any decision of the Parties or any Committee: **[…***…]**.

1.46 "Damages" means all losses, costs, claims, damages, judgments, liabilities, and expenses (including reasonable attorneys' fees and other reasonable out-of-pocket costs in connection therewith).

1.47 "Data Security and Privacy Laws" means any Applicable Law relating to the privacy, data protection, integrity, Processing and security of Personal Data, including but not limited to: (a) federal and state Applicable Law, including the Health Insurance Portability and Accountability Act of 1996, as amended and all implementing regulations, (b) state data protection laws, (c) state breach notification laws, (d) the General Data Protection Regulation (EU) 2016/679, and (e) any related Applicable Law implementing the foregoing.

1.48 "Detail" means face-to-face (either in person or virtual) discussions with physicians and other health care practitioners who are permitted under Applicable Law to prescribe the Licensed Product for the purpose of promoting the Licensed Product to such physicians or practitioners.

1.49 "Detailing FTE Rate" means $**[…***…]** per annum during calendar year 2021, such amount to be adjusted as of January 1, 2022 and annually thereafter by the **[…***…]**, which rate, for the avoidance of doubt, includes **[…***…]**.

1.50 "Development" means activities that relate to obtaining, maintaining or expanding Regulatory Approval of the Licensed Product and to supporting usage for the Licensed Product for one or more Indications in the Field, including: (a) the conduct of research activities (including drug discovery, identification, or synthesis) with respect to the Licensed Product; and (b) preclinical and clinical drug development activities and other development activities with respect to the Licensed Product, including test method development and stability testing, toxicology, formulation, process development, qualification and validation, quality assurance, quality control, Clinical Trials, statistical analysis and report writing, the preparation and

submission of INDs and MAAs, regulatory affairs with respect to the foregoing. For clarity, "Development" does not include Manufacturing or Medical Affairs Activities. When used as a verb, "Develop" means to engage in Development.

1.51 "Development Costs" means, with respect to a given Global Monotherapy Trial, the sum of the following: (a) **[…***…]**, (b) **[…***…]** and (c) **[…***…]**, in each case (clauses (a) through (c)) incurred by a Party or its Affiliate from time to time after such time as such Global Monotherapy Trial is commenced in accordance with the Additional Global Development Plan and that are reasonably allocable to the conduct of such Global Monotherapy Trial in accordance with the Additional Global Development Plan. For purposes of this definition, (i) **[…***…]** means **[…***…]**; (ii) **[…***…]** means **[…***…]**; (iii) **[…***…]** means **[…***…]**; (iv) **[…***…]** means a rate of $**[…***…]** per annum during Calendar Year 2021, such amount to be adjusted as of January 1, 2022 and annually thereafter by **[…***…]**. For the avoidance of doubt, such rate is intended to cover the cost **[…***…]**.

1.52 "Development Plan" means the Initial Global Development Plan or the Additional Global Development Plan, as applicable.

1.53 "Divestiture" means, with respect to a Competing Product: (a) the divestiture of such Competing Product through: (i) an outright sale or assignment of all material rights in such Competing Product to a Third Party; (ii) an exclusive out-license to a Third Party of all development, manufacture, and commercialization rights and the right to conduct Medical Affairs Activities, with respect to such Competing Product, with no further role, influence, or authority of the applicable Party, directly or indirectly, with respect to such Competing Product; or (iii) a combination of the transactions contemplated by the foregoing clauses (i) and (ii); or (b) the cessation of all Development, Manufacture and Commercialization activities and Medical Affairs Activities with respect to such Competing Product (subject, if applicable, to applicable wind-down activities and applicable requirements of Applicable Law). For clarity, subject to the preceding sentence, the right of the applicable Party to receive royalties, milestones, or other payments in connection with an acquirer's, assignee's, or licensee's Development, Manufacture, or Commercialization of a Competing Product pursuant to sub-section (a) above shall not, in and of itself, be deemed to disqualify the applicable sale, assignment, or license from constituting a Divestiture. When used as a verb, "Divest" and "Divested" mean to cause or have caused a Divestiture.

1.54 "Dollars" or "$" means the legal tender of the United States.

1.55 "EU" means all countries that are officially recognized as member states of the European Union at any particular time; provided, that, the EU will always be deemed to include France (including its territories and possessions), Germany, Italy and Spain for purposes of this Agreement.

1.56 "European Regulatory Approval" means, with respect to a Licensed Product and a particular Indication: (a) Regulatory Approval of such Licensed Product for such Indication in **[…***…]** Major European Markets, by the European Commission (in the case of any Major European Markets other than the United Kingdom) or the MHRA (in the case of the United

Kingdom) and (b) Pricing Approvals for such Licensed Product for such Indication in such Major European Markets, by the European Commission (in the case of any Major European Markets other than the United Kingdom) or the MHRA (in the case of the United Kingdom).

1.57 "Executive Officers" means: (a) with respect to BeiGene, the **[…***…]** or his/her designee; and (b) with respect to Novartis, the **[…***…]** or his/her designee.

1.58 "Existing IND" means the IND for the conduct of the BeiGene Ongoing Clinical Trial as more particularly identified on Schedule 1.58.

1.59 "Field" means the treatment, diagnosis or prevention of any human disease, disorder, or condition.

1.60 "First Commercial Sale" means, on a country-by-country basis, the first sale of the Licensed Product in such country for use or consumption by the general public (following receipt of all Regulatory Approvals that are required in order to sell the Licensed Product in such country); provided, that, the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or Sublicensee or (b) any sale, disposition or transfer for use of the Licensed Product in Clinical Trials or for development activities outside of the conduct of Clinical Trials by or on behalf of a Party, or disposal or transfer of the Licensed Product for a bona fide charitable purpose, compassionate use, or samples if no monetary consideration is received for such use or transfer.

1.61 "FTE" means a full-time employee, or in the case of less than a full-time employee, a full-time equivalent employee year, carried out by an appropriately qualified employee of a Party or its Affiliate, based on **[…***…]** per year (excluding vacations and holidays). For clarity, **[…***…]** shall not constitute FTEs.

1.62 "GCP" means the applicable then-current ethical and scientific quality standards for designing, conducting, recording, and reporting Clinical Trials as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including in the United States, Good Clinical Practices established through FDA guidance, and, outside the United States, Guidelines for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6).

1.63 "Global Development Activities" means, collectively, the activities undertaken pursuant to the Initial Global Development Plan and the Additional Global Development Plan.

1.64 "GLP" means the applicable then-current good laboratory practice standards as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction, including in the United States, those promulgated or endorsed by the FDA in U.S. 21 C.F.R. Part 58, or the equivalent thereof as promulgated or endorsed by the applicable Regulatory Authorities outside of the United States.

1.65 "GMP" means all applicable then-current good manufacturing practice standards for fine chemicals, intermediates, bulk products, or finished pharmaceutical products, as are required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction,

including, as applicable: (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, U.S. 21 C.F.R. Parts 210 and 211; (b) all applicable requirements detailed in the EMA's "The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products;" and (c) all Applicable Law promulgated by any Governmental Authority having jurisdiction over the manufacture of the applicable compound or pharmaceutical product, as applicable.

1.66 "GPV" means all applicable then-current good pharmacovigilance practice standards as required by applicable Regulatory Authorities or Applicable Law in the relevant jurisdiction.

1.67 "Governmental Authority" means any: (a) federal, state, local, municipal, foreign, or other government; (b) governmental or quasi-governmental authority of any nature (including any agency, board, body, branch, bureau, commission, council, department, entity, governmental division, instrumentality, office, officer, official, organization, representative, subdivision, unit, and any court or other tribunal); (c) multinational governmental organization or body; or (d) entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military, or taxing authority or power of any nature.

1.68 "**[…***…]**" means, with respect to the Licensed Product in a particular country or tiered group of countries, the **[…***…]** of the Licensed Product in such country or countries.

1.69 "HGRAC" means the Human Genetics Resources Administration of China.

1.70 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. § 18a).

1.71 "HSR Filing" means a filing by each of BeiGene and Novartis with the FTC and the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.72 "IND" means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the United States for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the EU).

1.73 "Indication" means an entirely separate and distinct disease or medical condition in humans for which a biopharmaceutical product: (a) that is in a Clinical Trial is intended to treat in such Clinical Trial; or (b) has received a separate and distinct Regulatory Approval with an approved label claim to treat such disease or condition, as applicable. For purposes of clarity, distinctions between human indications, diseases or conditions with respect to the Licensed Product shall be made by reference to the World Health Organization International Classification of Diseases, version 10 (as revised and updated, the "ICD10").

1.74 "Initial Global Development Plan" means the initial global Development plan for the Development of Licensed Products, as such plan may be amended from time to time in accordance with this Agreement. The Initial Global Development Plan as of the Execution Date is attached hereto as Exhibit A.

1.75 "Invention" means any process, method, composition of matter, article of Manufacture, discovery, or finding that is conceived or reduced to practice, constructively or actually, by either Party or jointly by the Parties in connection with the Development, Manufacture, or Commercialization of, and/or the conduct of Medical Affairs Activities with respect to, a Licensed Compound or the Licensed Product under this Agreement.

1.76 "Investigator Sponsored Study" means a Clinical Trial using the Licensed Product, either as a Monotherapy or as a Combination Regimen sponsored and initiated by a Third Party.

1.77 "Japan Regulatory Approval" means, with respect to a Licensed Product in an Indication, Regulatory Approval (including Pricing Approvals) by the MHLW of such Licensed Product, and any required companion diagnostic, for such Indication.

1.78 "Joint Invention" means any Invention that is jointly conceived or reduced to practice by one or more employees of or consultants to Novartis or its Affiliates and one or more employees of or consultants to BeiGene or its Affiliates in the conduct of the activities contemplated by this Agreement.

1.79 "Joint IP" means, collectively, the Joint Inventions and the Joint Patents.

1.80 "Joint Patent" means any Patents that contain one or more claims that cover a Joint Invention.

1.81 "Know-How" means algorithms, data, information, Inventions, knowledge, methods (including methods of use or administration or dosing), practices, results, software, techniques, technology, know-how and trade secrets, including analytical and quality control data, analytical methods (including applicable reference standards), assays batch records, chemical structures and formulations, compositions of matter, formulae, manufacturing processes and data, pharmacological, toxicological and clinical test data and results, processes, reports, research data, research tools, sequences, standard operating procedures, and techniques, in each case, whether patentable or not, and, in each case, tangible manifestations thereof.

1.82 "Knowledge" means, with respect to BeiGene, **[…***…]**.

1.83 "Licensed Compound" means the proprietary PD-1 inhibitor of BeiGene designated as tislelizumab and described more fully on Schedule 1.83 attached hereto.

1.84 "Licensed Product" means (a) any product or product candidate that constitutes, incorporates, comprises or contains a Licensed Compound, whether or not as the sole active ingredient, and in all forms, presentations, and formulations (including manner of delivery and

dosage) and (b) any other product that becomes a Licensed Product pursuant to Sections 9.6.2(a), 9.6.2(b) and/or 9.6.2(c).

1.85 "MA" or "Marketing Authorization" means an MAA that has been approved by the applicable Governmental Authority to market the applicable product in a country or group of countries.

1.86 "MAA" means a Marketing Authorization Application, BLA, or similar application, as applicable, and all amendments and supplements thereto, submitted to the FDA, EMA, or any equivalent filing in a country or regulatory jurisdiction other than the United States or EU with the applicable Regulatory Authority, to obtain marketing approval for a pharmaceutical product, in a country or in a group of countries.

1.87 "Major European Markets" means France, Germany, Italy, Spain, and the United Kingdom.

1.88 "Manufacture" means activities related to the manufacturing of a product or any component or ingredient thereof, including the production, manufacture, processing, filling, finishing, packaging, sterilization, labeling, shipping, and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.89 "Master Cell Bank" or "MCB" means the reference deposit or collection of vials of the Product Cell Line, which has been prepared from the selected single cell clone under GMP conditions, and from which all subsequent lots of Working Cell Banks are derived.

1.90 "Materials" means all tangible biological materials, cells, reference standards, assays and media that are used in or held for use for, the Manufacture of the Licensed Product or the Licensed Compound; including the Product Cell Line, the Master Cell Bank, the Working Cell Bank and the Parental Cell Line.

1.91 "Material Safety Issue" means a significant safety concern that is bona fide, serious and unexpected or, if expected, is observed at a higher rate and grade, and is generally not monitorable or reversible and that, in any case, would significantly impact or delay anticipated Regulatory Approval for, or Commercialization of, the Licensed Product.

1.92 "Medical Affairs Activities" means the design, oversight and implementation of activities designed to ensure or improve appropriate medical use of, conduct medical education of, or support or conduct clinical studies regarding, the Licensed Product, including: (a) the activities to be conducted by Medical Liaisons; (b) sponsoring, or the obtaining of grants to support, continuing independent medical education (including independent symposia and congresses); (c) participation in international congresses and (d) the development, publication and dissemination of scientific and clinical information in support of an approved Indication for the Licensed Product, as well as medical information services (and the content thereof) provided in response to inquiries communicated via the sales representatives or other external-facing

representatives or received by letter, phone call or email or other means of communication agreed by the Parties in writing.

1.93 "Medical Affairs Plan" means, with respect to a Licensed Product, a written high-level strategic and tactical plan for the Medical Affairs Activities to be conducted with respect to such Licensed Product in the Novartis Territory or the BeiGene Territory, as applicable. The Medical Affairs Plan will include the following elements: **[…***…]**.

1.94 "Medical Liaisons" means the health care professionals employed or engaged by a Party with sufficient health care experience to engage in in-depth scientific dialogue with physicians regarding medical issues or relevant scientific topics associated with the Licensed Product and are not sales representatives or otherwise engaged in direct selling or promotion of the Licensed Product.

1.95 "Milestone Event" means, as applicable, a Development Milestone Event or a Commercialization Milestone Event.

1.96 "Milestone Payment" means, as applicable, a Development Milestone Payment or a Commercialization Milestone Payment.

1.97 "Monotherapy" means, with respect to the Licensed Product for a given Indication, the intended use of such Licensed Product alone for such Indication, and not as part of a Combination Regimen (including concomitant or sequential therapy), either (a) in a Clinical Trial for such Licensed Product for such Indication as set forth in the protocol for such Clinical Trial or (b) for commercial sale for such Indication as set forth in the approved label for such Licensed Product. For clarity, use of the Licensed Product together with approved chemotherapy treatments shall be considered Monotherapy.

1.98 "NDA" means a New Drug Application submitted to the FDA, or any successor application or procedure, as more fully defined in 21 C.F.R. § 314.50 et. seq.

1.99 "Net Sales" means the net sales recorded by Novartis or any of its Affiliates or Sublicensees (other than distributors and wholesalers) for any Licensed Product sold to Third Parties other than Sublicensees, as determined **[…***…]**. The deductions booked on an accrual basis by Novartis and its Sublicensees and Affiliates under their respective Accounting Standards to calculate the recorded net sales from gross sales include the following:

[…*…]**

With respect to the calculation of Net Sales:

(i) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party and sales between or among Novartis and its Affiliates and Sublicensees shall be disregarded for purposes of calculating Net Sales; and

(ii) If a Licensed Product is delivered to the Third Party before being invoiced (or is not invoiced), Net Sales will be calculated at the time all the revenue recognition criteria under Novartis' or its Sublicensee's Accounting Standards are met.

(iii) In the event that the Licensed Product is sold in a finished dosage form containing the Licensed Compound in combination with one or more other active ingredients (a "Finished Dosage Combination Product"), the Net Sales of such Finished Dosage Combination Product will be calculated by **[…***…]**.

1.100 "Novartis Controlled Compound" means any compound or other active pharmaceutical ingredient that is (a) proprietary to Novartis (or its Affiliates) or (b) proprietary to a Third Party and in-licensed by Novartis (or its Affiliates), including in either case, compounds or active pharmaceutical ingredients that are part of a Combination Regimen or Finished Dosage Combination Product but excluding the Licensed Compound or the Licensed Product.

1.101 "Novartis Anti-PD-1" means proprietary PD-1 inhibitor of Novartis designated as spartalizumab (PDR001) described more fully on Schedule 1.101 attached hereto.

1.102 "Novartis Invention" means any Invention that relates to the Licensed Compound and/or Licensed Product and that is conceived or first reduced to practice by employees of, or consultants to, Novartis, alone or jointly with any Third Party, without the use in any material respect of any BeiGene IP or Joint IP.

1.103 "Novartis Invention Patents" means any and all Patents Controlled by Novartis during the Term that contain one or more claims that Cover Novartis Inventions.

1.104 "Novartis IP" means, collectively, the Novartis Patents, the Novartis Know-How and the Novartis Inventions.

1.105 "Novartis Know-How" means any Know-How Controlled by Novartis or any of its Affiliates developed pursuant to this Agreement after the Execution Date and during the Term which is necessary or reasonably useful for the Development, Manufacture, or Commercialization of, and/or the conduct of Medical Affairs Activities with respect to, the Licensed Products in the Field in the Novartis Territory. For clarity, Novartis Know-How shall not include any Know-How to the extent that such Know-How relates to a Novartis Controlled Compound.

1.106 "Novartis Patents" means any and all Patents Controlled by Novartis or its Affiliates developed pursuant to this Agreement the Execution Date and during the Term which are necessary or reasonably useful for the Development, Manufacture, or Commercialization of, and/or the conduct of Medical Affairs Activities with respect to, the Licensed Products in the Field. For clarity, Novartis Patents shall include Novartis Invention Patents but shall not include any Patents that relate to a Novartis Controlled Compound.

1.107 "Novartis Territory" means the United States, Canada, Mexico, the member countries of the European Union as of the Effective Date, United Kingdom (including its territories and possessions), Norway, Switzerland, Lichtenstein, Iceland, Russia and Japan.

1.108 "Parental Cell Line" means the **[…***…]**, within the meaning of the Clinical Supply Agreement.

1.109 "Patents" means: (a) all patents and patent applications in any country or supranational jurisdiction worldwide; and (b) any substitutions, divisionals, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, and the like of any such patents or patent applications.

1.110 "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.111 "Personal Data" means (a) all information identifying, or in combination with other information, identifiable to, an individual, including pseudonymized (key-coded) clinical data containing such information; and (b) any other information that is governed, regulated or protected by one or more Data Security and Privacy Laws.

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

1.113 "Pricing Approval" means any approval, agreement, determination, or decision establishing prices that can be charged to consumers for a pharmaceutical product or that will be reimbursed by Governmental Authorities or other payers for a biopharmaceutical product, in each case, in a country where Governmental Authorities approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.114 "**[…***…]**" means (i) for the United States, an ASP for the Licensed Product equal to **[…***…]** of the ASP for **[…***…]** and (ii) for any country or tiered group of countries (as applicable), other than **[…***…]**, a WAC for the Licensed Product equal to **[…***…]** in the applicable country, or **[…***…]**. For the sake of clarity, **[…***…]** shall apply with respect to **[…***…]**.

1.115 "**[…***…]**" means, with respect to **[…***…]**.

1.116 "Primary Detail" means a Detail in which information regarding the Licensed Product is the first and most prioritized product information communicated by the applicable sales representative and for which the majority of the sales representative's incentive compensation in respect of such Detail is based on the communication of information regarding the Licensed Product.

1.117 "Prior CDA" means that certain confidentiality agreement, by and between BeiGene and Novartis Pharmaceuticals Corporation dated **[…***…]**.

1.118 "Processing" (or its conjugates) means any operation or set of operations that is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alternation, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

1.119 "Product Cell Line" means the **[…***…]**, within the meaning of the Clinical Supply Agreement.

1.120 "Prosecution and Maintenance" or "Prosecute and Maintain" means, (i) with regard to a Patent, the preparation, filing, prosecution, and maintenance of such Patent, as well as re-examinations, reissues, appeals, and requests for patent term adjustments, patent term extensions and Supplemental Protection Certificates with respect to such Patent, together with the initiation or defense of interferences, oppositions, post grant review, inter partes review, derivations, re-examinations, post-grant proceedings, and other similar proceedings (or other defense proceedings with respect to such Patent, but excluding the defense of challenges to such Patent as a counterclaim in an infringement proceeding) with respect to the particular Patent, and any appeals therefrom and (ii) with regard to a trademark, the preparation, filing, prosecution, registration, renewal and maintenance of such trademark, as well the initiation or defense of oppositions, cancellations and other similar proceedings (or other defense proceedings with respect to such trademark, but excluding the defense of challenges to such trademark as a counterclaim in an infringement proceeding) with respect to the particular trademark, and any appeals therefrom.

1.121 "Registrational Clinical Trial" means: (a) a human clinical trial of a compound or product that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) or corresponding foreign regulations or (b) a human clinical trial of a compound or product that is intended to: (i) establish that the compound or product is safe and efficacious for its intended use; (ii) define contraindications, warnings, precautions, and adverse reactions that are associated with the compound or product in the dosage range to be prescribed; and (iii) support Regulatory Approval for such compound or product (whether conditional or final), but may not include the data that may be necessary to support the Pricing Approvals; or (c) a human clinical trial similar to a human clinical trial described in sub-clause (a) prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.122 "Regulatory Approval" means, with respect to a particular Licensed Product and a particular Indication and a particular country, the regulatory approval of the applicable Regulatory Authority necessary for the marketing and sale of such Licensed Product for such particular Indication in such country (excluding Pricing Approval, unless otherwise provided herein).

1.123 "Regulatory Authority" means any national or supranational Governmental Authority, including the U.S. Food and Drug Administration (and any successor entity thereto)

(the "FDA") in the United States, the European Medicines Agency (and any successor entity thereto) (the "EMA") or the European Commission (and any successor entity thereto), as applicable, in the EU, and the Ministry of Health, Labour, and Welfare of Japan, or the Pharmaceuticals and Medical Devices Agency of Japan (or any successor to either of them) as the case may be (the "MHLW") in Japan, the Medicines and Healthcare Products Regulatory Agency (the "MHRA") in the United Kingdom, or any health regulatory authority in any country that is a counterpart to the foregoing agencies, including, without limitation, HGRAC, in each case, that holds responsibility for development and commercialization of, and the granting of Regulatory Approval for, a pharmaceutical product in such country.

1.124 "Regulatory Exclusivity" means, with respect to a particular Licensed Product in a country in the Novartis Territory, any exclusivity (including for clarity new biologic exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity) conferred by the Regulatory Authority in such country which confers an exclusive commercialization period during which Novartis, its Affiliates or Sublicensees have the exclusive right to market and sell the Licensed Product in such country, excluding any rights conferred by or based on any Patents.

1.125 "Regulatory Filing" means any filing with any Regulatory Authority with respect to the research, development, manufacture, distribution, pricing, reimbursement, marketing or sale of a Licensed Product. For clarity, the term "Regulatory Filing" shall not mean, or apply to, any submission to any regulatory authority of adverse event reports, periodic safety reports, or other similar safety submissions, which shall each be governed by the Pharmacovigilance Agreement.

1.126 "Regulatory Materials" means the regulatory registrations, applications, authorizations, and approvals (including MAs, supplements and amendments, pre- and post-approvals, Pricing Approvals, and labeling approvals), Regulatory Approvals, and other submissions made to or with, and minutes of meetings with, any Regulatory Authority for research, development (including the conduct of Clinical Trials), Manufacture, or commercialization of a pharmaceutical product in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents, referenced in the complete regulatory chronology for each such submission including all drug master files (if any), INDs, BLAs and NDAs, and foreign equivalents of any of the foregoing.

1.127 "Regulatory Transition Plan" means the written plan to be prepared by the JRSC which will set forth the Regulatory Transition Activities to be conducted by BeiGene and Novartis pursuant to Section 4.2.2, as such written plan may be amended, modified or updated by the mutual agreement of the Parties or, after the Effective Date, the JDC.

1.128 "RMM FTE Rate" means $**[…***…]** per annum during calendar year 2021, such amount to be adjusted as of January 1, 2022 and annually thereafter **[…***…]**, which rate, for the avoidance of doubt, includes **[…***…]**.

1.129 "Royalty Term" means, on a country-by-country basis, the period of time commencing on the First Commercial Sale of the Licensed Product in such country and expiring

upon the latest of: (a) the expiration of the last Valid Claim within the BeiGene Patents which Covers the composition of matter, or approved methods of use of such Licensed Product in such country; (b) the ten (10) year anniversary of the date of First Commercial Sale of the first Licensed Product in such country; and (c) the expiration of Regulatory Exclusivity with respect to such Licensed Product in such country.

1.130 "Segregate" means, with respect to a Competing Product and/or the Novartis Anti-PD-1, to segregate **[…***…]**. Notwithstanding the foregoing, with respect to the Novartis Anti-PD-1 (i) the restrictions set forth in subsections **[…***…]** above shall not be deemed to apply to **[…***…]**.

1.131 "Shared Development Costs" means, with respect to a Global Monotherapy Trial that the Parties mutually agree to conduct, the Development Costs incurred by each Party (or its Affiliates, as applicable) in respect of the conduct of such Global Monotherapy Trial in accordance with the Additional Global Development Plan, but solely to the extent that such Development Costs are **[…***…]** of the Development Costs for such Global Monotherapy Trial included in the Additional Global Development Budget, unless an amendment to the Additional Global Development Plan (a) is mutually agreed to through the JSC or (b) determined to be made pursuant to the dispute resolution provisions of Section 16.7.2.

1.132 "Sublicensee" means, with respect to Novartis, a Third Party to whom Novartis has granted a sublicense, either directly or indirectly, under the BeiGene IP licensed to Novartis by BeiGene pursuant to this Agreement, to Develop, Manufacture, or Commercialize the Licensed Products in the Field in the Novartis Territory, but excluding: (a) any Third Party acting as a distributor; and (b) BeiGene and any of its Affiliates.

1.133 "Tax" means any direct or indirect tax, excise or duty and any surcharge thereon levied by any Governmental Authority in accordance with Applicable Law.

1.134 "Territory" means the BeiGene Territory or the Novartis Territory, as applicable.

1.135 "Third Party" means any Person other than BeiGene or Novartis that is not an Affiliate of BeiGene or of Novartis.

1.136 "Third Party Claim" means any and all suits, claims, actions, proceedings, or demands brought by a Third Party.

1.137 "United States" or "U.S." means the United States of America and all of its territories and possessions.

1.138 "U.S. Regulatory Approval" means with respect to the Licensed Product and a given Indication, Regulatory Approval by the FDA of the Licensed Product, and any required companion diagnostic, for that Indication.

1.139 "Valid Claim" means a claim of a Patent within the BeiGene Patents that is exclusively licensed to Novartis and: (a) has issued and has not expired, lapsed, been cancelled,

or abandoned, or been dedicated to the public, disclaimed, or held unenforceable, invalid, unpatentable, revoked, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including through opposition, reexamination, reissue, disclaimer, inter partes review, post grant review, post grant procedures, or similar proceedings; or (b) is a pending claim of an unissued, pending patent application, **[…***…]**. For clarity, a claim which issues later from such pending patent application above shall be considered a Valid Claim as defined in this Section as of the date of issuance.

1.140 "WAC" means, with respect to a particular product and a particular country or tiered group of countries, the wholesale acquisition cost for such product in such country or tiered group of countries.

1.141 "Working Cell Bank" or "WCB" means a vialed collection of serially sub-cultivated cells expressing the Licensed Compound that is derived from the Master Cell Bank under GMP conditions, and used to establish seed cultures for the Manufacturing of drug substance.

1.142 Additional Definitions. Each of the following terms has the meaning described in the corresponding section of this Agreement indicated below:

Definition	**Section**
Acquired Party	1.31
Acquiring Party	9.6.5
Agreement	Preamble
Audited Party	8.5.2
Auditing Party	8.5.2
Auditor	8.5.2
BeiGene	Preamble
BeiGene Indemnitees	14.1
BeiGene Ongoing Clinical Trial Data	10.1.2
BI Clinical Supply Agreement	1.23
CIA	5.8
Commercialization Milestone Event	8.2.3
Commercialization Milestone Payment	8.2.3
Competing Infringement	10.3.1
Cure Period	15.2.1
Development Milestone Event	8.2.1
Development Milestone Payment	8.2.1
Disclosing Party	12.1
Dispute	16.7.2(a)
DOJ	11.1
Effective Date	15.1.1

Electronic Delivery	16.12
EMA	1.123
Execution Date	Preamble
Existing Regulatory Materials	4.2.1
FDA	1.123
Finished Dosage Combination Product	1.99
FTC	11.1
GAAP	1.1
Global Monotherapy Trial	3.1.2(b)
IFRS	1.1
Indemnification Claim Notice	14.3.1
Indemnitee	14.3.1
Indemnitor	14.3.1
Insolvency Event	15.6.1
Joint Commercialization Committee or JCC	2.4
Joint Development Committee or JDC	2.1.3(d)
Joint Medical Affairs Committee or JMAC	2.3
Joint Steering Committee or JSC	2.1.1
Manufacturing Know-How and Materials	7.4(a)
MHLW	1.123
MHRA	1.123
Novartis	Preamble
Novartis Indemnitees	14.2
Party	Preamble
Permitted Combination Studies	3.2
Quality Agreement	7.3(c)(ii)
Receiving Party	12.1
Securities Regulators	12.3.1(a)
Term	15.1.1
Third Party Acquisition	9.6.5
Third Party Infringement	10.5.1
Third Party Personnel	5.8
[…*…]**	1.22

ARTICLE 2
GOVERNANCE

2.1 Joint Steering Committee.

2.1.1 Establishment; Responsibilities. Within **[…***…]** after the Effective Date, the Parties shall establish a joint steering committee (the "JSC") as more fully described in

this Section 2.1. The JSC will be a forum for discussion, review and coordination regarding the Development, Manufacture and Commercialization of, and the conduct of Medical Affairs Activities with respect to, Licensed Compounds and Licensed Products in the Novartis Territory and the BeiGene Territory and in connection therewith, each Party agrees to keep the JSC reasonably informed, on a summary level, of its progress and activities with respect thereto.

2.1.2 Specific Responsibilities. The Alliance Managers, in concert with the JSC members, will be responsible for coordinating the JSC, facilitating the scheduling and conduct of the JSC meetings, being responsible for the preparation and circulation of the JSC meeting agenda and minutes and ensuring that relevant action items from JSC meetings are carried by the parties or otherwise addressed, and bringing matters to the attention of the relevant JSC subcommittee, as applicable. In addition to the JSC's general discussion, the review and coordination regarding the Development, Manufacture and Commercialization of, and/ or the conduct of Medical Affairs Activities with respect to, Licensed Compounds and Licensed Products, the JSC will:

(a) subject to Section 2.5.2, resolve all matters that are required to be determined by any other Committee that are in dispute;

(b) review and approve each Additional Global Development Plan and Additional Global Development Plan Budget;

(c) review and approve all amendments to the Additional Global Development Plan and the Additional Global Development Budget;

(d) oversee the expansion of the responsibilities of the JSC as mutually agreed by the Parties; and

(e) make such other decisions as may be expressly delegated to the JSC pursuant to this Agreement or by mutual written agreement of the Parties during the Term.

2.1.3 Decisions. Except as otherwise set forth in this Agreement, all decisions required to be made by the JSC shall be made by **[…***…]**, **[…***…]**. If the JSC is unable to agree on any such matter, then either Party's Alliance Manager may, by providing written notice to the other Party, have such matter referred to the Executive Officers for resolution. Any final decision mutually agreed to by the Executive Officers with respect to such issue shall be conclusive and binding on the Parties. If the Executive Officers are unable to resolve the matter within **[…***…]** (or such other longer time frame that the Executive Officers may otherwise agree upon) after the matter is referred to them in accordance with this Section 2.1.3, then the following will apply:

(a) Without limiting Section 2.5.2 and subject to Section 2.1.3(d), if the JSC is unable to reach **[…***…]** on a non-Critical Matter requiring determination by the JSC, then, subject to subsection (b), the final decision may be made by the members of the JSC:

(i) appointed by BeiGene if such non-Critical Matter is related primarily to any of the following, **[…***…]**.

(ii) appointed by Novartis if such non-Critical Matter is related primarily to any of the following, **[…***…]**.

(b) For clarity, the foregoing shall not apply, and nothing in this Section 2.1.3 shall be deemed to restrict, the ability of a Party to **[…***…]**.

(c) If the Executive Officers are unable to reach consensus with respect to **[…***…]**, any Critical Matter, or any other matter required to be determined by the JSC, then the matter will be submitted for resolution by Accelerated Arbitration in accordance with Section 16.7.2(i).

(d) In the event that the JSC cannot reach **[…***…]** on any matter with respect of which the members of the JSC appointed by BeiGene have the right to make the final decision pursuant to Section 2.1.3(a)(i), then, if such decision relates to a matter that could reasonably be expected to **[…***…]**, then any member of the JSC appointed by Novartis may promptly refer such matter to the Executive Officers for discussion and the BeiGene members on the JSC shall not exercise their final decision making authority in respect thereof until the earlier of such time as the Executive Officers have discussed such matter or the date that is **[…***…]** after such referral.

2.2 Joint Development Committee. Within **[…***…]** following the Effective Date, the Parties shall establish a joint development committee (the "JDC"). The JDC shall include individuals from each Party with reasonable expertise in the areas of product development, clinical development and regulatory matters.

2.2.1 Specific Responsibilities. In addition to the JDC's general discussion, review and coordination regarding the Development of Licensed Compounds and Licensed Products and regulatory matters with respect to the Licensed Product, the JDC will:

(a) review all data and updates with respect to the conduct by BeiGene of the BeiGene Ongoing Clinical Trials and any other Clinical Trials included as a BeiGene responsibility as part of the Initial Global Development Plan;

(b) oversee the conduct of Development activities undertaken with respect to the Licensed Compound and the Licensed Product in the Novartis Territory;

(c) review all data and updates with respect to the Development by Novartis of the Licensed Compound and the Licensed Product in the Novartis Territory;

(d) review and approve any amendments to the Initial Global Development Plan;

(e) review and approve any amendments to the Regulatory Transition Plan;

(f) review and recommend to the JSC whether or not to approve, each Additional Global Development Plan and Additional Global Development Plan Budget;

(g) review the conduct by the Parties of Additional Global Development Activities, including matters related to progress, timelines, status, safety and budget;

(h) review and recommend to the JSC whether or not to approve, all amendments to the Additional Global Development Plan and the Additional Global Development Budget;

(i) review the Shared Development Costs Reports provided by each Party, prepare and submit to each Party the Shared Development Reconciliation Reports and attempt to resolve any disputes between the Parties with respect to any Shared Development Cost or Shared Development Reconciliation Report;

(j) oversee the implementation of, and the coordination between the Parties of activities to be performed under, the Pharmacovigilance Agreement and any other written agreement between the Parties with respect to the conduct of Development activities under this Agreement;

(k) review high level information regarding the clinical supply chain for the Licensed Compound and Licensed Products, including back-up mandatory sites and the ability to meet forecasted demand; and

(l) make such other decisions as may be expressly delegated to the JDC pursuant to this Agreement or by mutual written agreement of the Parties during the Term.

2.3 Joint Medical Affairs Committee. Within **[…***…]** following the Effective Date, the Parties shall establish a joint medical affairs committee (the "JMAC"). The JMAC shall include individuals from each Party with reasonable expertise in the conduct of Medical Affairs Activities.

2.3.1 Specific Responsibilities. In addition to the JMAC's general discussion, review and coordination regarding the conduct of Medical Affairs Activities, including Investigator Sponsored Studies supported by the Parties or their Affiliates, for Licensed Products, the JMAC will:

(a) review and discuss the Parties' Medical Affairs Plans in order to align the Medical Affairs Activities to be conducted by the Parties to ensure that a consistent global scientific narrative is delivered for the Licensed Products;

(b) review and discuss all material amendments to the Medical Affairs Plans;

(c) review all Medical Affairs Reports provided by the Parties; and

(d) make such other decisions as may be expressly delegated to the JMAC pursuant to this Agreement or by mutual written agreement of the Parties during the Term.

2.4 Joint Commercialization Committee. Within **[…***…]** following the Effective Date, the Parties shall establish a joint commercialization committee (the "JCC"). The JCC shall include individuals from each Party with reasonable expertise in the areas of sales and marketing, operations, and market access.

2.4.1 Specific Responsibilities. In addition to the JCC's general discussion, review and coordination regarding the Commercialization of Licensed Products, the JCC will:

(a) review and discuss the Commercialization Plan and the branding strategy for the Novartis Territory;

(b) review updates with respect to the Commercialization by Novartis of the Licensed Compound and the Licensed Product in the Novartis Territory;

(c) review high level information regarding the commercial supply chain for the Licensed Compound and Licensed Products, including back-up mandatory sites and the ability to meet forecasted demand;

(d) review the allocation between the Parties of specific customers and accounts with respect to Details in countries and Indications in respect of which BeiGene has exercised the Co-Detailing Right as proposed by Novartis pursuant to Section 5.7.2(a);

(e) review and approve terms for **[…***…]**; and

(f) make such other decisions as may be expressly delegated to the JCC pursuant to this Agreement or by mutual written agreement of the Parties during the Term.

2.5 Joint **[…***…]**. Within **[…***…]** following the Effective Date, the Parties shall establish a joint **[…***…]** which will be a subcommittee of the JCC, to exchange information **[…***…]** respect to the Licensed Product.

2.5.1 Specific Responsibilities. In addition to the **[…***…]** general discussion, review and coordination regarding the pricing of Licensed Products, the **[…***…]** will:

(a) **[…***…]**;

(b) review and approve the **[…***…]** proposed to be established by Novartis for the Licensed Product in **[…***…]** in the Novartis Territory **[…***…]** a reasonable period of time prior to the submission of any **[…***…]** in such country or countries;

(c) review and approve **[…***…]** in any **[…***…]** that is **[…***…]** for such country **[…***…]**;

(d) review and approve **[…***…]** in any **[…***…]** that is **[…***…]** established for all other countries **[…***…]** for which Novartis has established a **[…***…]**;

(e) discuss **[…***…]** to be made pursuant to clause (b) of the definition thereof with respect to any country or group of countries;

(f) discuss and approve a **[…***…]**; and

(g) make such other decisions as may be expressly delegated to the **[…***…]** pursuant to this Agreement or by mutual written agreement of the Parties during the Term.

2.5.2 Final Determinations by **[…***…]**. Notwithstanding Section 2.1.3 or anything else to the contrary herein, in the event the **[…***…]** is unable to unanimously agree on any matter specified in clause **[…***…]** of Section 2.5.1, **[…***…]**.

2.6 Joint Regulatory Filing Team. Within **[…***…]** following the Execution Date, the Parties shall establish a joint regulatory filing team (the "JRFT") comprised of **[…***…]** representatives (or such other number of representatives as the Parties may mutually agree) from each of Novartis and BeiGene, to prepare the Regulatory Transition Plan.

2.7 Committee Membership; Meetings; Minutes; Decision Making; Term.

2.7.1 Representatives. Each Committee shall be comprised of **[…***…]** representatives (or such other number of representatives as the Parties may mutually agree) from each of Novartis and BeiGene. Each representative of a Party shall have sufficient seniority and expertise to participate on the Committee as determined in such Party's reasonable judgment. Each Party will select a co-chairperson of each Committee (the "Chairpersons"). Each Party may replace any or all of its representatives on a Committee at any time upon written notice to the other Party in accordance with Section 16.2. Each Party may invite non-member representatives of such Party and any Third Party to attend meetings of the Committee as non-voting participants; provided, that any such non-member or Third Party is bound by obligations of confidentiality, non-disclosure, and non-use no less restrictive than those set forth in Article 12 prior to attending any such meeting.

2.7.2 Meetings. The first scheduled meeting of each Committee shall be held no later than **[…***…]** after establishment of such Committee unless otherwise agreed by the Parties. After the first scheduled meeting of each Committee, the Committee shall meet in person or telephonically at least **[…***…]**, or more or less frequently as the Parties agree, on such dates and at such places and times as provided herein or as the Parties shall agree. In addition, the JCC and the JMAC shall meet jointly **[…***…]** to discuss matters that relate to activities with the scope of both such Committees. Special meetings of a Committee may be convened by any representative upon not less than **[…***…]** written notice to the other representatives (or, if such meeting is proposed to be conducted by teleconference, upon not less **[…***…]**); provided, that, (a) notice of any such special meeting may be waived at any time, either before or after such meeting and (b) attendance of any representative at a special meeting shall constitute a valid

waiver of notice from such member. The representatives of the Committee may also convene or be consulted from time to time by means of telecommunications, video conferences, electronic mail, or correspondence, as deemed necessary or appropriate. Each Party shall bear all costs and expenses it incurs in participating in all meetings of the Committees, including all travel and living expenses.

2.7.3 Decisions for Committees other than the JSC. Except as otherwise set forth in this Agreement, all decisions of Committees other than **[…***…]** shall be made by **[…***…]**, with each Party having **[…***…]**. If the applicable Committee is unable to agree on any matter that this Agreement expressly specifies is to be agreed upon or determined by the Committee, then either Party may, by providing written notice to the other Party, have such matter referred to the JSC for resolution.

2.7.4 Minutes. For JSC meetings, the Alliance Managers shall be responsible for working with Co-Chairpersons for preparing and circulating the minutes of each meeting, setting forth an overview of the discussions at the meeting. Definitive minutes of all Committee meetings shall be finalized no later than **[…***…]** after the meeting to which the minutes pertain. Minutes shall be deemed approved unless one or more members object to the accuracy of such minutes within **[…***…]** of receipt. For other committees, the Co-chairpersons or their delegates will take the responsibility for minutes as described above for JSC.

2.7.5 Term of Committees. Each shall remain in effect from the date on which it is established until the end of the Term or until the Parties mutually agree to disband such Committee.

2.7.6 Committee Authority. The Committees shall only have the authority to decide or approve matters that this Agreement expressly contemplates that the applicable Committee is to decide or approve.

2.8 Alliance Managers. Each Party will appoint an individual who possess a general understanding of Development, Regulatory, Manufacturing, Medical Affairs Activities and Commercialization to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "Alliance Manager"). The Alliance Managers will (a) help develop a mutually agreed alliance launch plan (kick-off) covering transition planning and implementation, of any activities and systems that the Parties need to put in place within the first **[…***…]** following the Effective Date to support the Development and Commercialization of the Product; (b) 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; (c) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties; (d) facilitate the prompt resolution of any disputes; (e) be charged with creating and maintaining a collaborative work environment within and among the governance committees and (f) responsible for scheduling and conduct of the Joint Steering Committee and entitled to attend all governance committee meetings, in each case, as a non-voting member. An Alliance Manager may also bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter

warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other.

2.9 Sub-Committees and Project Teams. The JSC may, at any time that it deems necessary or appropriate, establish additional joint committees and or project teams, including a patent committee, and delegate such of its responsibilities as it determines appropriate to such joint committees and joint project teams.

ARTICLE 3
DEVELOPMENT

3.1 Development Activities.

3.1.1 Initial Global Development Activities and Bridging Studies.

(a) BeiGene Activities. BeiGene shall be solely responsible, at its sole cost and expense, for the conduct of, and shall use Commercially Reasonable Efforts to continue to conduct, the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan, in each case, in accordance with the protocol set forth in the Initial Global Development Plan, as may be amended from time to time by BeiGene, with approval of the JDC, to the extent required by Applicable Law or any relevant Regulatory Authority until Completion of the BeiGene Ongoing Clinical Trials or such other Clinical Trial.

(b) Novartis Activities. Novartis shall be solely responsible, at its sole cost and expense, for the conduct of (A) any Registrational Clinical Trial and any Bridging Study that Novartis determines, in its sole discretion, to conduct that may be required in order to obtain Regulatory Approval for the Licensed Product in any country in the Novartis Territory (including Bridging Studies required for approval by Regulatory Authorities of secondary manufacturing of Licensed Products) and (B) any post-marketing Clinical Trials that may be required by any Regulatory Authority in any country in the Novartis Territory.

3.1.2 Additional Global Development Activities.

(a) Subject to the terms and conditions of this Agreement, and, except with respect to the conduct by BeiGene of (i) the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan pursuant to Section 3.1.1(a), (ii) any Development activities that are assigned to BeiGene under the Additional Global Development Plan, in each case whether directly or through its Affiliates, licensees or contractors and (iii) any Permitted Combination Studies conducted by BeiGene pursuant to Section 3.2), Novartis shall have the sole right to Develop the Licensed Compound and the Licensed Product in the Field in the Novartis Territory and shall be solely responsible for, at its sole cost and expense, itself or with or through its Affiliates, Sublicensees, or other Third Parties, the Development of the Licensed Compound and the Licensed Product in the Field in the Novartis Territory.

(b) Notwithstanding anything to the contrary in this Section 3.1.2, any global Monotherapy Clinical Trial (other than the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan) to be conducted with the Licensed Product ("Global Monotherapy Trials") shall be subject to the mutual agreement of the Parties. If either Party (a "Proposing Party") wishes to conduct a Global Monotherapy Trial, the Proposing Party shall submit the proposed strategy, protocol design, budget and internal process timeline for such Global Monotherapy Trial in reasonable detail at least **[…***…]** in advance of its anticipated date of initiation for the JDC's review and the non-Proposing Party will have **[…***…]** from the date of submission to the JDC to agree to conduct the Global Monotherapy Trial as part of the Additional Global Development Plan. To the extent the Parties agree to conduct any such Global Monotherapy Trial, the Parties shall share responsibility for all Shared Development Costs that are incurred in the conduct of such Global Monotherapy Trial as follows: (i) Novartis shall bear **[…***…]** of such Shared Development Costs; and (ii) BeiGene shall bear **[…***…]** of such Shared Development Costs. To the extent that the Parties agree to conduct any such Global Monotherapy Trial, within **[…***…]** following the end of each Calendar Quarter thereafter, each of BeiGene and Novartis shall submit to the JDC a written report (a "Shared Development Costs Report") setting forth in reasonable detail all Shared Development Costs incurred by each such Party over such Calendar Quarter. Within **[…***…]** following the JDC's receipt of such Shared Development Costs Reports, the JDC shall prepare and submit to each Party a written report (a "Shared Development Reconciliation Report") setting forth in reasonable detail (i) the calculation of all Shared Development Costs incurred by both Parties over such Calendar Quarter and (ii) the calculation of the net amount owed by BeiGene to Novartis or by Novartis to BeiGene in order to ensure the sharing of the Shared Development Costs in accordance with the Parties percentages as set forth above. The net amount payable shall be paid by BeiGene or Novartis to the other, as applicable, within **[…***…]** after the distribution by the JDC of such Shared Development Reconciliation Report. If a Party disputes any portion of a Shared Development Cost or the Shared Development Reconciliation Report, it shall provide the JDC and the other Party with written notice of the disputed portion and its reasons therefor within **[…***…]** of receipt of such Shared Development Cost Report or Shared Development Reconciliation Report and the Parties shall pay any undisputed amount for which it is responsible within **[…***…]** after receipt of such Shared Development Reconciliation Report. If the Parties cannot agree on the resolution of any such dispute, then such dispute shall be referred to the JSC for resolution.

(c) If a Proposing Party wishes to conduct a Global Monotherapy Trial and the other Party does not agree to co-fund such proposed Global Monotherapy Trial as provided in Section 3.1.2(b) then, unless **[…***…]** the Proposing Party may conduct the Global Monotherapy Trial (any such Clinical Trial, a "Unilateral Study"), subject to the following conditions: (A) such Unilateral Study is approved by all applicable IRBs, and is otherwise conducted in compliance with all Applicable Law; and (B) the Proposing Party submits the proposed strategy, protocol design, budget and internal process timeline for such Unilateral Study in reasonable detail at least **[…***…]** in advance of its anticipated date of initiation for the JDC's review. Subject to the foregoing, the Proposing Party may conduct such Unilateral Study in its sole discretion and at its sole expense. If the Proposing Party conducts any such Unilateral Study, the Proposing Party will provide written updates not less than **[…***…]** to the

JDC with respect to the conduct of such Unilateral Study. The Proposing Party may apply for Regulatory Approval for any such Unilateral Study in, if the Proposing Party is BeiGene, the BeiGene Territory and, if the Proposing Party is Novartis, the Novartis Territory. If the other Party believes that the results of the completed Unilateral Study are sufficient to support the expansion of the label for the Licensed Product to include an Indication included in such Unilateral Study in, with respect to a filing by BeiGene, the PRC or, with respect to a filing by Novartis, in the United States or a Major European Market or Japan, then such other Party shall be entitled to use such data for Regulatory Filings in such other Party's respective territory. If the other Party receives Regulatory Approval for the Licensed Product that includes on its label an Indication included in such Unilateral Study in, for a BeiGene Regulatory Approval, the PRC or, with respect to Novartis Regulatory Approval, the first to occur of the United States or a Major European Market or Japan (as applicable, a "Label Expansion"), then such other Party shall pay the Proposing Party, on or before **[…***…]** from the date of receipt of such Regulatory Approval in such country, an amount equal to **[…***…]**; provided, that the Proposing Party provides the other Party a reasonable written accounting of all such Shared Development Costs at least **[…***…]** prior to the date on which such payment is due. If the results of any completed Unilateral Study do not result in a Label Expansion for the other Party, such other Party shall have no obligation to pay the Proposing Party its share of the Shared Development Costs in respect of the conduct of such Unilateral Study in such country(ies).

3.2 Right to Conduct Permitted Combination Studies. Subject to the terms of this Section 3.2 either Party will have the right (by itself, or with or through any Third Party), at its sole cost and expense, to conduct Clinical Trials (including multiregional Clinical Trials) ("Permitted Combination Study") involving the use of the Licensed Compound as part of a Combination Regimen with one or more proprietary pipeline products of such Party (other than the Licensed Compound) and/or one or more products owned or controlled by any Third Party (any such pipeline product or product owned or controlled by a Third Party, a "Permitted Combination Product" and any such combination, a "Permitted Combination") in either the Novartis Territory or the BeiGene Territory. If a Party desires to conduct any such Permitted Combination Study, it will notify the other Party in writing, which notice will include a proposed protocol synopsis for such Permitted Combination Study not less than **[…***…]** prior to the proposed date of initiation of such Permitted Combination Study. Unless the other Party **[…***…]**, the Party proposing to conduct such Permitted Combination Study (itself, or with or through any Third Party) may thereafter conduct such Permitted Combination Study at its sole cost and expense. The Party performing such Permitted Combination Study shall provide the JDC with summary updates not less than **[…***…]** with respect to the conduct of any such Permitted Combination Study that includes one or more proprietary pipeline products of such Party. Notwithstanding the foregoing, **[…***…]**.

3.3 Right to Support Investigator Sponsored Studies. BeiGene shall have the right (by itself, or with or through any Third Party), at its sole cost and expense, to continue to facilitate the conduct of Investigator Sponsored Studies in the Novartis Territory that are ongoing as of the Effective Date. In addition, BeiGene shall have the right (by itself, or with or through any Third Party), at its sole cost and expense, to support the conduct of new Investigator Sponsored Studies in the Novartis Territory to the extent involving a BeiGene Permitted Combination Product for

use in a Permitted Combination, and Novartis shall have the right (by itself, or with or through any Third Party), at its sole cost and expense, to support the conduct of Investigator Sponsored Studies in the BeiGene Territory to the extent involving a BeiGene Permitted Combination Product for use in a Permitted Combination.

3.4 Development Plans.

3.4.1 Initial Global Development Plan. The Initial Global Development Plan, is attached as Exhibit A. During the Term, the JDC shall review, discuss and approve potential amendments to the Initial Global Development Plan, at least **[…***…]**.

3.4.2 Additional Global Development Plan. Any Additional Global Development Plan, including the Additional Global Development Budget, shall be approved by the JDC and attached hereto as Exhibit B and shall remain in effect unless and until amended as provided herein. From the date of approval by the JDC of any Additional Global Development Plan and continuing for the remainder of the Term, the JDC shall review and discuss potential amendments to the Additional Global Development Plan, including the Additional Global Development Budget, at least **[…***…]**.

3.5 Development Diligence. Subject to the terms and conditions of this Agreement, Novartis, itself or with or through its Affiliates, Sublicensees, or other Third Parties, shall use Commercially Reasonable Efforts to (a) Develop the Licensed Compound and the Licensed Product in the Novartis Territory, (b) conduct Medical Affairs Activities with respect to the Licensed Compound and the Licensed Product in the countries in the Novartis Territory in which the Licensed Product has received Marketing Authorization, (c) provide information and data to support the inclusion of the Licensed Product in the National Comprehensive Cancer Network Guidelines in the United States (the "NCCN Guidelines") for **[…***…]**, and (d) obtain Regulatory Approvals for the Licensed Product in the Novartis Territory.

3.6 Standards of Conduct.

(a) Novartis shall perform, and shall ensure that its Affiliates perform, and use Commercially Reasonable Efforts to cause its Sublicensees and Third Party contractors to perform, its Development activities and Medical Affairs Activities with respect to the Licensed Compound and the Licensed Product in good scientific manner, and in compliance with the requirements of Applicable Law, including GLP, GCP, GMP, GPV and part 11 of Title 21 of the Code of Federal Regulations (Electronic Systems and Data Integrity) (21 CFR Part 11) to the extent applicable (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any Regulatory Authority in any applicable country).

(b) BeiGene shall perform, and shall ensure that its Affiliates perform, and use Commercially Reasonable Efforts to cause its sublicensees and Third Party contractors to perform, its Development activities and Medical Affairs Activities pursuant to this Agreement in good scientific manner, and in compliance with the requirements of Applicable Law, including GLP, GCP, GMP, GPV and part 11 of Title 21 of the Code of Federal Regulations (Electronic Systems and Data Integrity) (21 CFR Part 11) to the extent applicable (and, if and as appropriate

under the circumstances, ICH guidance or other comparable regulation and guidance of any Regulatory Authority in any applicable country).

3.7 Development Records. Each Party shall maintain and shall cause its Affiliates and licensees and Sublicensees to maintain reasonably complete and accurate records regarding their Development of the Licensed Compound and the Licensed Product in the Field in the Novartis Territory (with respect to Novartis) or the BeiGene Territory (with respect to BeiGene), as applicable. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Compound and the Licensed Product in good scientific manner appropriate for regulatory and patent purposes. Each Party will document all non-clinical and preclinical studies and Clinical Trials in formal written study reports in accordance with GLP, GMP, GCP, GPV, and part 11 of Title 21 of the Code of Federal Regulations (Electronic Systems and Data Integrity) (21 CFR Part 11) as applicable, and in compliance with other Applicable Law. Upon the other Party's reasonable request not more frequently than **[…***…]** during which a Party or its Affiliates, licensees, Sublicensees, or Third Party subcontractors are performing or having performed Development activities for the Licensed Compound and the Licensed Product, such Party will provide the other Party such copies of or access to such records as such Party may reasonably request in connection with its own permitted Development of the Licensed Compound or Licensed Product.

3.8 Development Updates. At least **[…***…]**, each Party shall provide the JDC with a summary update of its material Development activities with respect to the Licensed Compound and the Licensed Product since such Party's delivery of the prior report.

ARTICLE 4
REGULATORY

4.1 Regulatory Matters.

4.1.1 Responsibility. Except as set forth in Section 4.1.6 and Section 4.2 or as contemplated in the Regulatory Transition Plan, on and after the Effective Date (a) Novartis shall have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, Sublicensees, BeiGene or other Third Parties, at Novartis's sole cost and expense to: (i) prepare and submit to applicable Regulatory Authorities all Regulatory Materials, including INDs and BLAs, for the Licensed Product in the Novartis Territory and (ii) obtain and maintain all Regulatory Approvals for the Licensed Compound and the Licensed Product in the Novartis Territory and (b) BeiGene shall not communicate with any Regulatory Authority regarding any such Regulatory Materials, or make any further Regulatory Materials for the Licensed Compound in the Novartis Territory other than with the prior written consent of Novartis.

4.1.2 Review of Regulatory Materials.

(a) On and after the Execution Date until the completion of the Regulatory Transition Activities described in the Regulatory Transition Plan, BeiGene will provide to Novartis for its review and comment drafts of all material Regulatory Materials, other than the Existing Regulatory Materials existing as of the Execution Date, to be submitted to

Regulatory Authorities in the Novartis Territory for the Licensed Compound and/or the Licensed Product prior to submission within a reasonable amount of time (but not less than **[…***…]**, unless such time period is not practicable, in which case the maximum amount of time practicable) to allow Novartis to review and comment thereon, and BeiGene will consider any reasonable comments received from Novartis with respect to such Regulatory Materials. Novartis will provide any comments on any such drafts, and BeiGene will consider any reasonable comments received by BeiGene from Novartis with respect to such material Regulatory Materials; provided, that, (i) unless otherwise agreed by the Parties, Novartis shall provide its comments within **[…***…]** of receipt; (ii) prior to the Effective Date, BeiGene shall have the right to make the final decision whether to include any such comments; and (iii) on and after the Effective Date, Novartis shall have the right to make the final decision whether to include any such comments. In addition, BeiGene will notify Novartis of any material comments or other material correspondence related thereto submitted to or received from any Regulatory Authority in the Novartis Territory for the Licensed Compound and/or the Licensed Product within **[…***…]** of such receipt or submission and will provide Novartis with copies thereof promptly after its submission or receipt.

(b) On and after the Effective Date and, unless otherwise agreed by the Parties, until such time, on a Licensed Product by Licensed Product and country-by country basis, as a Biosimilar Product in respect of such Licensed Product is first commercially sold in such country, Novartis will provide to BeiGene for its review and comment drafts of all material Regulatory Materials to be submitted to Regulatory Authorities in connection with seeking Regulatory Approvals for the Licensed Product in the Novartis Territory prior to submission to allow BeiGene to review and comment thereon, and Novartis will consider any reasonable comments received from BeiGene with respect to such Regulatory Materials; provided, that, (i) unless otherwise agreed by the Parties, BeiGene shall provide its comments within **[…***…]** of receipt and (ii) Novartis shall have the right to make the final decision whether to include any such comments. In addition, Novartis will notify BeiGene of any material comments or other material correspondence related thereto submitted to or received from any Regulatory Authority in the Novartis Territory for the Licensed Compound and/or the Licensed Product within **[…***…]** of such receipt or submission and will provide BeiGene with copies thereof promptly after its submission or receipt.

4.1.3 Communication with Regulatory Authorities.

(a) On and after the Execution Date until the completion of the Regulatory Transition Activities described in the Regulatory Transition Plan, if any Regulatory Authority in the Novartis Territory takes or gives notice of its intent to take any material regulatory action with respect to the Licensed Compound or the Licensed Product, BeiGene shall (a) promptly notify Novartis of such contact, inspection or notice or action; (b) be responsible for preparing draft responses to any such regulatory action; and (c) provide such draft responses to Novartis for its review and comment and reasonably consider Novartis' comments in good faith; provided, that, (i) unless otherwise agreed by the Parties, Novartis shall provide its comments within **[…***…]** of receipt; (ii) prior to the Effective Date, BeiGene shall have the right to make the final decision whether to include any such comments; and (iii) on and after the Effective

Date, Novartis shall have the right to make the final decision whether to include any such comments.

(b) Subject to Section 4.1.2, Novartis shall have the exclusive right, following the completion of the Regulatory Transition Activities described in the Regulatory Transition Plan, to correspond or communicate with Regulatory Authorities in the Novartis Territory regarding the Licensed Compound and/or the Licensed Products. If any such Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to the Licensed Compound or the Licensed Product, Novartis shall (a) promptly notify the JDC of such contact, inspection or notice or action; (b) be responsible for preparing draft responses to any such regulatory action; and (c) provide such draft responses to BeiGene through the JDC for its review and comment; provided, that, (i) unless otherwise agreed by the Parties, BeiGene shall provide its comments within **[…***…]** of receipt and (ii) Novartis shall have the right to make the final decision whether to include any such comments. If BeiGene, any of its Affiliates, or any of its permitted subcontractors receives any material correspondence or other material communication from a Regulatory Authority regarding the Licensed Compound or the Licensed Product, BeiGene shall promptly provide Novartis with access to or copies of all such material written or electronic correspondence promptly after its receipt.

4.1.4 Notice of Regulatory Meetings.

(a) On and after the Execution Date until the completion of the Regulatory Transition Activities described in the Regulatory Transition Plan, BeiGene will provide Novartis with notice of any meeting or discussion with any Regulatory Authority in the Novartis Territory related to the Licensed Compound and/or the Licensed Product (including as part of any Permitted Combination Studies) no later than **[…***…]** after receiving notice thereof. On and after the Execution Date and until the Effective Date, BeiGene will allow Novartis to attend, but not participate in, any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. On and after the Effective Date, BeiGene will allow Novartis to attend, participate in and control any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. If Novartis does not attend such meeting or discussion, BeiGene will provide to Novartis a written summary thereof following such meeting.

(b) Following the Effective Date, Novartis will provide BeiGene with notice of any meeting or discussion with any Regulatory Authority in the Novartis Territory that is reasonably expected to cover material topics related to the Licensed Compound and/or the Licensed Product (including as part of any Permitted Combination Studies) no later than **[…***…]** after receiving notice thereof. Novartis will lead any such meeting or discussion, but will consider in good faith any request on the part of BeiGene to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. If BeiGene elects not to attend such meeting or discussion, Novartis will provide to BeiGene a written summary thereof following such meeting.

4.1.5 BeiGene Support. BeiGene shall provide support to Novartis as may be reasonably requested by Novartis from time to time in connection with Novartis’s preparation,

submission to Regulatory Authorities, and maintenance of Regulatory Materials for the Licensed Compound or the Licensed Product, including, upon Novartis's reasonable request, upon reasonable advance notice, attending meetings with Regulatory Authorities regarding the Licensed Compound or the Licensed Product and providing written responses to questions relating to Development activities conducted by or on behalf of BeiGene, which responses will be provided within the timeframe reasonably requested by Novartis.

4.1.6 Rights of BeiGene. Subject to Section 4.2, BeiGene (a) shall remain as the holder of the Existing IND; (b) shall be solely responsible for all communications and interactions with Regulatory Authorities with respect to the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan; and (c) shall have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, or other Third Parties, at BeiGene's sole cost and expense to: (i) prepare and submit to applicable Regulatory Authorities all Regulatory Materials, including INDs, for BeiGene Permitted Combination Products for use in Permitted Combinations in the Novartis Territory, and (ii) obtain and maintain all Regulatory Approvals for BeiGene Permitted Combination Products for use in Permitted Combinations in the Novartis Territory. For any Permitted Combinations that include a Permitted Combination Product owned or controlled by any Third Party (but do not include a BeiGene proprietary product other than the Licensed Product), Novartis or BeiGene, as applicable, may include in and reference in any such Regulatory Materials, the generic name of the Licensed Product (tislelizumab), and, to the extent mutually agreed by the Parties on a Permitted Combination Product by Permitted Combination Product basis and to the extent permitted by Applicable Law, the brand name of the Licensed Product. For BeiGene Permitted Combinations that include a BeiGene proprietary product (other than the Licensed Product), BeiGene may, with Novartis' prior written consent, not to be unreasonably withheld, conditioned or delayed, and to the extent permitted by Applicable Law, include in and reference in any such Regulatory Materials, the brand name of the Licensed Product in the applicable country or region. For the sake of clarity, Novartis or its Affiliate or Sublicensee shall have the right to file any INDs in respect of Clinical Trials sponsored or supported by any of them in respect of the Licensed Compound or Licensed Product after the Effective Date. Novartis shall provide support to BeiGene as may be reasonably requested by BeiGene from time to time in connection with the conduct by BeiGene of activities under this Section 4.1.6, by providing such documents and information Controlled by Novartis that are reasonably requested by BeiGene and relevant to the registration and maintenance of Regulatory Approvals and/or reimbursement applications in respect of the Licensed Product in the BeiGene Territory.

4.2 Regulatory Materials.

4.2.1 Existing Regulatory Materials. Prior to the transfer of any Regulatory Materials for the Licensed Compound held or filed by or on behalf of BeiGene or its Affiliates prior to the Effective Date (the "Existing Regulatory Materials") in accordance the Regulatory Transition Plan, BeiGene (or its designee) shall, subject to Section 4.1, have the sole right to file, maintain, and hold title to such Existing Regulatory Materials.

4.2.2 Regulatory Transition Activities. BeiGene shall, within the timelines specified in the Regulatory Transition Plan, assign and transfer (and hereby does assign and transfer) to Novartis (or its designee) any and all Regulatory Materials for or in respect of the Licensed Compound in the Novartis Territory held or filed by or on behalf of BeiGene or its Affiliate prior to or after the Effective Date (the "Transferred Regulatory Materials"), by undertaking the steps described in the Regulatory Transition Plan within the timelines set forth in the Regulatory Transition Plan (the "Regulatory Transition Activities"); provided, that, such Regulatory Transition Activities shall be subject to any obligations of BeiGene under Applicable Law, **[…***…]**. Unless otherwise required by Applicable Law, from and after such assignment and transfer, Novartis (or its designee) shall have the sole right, in its sole discretion, to file, maintain, and hold title to all Transferred Regulatory Materials. As promptly as practicable following the Execution Date, the Parties shall cooperate reasonably and in good faith to make arrangements to allow for the completion of the Regulatory Transition Activities as promptly as practicable after the Effective Date. Without limiting the foregoing, from and after the Execution Date and until the completion of the Regulatory Transition Activities, BeiGene shall (i) make available its personnel as reasonably requested by Novartis to answer questions, (ii) provide Novartis reasonable access to Regulatory Materials, (iii) use Commercially Reasonable Efforts to obtain any approvals or authorizations as may be required under Applicable Law or otherwise to effect such Regulatory Transition Activities, and (iv) otherwise support the transfer of the Transferred Regulatory Materials as contemplated hereby.

4.2.3 New Regulatory Materials. Except as set forth below, all Regulatory Materials for the Licensed Compound or the Licensed Product generated by Novartis under this Agreement in the Novartis Territory shall be owned by and held in the name of Novartis or its designee, and, except for the Existing Regulatory Materials (which are addressed in Section 4.2.1), any such Regulatory Materials issued in the name of BeiGene or its Affiliates shall promptly be assigned by BeiGene to Novartis or its designee to the extent permitted by Applicable Law or, in the event assignment is not permitted under Applicable Law, held in trust for, or for the sole benefit of, Novartis or its designee. Notwithstanding the foregoing, all Regulatory Materials for any BeiGene Permitted Combination Products in Permitted Combinations in the Novartis Territory shall be owned by and held in the name of BeiGene or its designee.

4.2.4 Regulatory Materials in BeiGene Territory. BeiGene will provide to Novartis for its review and comment drafts of all material Regulatory Materials for the Licensed Compound and/or the Licensed Product that are to be filed or submitted in the Australia by or on behalf of BeiGene during the Term. Novartis will have **[…***…]** (unless such time period is not practicable, in which case the maximum amount of time practicable) to review and provide comments on any such drafts, and BeiGene will consider any reasonable comments received from Novartis with respect to such Regulatory Materials within such **[…***…]** period. In addition, BeiGene will (i) provide Novartis with copies of all material Regulatory Materials for the Licensed Compound and/or Licensed Product that are filed or submitted in any other country in the BeiGene Territory after the filing thereof and (ii) notify Novartis of any material comments or other material correspondence related thereto submitted to or received from any Regulatory Authority in the BeiGene Territory for the Licensed Compound and/or the Licensed

Product during the Term and will provide Novartis with copies thereof promptly after its submission or receipt.

4.3 Right of Reference; Access to Data.

(a) Novartis Right of Reference. Novartis and its designees shall have, and BeiGene (on behalf of itself and its Affiliates) hereby grants to Novartis and its designees, access and a right of reference (without any further action required on the part of BeiGene or its Affiliates, whose authorization to file this consent with any Regulatory Authority is hereby granted) to all Regulatory Materials (including, for clarity, INDs) Controlled by BeiGene with respect to the Licensed Compound and the Licensed Product, and all data contained or referenced in any such Regulatory Materials, including the applicable data in an any Regulatory Materials related to a BeiGene Permitted Combination Product for use in a Permitted Combination, for Novartis and its designees to exercise its rights and perform its obligations under this Agreement. Novartis and its designees shall have access to all data contained or referenced in any such Regulatory Materials in order to exercise such access and right of reference, and BeiGene shall ensure that Novartis and its designees are afforded such access, subject to any obligations of BeiGene under Applicable Law, **[…***…]**, which approvals BeiGene shall use Commercially Reasonable Efforts to timely obtain. BeiGene shall provide or submit any written consents or notices as may be required in order for Novartis to exercise such rights contemplated in this Section 4.3(a).

(b) BeiGene Right of Reference. BeiGene and its designees shall have, and Novartis (on behalf of itself and its Affiliates) hereby grants to BeiGene and its designees, access and a right of reference (without any further action required on the part of Novartis or its Affiliates, whose authorization to file this consent with any Regulatory Authority is hereby granted) to all Regulatory Materials Controlled by Novartis with respect to the Licensed Compound and the Licensed Product and all data contained or referenced in any such Regulatory Materials, including the applicable data in an any Regulatory Materials related to a Novartis Permitted Combination Product for use in a Permitted Combination, for BeiGene and its designees to the extent necessary to exercise its rights and perform its obligations under this Agreement. BeiGene and its designees shall have access to all data contained or referenced in any such Regulatory Materials in order to exercise such access and right of reference to the extent necessary to comply with this Agreement, and Novartis shall ensure that BeiGene and its designees are afforded such access to the extent necessary to comply with this Agreement. Novartis shall provide or submit any written consents or notices as may be required in order for BeiGene to exercise such rights contemplated in this Section 4.3(b).

ARTICLE 5
COMMERCIALIZATION

5.1 General.

5.1.1 Novartis Responsibilities. Subject to the terms and conditions of this Agreement, including Section 5.1.2 and Section 5.5: (i) Novartis shall have the sole right to Commercialize the Licensed Product in the Field in the Novartis Territory and the sole right and

responsibility, at Novartis's sole cost and expense, itself or with or through its Affiliates, Sublicensees, or other Third Parties, to (A) book all sales of the Licensed Product in the Novartis Territory as a Monotherapy and/or for use in any Combination Regimen, (B) subject to Section 5.2, develop and implement the brand and commercial strategy to be used for the Licensed Product in the Novartis Territory and (C) conduct all marketing, promotion and sales activities for the Licensed Product in the Novartis Territory and (ii) except for the conduct by or behalf of BeiGene, whether directly or through its Affiliates, licensees or contractors, of BeiGene Permitted Commercialization Activities, Medical Affairs Activities in relation to the BeiGene Ongoing Clinical Trials, any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan and Permitted Combinations that include a BeiGene Permitted Combination Product, and Third Party Permitted Commercialization Activities pursuant to this Agreement, BeiGene and its Affiliates shall not have any right to, and shall not, conduct any Commercialization of the Licensed Product in the Field in or in respect of the Novartis Territory.

5.1.2 Permitted Commercialization Activities.

(a) By BeiGene. Notwithstanding anything to the contrary in Section 5.1.1, BeiGene will retain the right, in its sole discretion, to promote in the Novartis Territory any Combination Regimen consisting of the Licensed Product and one or more Permitted Combination Products ("BeiGene Permitted Commercialization Activities"). As part of such BeiGene Permitted Commercialization Activities, BeiGene will have the right, in its sole discretion, to promote in the Novartis Territory any Combination Regimen consisting of the Licensed Product and one or more of BeiGene's proprietary compounds and/or proprietary compounds of any Third Party Controlled by BeiGene, including any Permitted Combination referencing the generic name of the Licensed Product (tislelizumab) and, subject to Novartis' prior written consent, not to be unreasonably withheld, conditioned or delayed, to the extent mutually agreed by the Parties in writing on a Combination Regimen by Combination Regimen basis and permitted by Applicable Law, the brand name and logo of the Licensed Product; provided, however, that BeiGene agrees and acknowledges that, as a condition to any such consent, Novartis shall require the right to review, without undue delay, prior to the use of any such brand name or logo and to require BeiGene to commit to customary quality and other standards and requirements relating to the use of proprietary marks; provided, further, that such materials shall comply with Applicable Law and, to the extent applicable, the CIA.

(b) By Novartis. In addition to its rights in Section 5.1.1, Novartis will have the right, in its sole discretion, to promote in the BeiGene Territory any Combination Regimen consisting of the Licensed Product and one or more Permitted Combination Products ("Novartis Permitted Commercialization Activities"). As part of such Novartis Permitted Commercialization Activities, Novartis will have the right, in its sole discretion, to promote in the BeiGene Territory any Combination Regimen consisting of the Licensed Product and one or more of Novartis's proprietary compounds and/or proprietary compounds of any Third Party Controlled by Novartis, including any Permitted Combination, referencing the generic name of the Licensed Product (tislelizumab) and, to the extent mutually agreed by the Parties in writing

on a Combination Regimen by Combination Regimen basis and permitted by Applicable Law, the brand name of the Licensed Product.

(c) By Third Parties. Notwithstanding anything to the contrary in Section 5.1.1, nothing in this Agreement shall prohibit any Third Party that owns or controls a proprietary compound included in any Combination Regimen that has received Regulatory Approval in the applicable country and who is the MA holder, or is authorized by the MA holder, for such compound from promoting or co-promoting with BeiGene or Novartis in the BeiGene Territory or the Novartis Territory any Combination Regimen consisting of the Licensed Product and one or more of such Third Party's proprietary compounds referencing the generic name of the Licensed Product (tislelizumab) and, with the prior written permission of BeiGene in the BeiGene Territory, to the extent permitted by Applicable Law, the brand name of the Licensed Product in the BeiGene Territory or, with the prior written permission of Novartis in the Novartis Territory, to the extent permitted by Applicable Law, the brand name of the Licensed Product in the Novartis Territory ("Third Party Permitted Commercialization Activities"). Novartis will not prevent any such Third Party from obtaining supply of Licensed Product in the Novartis Territory from wholesalers on the open market, subject to the availability of supply of the Licensed Product.

5.2 Commercialization Plan.

5.2.1 Branding Strategy. No later than **[…***…]** from the Effective Date with respect to the initial Indication with respect to which a BLA for the Licensed Product is filed in the United States and no later than **[…***…]** prior to the expected date of First Commercial Sale of any other Licensed Product in the Novartis Territory, Novartis will prepare and present to the JCC a branding and messaging strategy (the "Branding Strategy") with respect to the Licensed Product in the Novartis Territory. Novartis will provide the proposed Branding Strategy to the JCC for its review and will reasonably consider any recommendations and suggestions of the JCC, including any suggestions regarding whether or not the brand name, logo and trademark used by Novartis for the Licensed Product in the Novartis Territory should be consistent with the brand name, logo and trademark used by BeiGene for the Licensed Product in the BeiGene Territory. Thereafter, not less than **[…***…]**, the JCC will discuss the Branding Strategy and Novartis will share market updates with the JCC.

5.2.2 Commercialization Plan. In relation to the Commercialization Plan with respect to the initial Indication with respect to which a BLA for Licensed Product is filed in the United States, Novartis will prepare and provide to the JCC for its review (i) the Strategy comprising such Commercialization Plan no later than **[…***…]** from the Effective Date and (ii) the Tactical Plan comprising such Commercialization Plan no later than **[…***…]** from the Effective Date. With respect to any future Indication, Novartis will prepare and provide to the JCC for its review a Commercial Plan for the Licensed Product and such Indication no later than **[…***…]** prior to the expected date of First Commercial Sale of such other Licensed Product and thereafter shall provide the JCC with reports on the progress of each such Commercialization Plan not less than **[…***…]** thereafter, which reports shall include Novartis' estimates for sales of the Licensed Product for the **[…***…]** period thereafter, it being agreed and understood that

Novartis shall have no obligation to create any such estimates that do not then exist and that such estimates shall not be binding in any way. Any material amendments or modifications to the Commercialization Plan for the Licensed Product shall be prepared by Novartis and delivered promptly to the JCC.

5.3 **[…***…]**.

5.3.1 Novartis shall use Commercially Reasonable Efforts: **[…***…]**.

5.3.2 Not later than **[…***…]** prior to the anticipated First Commercial Sale for the Licensed Product **[…***…]**, of which Novartis shall give notice to the JCC, Novartis shall notify **[…***…]** of **[…***…]**. For all other countries in the Novartis Territory, other than **[…***…]**, for which Novartis expects to Commercialize the Licensed Product, not later than **[…***…]** prior to **[…***…]**, Novartis shall **[…***…]** for which Novartis determines **[…***…]**. In addition, in the event that Novartis determines, from time to time, **[…***…]** that is **[…***…]**.

5.3.3 Novartis may propose to **[…***…]** from time to time that either (i) the **[…***…]**, by the Executive Officers or through Accelerated Arbitration in accordance with this Agreement shall become effective upon such agreement or determination.

5.3.4 BeiGene shall **[…***…]** with an overview of **[…***…]** the Licensed Product in the BeiGene Territory on a **[…***…]** basis. **[…***…]**.

5.4 Diligence. Novartis will use Commercially Reasonable Efforts to Commercialize the Licensed Product in each country in the Novartis Territory in which Novartis receives Regulatory Approval for such Licensed Product in the Indications for which it receives Regulatory Approval in the applicable country.

5.5 Reports; Branding Strategy Meetings. For each Calendar Year following Regulatory Approval for the Licensed Product in the Novartis Territory, Novartis shall provide to JCC a **[…***…]** written report that provides **[…***…]**, to the extent that the Licensed Product is being Commercialized in such countries.

5.6 Medical Affairs Activities.

5.6.1 Medical Affairs Plan. Each Party will prepare and provide to the JMAC for its review a Medical Affairs Plan with respect to the Licensed Product no later than **[…***…]** after the Effective Date with respect to the Licensed Product with respect to (i) in Novartis's case, the initial Indication with respect to which a BLA for Licensed Product is filed in the United States and (ii) in BeiGene's case, any Indication in respect of which BeiGene has received Regulatory Approval or has filed a MAA in the BeiGene Territory. Thereafter, no later than **[…***…]** prior to the expected date of First Commercial Sale of any other Licensed Product, each Party shall provide to the JMAC for its review a Medical Affairs Plan with respect to such Licensed Product. Each Party shall provide the JMAC with updates regarding the conduct of each such Medical Affairs Plan not less than **[…***…]** thereafter. Any amendments

or modifications to the Medical Affairs Plan for the Licensed Product shall be prepared by the applicable Party and delivered promptly to the JMAC.

5.6.2 Medical Affairs Reports. Following the first Regulatory Approval of a Licensed Product in the Novartis Territory, each Party will provide to the JMAC **[…***…]** reports (by means of a slide presentation or otherwise) providing an overview of the Medical Affairs Activities performed by or on behalf of such Party and its Affiliates and licensees or Sublicensees in such Party's Territory for each Licensed Product marketed in such Territory since the prior report provided by such Party.

5.7 BeiGene Co-Detailing Right.

5.7.1 Co-Detailing Right. BeiGene shall have a non-exclusive right to Detail the Licensed Product on an Indication-by-Indication basis in any or all of the United States, Canada and Mexico, to the extent the Licensed Product is marketed in such country, on the terms and conditions set forth in this Section 5.7 (the "Co-Detailing Right"). At least **[…***…]** prior to the anticipated launch readiness date of the Licensed Product for an Indication in the United States, Canada or Mexico, shall notify BeiGene of such anticipated launch readiness date which notice shall include **[…***…].** BeiGene may exercise its Co-Detailing Right by providing Novartis written notice at any time not later than **[…***…]** prior **[…***…]** Indication (the "Exercise Deadline"). In the event that BeiGene elects to not exercise the Co-Detailing Right in respect of a particular Indication in the United States, it shall so notify Novartis, not later than Exercise Deadline for such Indication in the United States. In addition, **[…***…]**. Novartis shall reimburse BeiGene for **[…***…]** of **[…***…]**. BeiGene shall provide an invoice to Novartis for such BeiGene FTE Cost on a quarterly basis, with reasonable supporting detail, and Novartis shall pay such invoices within **[…***…]** after receipt.

5.7.2 Effects of Exercise of Co-Detailing Right. If BeiGene exercises its Co-Detailing Right in respect of a country in accordance with the foregoing:

(a) No later than **[…***…]** prior to the anticipated launch readiness date of the Licensed Product in such country, on an Indication-by-Indication basis, Novartis shall notify BeiGene of **[…***…].** Within **[…***…]** following receipt of such notice, (i) BeiGene shall have the right to elect to assume responsibility for up to **[…***…]** of **[…***…]**.

(b) BeiGene shall be responsible for its costs in conducting its Detailing activities under this Section 5.7.2 as well as all incremental training and meeting costs in accordance with Section 5.7.2(d); provided, that, Novartis shall reimburse BeiGene for **[…***…]** of the BeiGene FTE Cost of its sales representatives in conducting Primary Detailing. BeiGene shall provide an invoice to Novartis for such BeiGene FTE Cost on a **[…***…]** basis, with reasonable supporting detail, and Novartis shall pay such invoices within **[…***…]** after receipt.

(c) The JCC shall have responsibility for general oversight of all of BeiGene's promotion and Detailing activities with respect to the Licensed Product in the applicable country(ies). **[…***…]**

(d) To the extent practicable, BeiGene's sales representatives will be included in the same training programs with respect to the Licensed Product that Novartis provides to its own sales representatives Detailing the Licensed Product. **[…***…]**.

(e) BeiGene's sales representatives shall be provided, at Novartis' expense, with the same promotional materials, including literature and samples, as Novartis provides to its own similarly-situated sales representatives.

(f) Novartis shall use Commercially Reasonable Efforts to ensure that BeiGene **[…***…]** and shall provide BeiGene such reasonable access to **[…***…]** Controlled by Novartis with respect to the Licensed Product as BeiGene requires in order to carry out its Detailing activities in respect of the Licensed Product in accordance herewith following exercise of its Co-Detailing Right. BeiGene will report to the JCC each Calendar Quarter the Details performed in respect of **[…***…]**.

(g) Novartis shall control all training and promotional materials for the Licensed Product (including messaging) in its sole discretion. BeiGene shall promote the Licensed Product in accordance with the standards reasonably established by Novartis for the Licensed Product; provided that if the standards BeiGene normally uses are more stringent than the standards established by Novartis, BeiGene may use its own standards, subject to Novartis' prior written approval, not to be unreasonably withheld, delayed or conditioned.

(h) If requested by either Party, the Parties will enter into local co-detailing agreements for countries in which the Co-Detailing Right is exercised, which local agreements shall be on terms consistent with this Section 5.7.2 and Section 5.8.

(i) In the event that BeiGene wishes to cease Detailing the Licensed Product in any Indication in any applicable country, BeiGene will so notify Novartis not later than **[…***…]** prior to the date on which it will cease such Detailing and the Parties will develop an appropriate wind-down plan in respect of such Detailing activities.

(j) **[…***…]**.

5.8 Compliance. Each of BeiGene and Novartis will conduct its Commercialization activities with respect to the Licensed Products in good scientific manner, and in compliance with Applicable Laws, including GLP, GCP, GMP or GPV to the extent applicable (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any Regulatory Authority in any country in the Novartis Territory). Novartis and BeiGene acknowledge that Novartis and its Affiliates are bound to comply with the Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and Novartis Corporation (the "CIA"). Pursuant to Sections II.C.11 and III.B.1 of the CIA and given that it would be commercially impracticable for Novartis to compel the compliance of BeiGene's personnel and contractors with the requirements set forth in the CIA, Novartis shall send BeiGene a "Third Party Personnel" letter on **[…***…]** basis outlining Novartis' obligations under the CIA and Novartis' commitment to full compliance with all federal health care program and FDA requirements. Such letter shall include with it a copy of

the Novartis Code of Ethics and a description of Novartis Compliance Program. In addition, the letter shall request BeiGene to either (a) make the Novartis Code of Ethics and the description of the Novartis Compliance Program available to its relevant personnel or (b) represent to Novartis in a letter substantially in the form attached hereto as Schedule 5.8 that BeiGene has and enforces a substantively comparable code of ethics and compliance program for its personnel and contractors acting as "Third Party Personnel" (as such term is defined in the CIA). Novartis shall include BeiGene's response in Novartis Corporation's Annual Report to the OIG. Further, BeiGene hereby represents to Novartis that the aforementioned requirements are in place as of the Effective Date.

ARTICLE 6
PHARMACOVIGILANCE: SAFETY

6.1 Pharmacovigilance. Within either **[…***…]** after the Effective Date or in time to ensure that all regulatory requirements are met, whichever is soonest, BeiGene and Novartis (or its applicable Affiliate(s)) will enter into a pharmacovigilance agreement (the "Pharmacovigilance Agreement") in order to, among other things, provide that the parties shall cooperate with regard to the reporting, handling and evaluation of safety information involving or relating to the Licensed Compound or the Licensed Product, establish a safety governance model, coordinate safety matters, specify the process for coordination of core safety data development, safety reporting and case processing for the BeiGene Territory and the Novartis Territory; share safety information, ensure respective regulatory compliance, agree on safety data handling conventions including any access restrictions based on combination use of the Licensed Compound and Licensed Product and allocate responsibilities for safety matters with respect to the Licensed Compound or the Licensed Product, which shall in any event be subject to any obligations of BeiGene under Applicable Law, **[…***…]**.

6.2 Global Safety Database. As soon as reasonably practicable following the Effective Date, Novartis will establish and maintain in compliance with the Pharmacovigilance Agreement and Applicable Laws, as they relate to the Parties' respective obligations, the global safety database for the Licensed Compound and the Licensed Products. BeiGene will maintain a safety database for the Licensed Compound and Licensed Product for the BeiGene Territory and for any other country in which BeiGene is conducting BeiGene Development or Commercialization activities which safety database shall be a subset of the global safety database. BeiGene's access to data from the global safety database shall be handled in accordance with the terms of the Pharmacovigilance Agreement. During the Term and thereafter as required in order to comply with the Pharmacovigilance Agreement and Applicable Law, each Party will provide the other Party with all information necessary or desirable for such other Party to comply with its pharmacovigilance responsibilities, including any adverse drug experiences, in each case in the form reasonably requested by such other Party, subject to any obligations of BeiGene under Applicable Law **[…***…]**.

6.3 Data Processing Agreement. Within **[…***…]** after the Effective Date and in any event prior to the exchange by the Parties of any Personal Data, BeiGene and Novartis (or its

applicable Affiliate(s)) will enter into a data processing agreement (the "Data Processing Agreement") in order to, among other things, establish the procedures to be used by the Parties to ensure compliance with all Data Security and Privacy Laws in connection with the exchange between the Parties of Personal Data, which shall be subject to any obligations of BeiGene under Applicable Law, **[…***…]**.

ARTICLE 7
ASSISTANCE; DISCLOSURE OF KNOW-HOW; TECHNOLOGY TRANSFER; MANUFACTURING

7.1 Disclosure of BeiGene Know-How. During the period between the Execution Date and the Effective Date, BeiGene will undertake such steps as BeiGene determines are reasonably necessary to prepare and assemble the BeiGene Know-How for transfer to Novartis pursuant to this Section 7.1, including such BeiGene Know-How as may be identified by Novartis as being a priority for transfer upon the Effective Date or as soon as practicable thereafter and all documents Controlled by BeiGene related to **[…***…]**. As soon as reasonably practicable (but in no event later than **[…***…]** following the Effective Date and thereafter during the Term as may be reasonably requested by Novartis from time to time (including after Completion of the BeiGene Ongoing Clinical Trial), BeiGene shall disclose to Novartis and its designees in English, including by providing electronic copies thereof, all BeiGene Know-How (other than BeiGene Know-How solely relating to the Manufacture of the Licensed Compound, which shall be disclosed to Novartis pursuant to Section 7.4, but including any such Know-How related to Manufacturing incorporated or referenced in any chemistry, manufacturing and controls ("CMC") information or otherwise, in any BLA in respect of the Licensed Product or any other Regulatory Materials), including any materials and documentation (including data and protocols) included therein and any other physical embodiments thereof. BeiGene shall, and shall cause its Affiliates to, cooperate with Novartis and its designees and provide reasonable assistance to Novartis and its designees to enable Novartis and its designees to Develop the Licensed Product, as and to the extent reasonably requested by Novartis, including by: (a) providing Novartis and its designees with such assistance as may be reasonably requested by Novartis with respect to Development transition matters related to the Licensed Product; and (b) providing Novartis and its designees with such access as may be reasonably requested by Novartis by teleconference or in-person (as requested by Novartis) to BeiGene personnel (and personnel of its Affiliates, the BeiGene Manufacturer and other Third Party contractors) involved in the Development of the Licensed Products to assist with the transition and answer questions related to the Licensed Product.

7.2 Manufacturing for the Novartis Territory. Subject to the terms and conditions of this Agreement, Novartis shall have the sole right (and shall solely control, at its discretion), itself or with or through its Affiliates, Sublicensees, or other Third Parties, to Manufacture the Licensed Product in the Field for the Novartis Territory. Notwithstanding the foregoing, BeiGene hereby retains the right to Manufacture the Licensed Compound and the Licensed Product in the Novartis Territory solely for use (i) by Novartis in the Field and in the Novartis Territory, (ii) by BeiGene in the conduct of (A) the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global

Development Plan; (B) any Permitted Combination Studies; and (C) any Global Monotherapy Trial mutually agreed by the Parties or any Unilateral Study conducted by BeiGene and (iii) by BeiGene in the Field and in the BeiGene Territory, in each case (A) through (C), whether directly or through its Affiliates or the BeiGene Manufacturer.

7.3 Supply of Licensed Compound and/or Licensed Product to Novartis.

(a) Terms of Supply. BeiGene shall be responsible for supplying Novartis or its designee with (as and to the extent requested by Novartis) such quantities of the Licensed Compound, as drug product or drug substance, as may be reasonably required and used by Novartis, in order for Novartis to Develop and Commercialize the Licensed Product in the Novartis Territory, for a duration of **[…***…]** with the option, at Novartis' sole discretion, to extend such period by up to **[…***…]** additional terms of **[…***…]** each, and otherwise in accordance with one or more supply agreement(s) providing for clinical and/or commercial supply of the Licensed Compound (such agreement or agreement(s), the "Supply Agreement") which shall be negotiated by the Parties in good faith and entered into by the Parties as soon as practicable after the Execution Date, the terms of which shall include the terms set forth on Schedule 7.3(a) hereto.

(b) BeiGene **[…***…]**. Notwithstanding anything to the contrary in this Agreement or the Supply Agreement, Novartis acknowledges and agrees that BeiGene shall have the right, in its sole discretion, to **[…***…]** in the United States owned by BeiGene, its Affiliate, or the BeiGene Manufacturer **[…***…]**; provided, however that, **[…***…]**, and, without limiting the foregoing:

(i) with respect to the proposed **[…***…]**, Novartis shall have the right, at its sole discretion, to: **[…***…]**;

(ii) BeiGene shall **[…***…]**;

(iii) in the event that the **[…***…]** fails to **[…***…]** in any manner that affects or could reasonably be expected to affect, **[…***…]**, or otherwise **[…***…]**, then Novartis will have the right to **[…***…]**.

Subject to the foregoing **[…***…]**, then Novartis shall agree **[…***…]**.

(c) Quality Matters; Audits.

(i) Pre-Qualification Audits. After the Execution Date, to the extent permitted under the terms of the relevant agreements (each, a "Third Party Contractor Agreement") by and between BeiGene and any Third Party that conducts Development (including research, non-clinical and clinical) or manufacturing activities for the Licensed Product (including drug substance, drug product or any component of the Licensed Product (including Materials suppliers and analytical laboratories)) (each, a "Third Party Contractor"),

BeiGene will **[…***…]**. To the extent the rights described in this Section 7.3(c) are not permitted under the terms of the relevant Third Party Contractor Agreement, **[…***…]**.

(ii) Quality Agreements. The Parties will negotiate in good faith one or more definitive agreements with regard to quality matters relating to clinical (GCP), non-clinical (GLP) and manufacturing (GMP) (including the with respect to the Media) (collectively, the "Quality Agreement") within **[…***…]** after the Effective Date. In the event of a discrepancy between this Agreement and the Quality Agreement, the Quality Agreement shall govern with respect to quality matters and this Agreement shall govern with respect to all other matters.

(iii) Changes. Any changes or variations to the Licensed Product (including the drug substance, drug product, Media, packaging, labelling or any component(s)), the manufacturing or any facilities involved in the Development or manufacturing of the Licensed Product (including the drug substance and components) may only be made in accordance with the Quality Agreement(s).

(iv) Quality and Safety Audits and Inspections.

(A) To the extent permitted under the terms of the Third Party Contractor Agreements, BeiGene will allow Novartis, its Affiliate or designated Third Party to perform GxP Audits and mock pre-approval inspections of any Facility on reasonable prior notice in preparation for an inspection by a Regulatory Authority or investigation of a compliance issue with a Regulatory Authority. BeiGene acknowledges that, in the case of suspected Critical Findings or Data Integrity issues, **[…***…]** prior notice is reasonable. BeiGene will use reasonable efforts to provide Novartis with a letter of authorization signed by each Third Party owner of the applicable Facilities enabling such an audit within **[…***…]** of the Effective Date. BeiGene will, or will use Commercially Reasonable Efforts to procure that its Third Party Contractors will, use Commercially Reasonable Efforts to mutually agree to any CAPAs within **[…***…]** of issue of the GxP Audit report and thereafter carry out such CAPAs or required CAPAs within the relevant timelines; and

(B) BeiGene will promptly inform Novartis of any intended or planned inspection by a Regulatory Authority of any Facility and no later than **[…***…]** of being notified. BeiGene will promptly provide (or cause its subcontractors to provide) Novartis with an executive summary of the results of the inspection, including explanations of any issues raised by the Regulatory Authorities which could reasonably be expected to impact the Licensed Product and any proposed CAPAs. BeiGene will promptly disclose to Novartis any Regulatory Authority inspection observations received by BeiGene, including any major observations from Regulatory Authorities due to inspection or any submitted document(s) or in a correspondence with authorities world-wide, including for example EIR, 483s, warning letters, EMA or European inspection reports, serious breaches, safety urgency measures, issues on PSURs, DSURs etc. and corresponding proposed responses, in each case related to the Licensed Product. In addition, if any such inspection that could reasonably be expected to have an impact on the patient safety,

efficacy or conduct of Clinical Trials with the Licensed Compound or Licensed Product and/or the Data Integrity. BeiGene shall, within no later than **[…***…]** (except warning letters which will be no later than **[…***…]**, provide copies to Novartis with respect to the issue raised in the relevant inspection report or correspondence. BeiGene will reasonably cooperate with Novartis in the preparation of any response or other communication to the Regulatory Authority, which could reasonably be expected to affect Data Integrity, an MAA or any regulatory dossier, in each case, in respect of the Licensed Compound or the Licensed Product.

(v) Anything to the contrary notwithstanding, with respect to the BeiGene Manufacturer's Facility located in Shanghai, China:

(A) BeiGene shall **[…***…]**;

(B) BeiGene shall **[…***…]**; and

(C) BeiGene shall **[…***…]**.

(vi) Certain Definitions. As used in this Section 7.3(c)(v), the following capitalized terms have the following meanings:

(A) "Critical Finding" means a condition which may seriously affect the quality of products, process, validity of data, purity, efficacy, integrity and/or regulatory compliance, could reasonably be expected to violate quality standards as defined in GMP, GCP, GLP and/or GPV or where there is scientific misconduct or an ethical concern identified in accordance with the dictates established in the Declaration of Helsinki, which in each case could reasonably be expected to lead to regulatory action and/or potential impact on patient safety or product quality requiring immediate corrective action.

(B) "Data Integrity" means the procedures and controls in place to ensure that all data (including physical and electronic records) are Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Available, Consistent and Enduring (ALCOA+) through from their creation, processing, review, reporting & retention (over the data lifecycle).

(C) "GxP Audit" means a GMP, GCP, GLP and/or GPV (collectively, "GxP") audit, which is comprised of an evaluation of the state of compliance of the systems and sub-systems, applicable to a manufacturing site, non-manufacturing site, investigator site or service provider site or a GxP system or process, with EU and US standards and ICH Guidelines, and the applicable Regulatory Authority regulations in the countries where the Product or relevant support service are used.

(d) Engagement of Additional CMOs. If the Parties determine to add one or more additional contract manufacturers to the BeiGene supply network to Manufacture the Licensed Compound (as finished product, drug product or drug substance) for Novartis for the Novartis Territory (each, an "Additional CMO"), **[…***…]** provided, that, **[…***…]**.

7.4 Manufacturing Technology Transfer.

(a) Manufacturing Technology Transfer Agreement. Without limiting the other provisions of this Article 7, as soon as reasonably practicable following the Execution Date, the Parties will enter into a Manufacturing Technology Transfer Agreement mutually acceptable to the Parties (the "Manufacturing Technology Transfer Agreement") pursuant to which BeiGene shall **[…***…]**. The Manufacturing Technology Transfer Agreement will include **[…***…]** and in any event within **[…***…]** thereafter; **[…***…]**.

(b) BeiGene Assistance. The Manufacturing Technology Transfer Agreement will provide that (i) at the request of Novartis from time to time, BeiGene shall **[…***…]** to Novartis and its designees and to assist Novartis and its designees in its Manufacture of the Licensed Compound for up to an aggregate of **[…***…]** and (ii) to the extent that BeiGene provides Novartis with such consultation and assistance **[…***…]** of **[…***…]**, Novartis will reimburse BeiGene for **[…***…]**. BeiGene agrees, that at Novartis' discretion, Novartis shall be entitled to enter into a separate Manufacturing technology transfer agreement with the BeiGene Manufacturer for transfer of the Licensed Compound and/or Licensed Product and applicable Manufacturing Know-How and Materials.

7.5 Supply of Licensed Compound to BeiGene. If at any time following the completion of Manufacturing Technology Transfer pursuant to Section 7.4, BeiGene requests Novartis to supply BeiGene with certain quantities of the Licensed Compound for BeiGene to Develop and Commercialize the Licensed Product in the BeiGene Territory, Novartis shall reasonably consider such request in good faith, subject to any issues of Manufacturing capability and capacity and potential regulatory impact on Novartis and/or its supply network. If Novartis agrees to supply BeiGene with the Licensed Compound in accordance with this Section 7.5, BeiGene shall pay Novartis a transfer price equal to **[…***…]**.

7.6 Obligation to Procure Rights. Without prejudice to any other rights Novartis may have under this Agreement, to the extent that BeiGene does not Control any Know-How, or possess any necessary rights from Third Parties, necessary to permit BeiGene to perform its obligations contemplated by Sections 7.3(a) or 7.4 hereof, or pursuant to the terms of the Supply Agreement that are set forth in Schedule 7.3(a) hereto as of the effective date of the Supply Agreement, including **[…***…]**, BeiGene shall use reasonable best efforts to obtain, as promptly as practicable, Control of such Know-How, or such rights, as applicable.

ARTICLE 8
FINANCIAL TERMS

8.1 Upfront Payment. Subject to the occurrence of the Effective Date, Novartis shall pay to BeiGene a one (1)-time non-refundable, non-creditable payment of Six Hundred Fifty Million Dollars ($650,000,000) in immediately available funds by wire transfer, within **[…***…]** of the Effective Date, in accordance with wire instructions to be provided in writing by BeiGene in a written invoice submitted by BeiGene to Novartis on or before the Effective Date.

8.2 Milestones.

8.2.1 Development/ Regulatory Milestones. Subject to the terms of this Section 8.2, Novartis shall notify BeiGene within **[…***…]** following the achievement by Novartis, its Affiliates, or its Sublicensees under this Agreement of each milestone event described under the heading "Milestone Event" in the table below in this Section 8.2.1 (each, a "Development Milestone Event") by the Licensed Product and Novartis shall thereafter pay the applicable amount set forth below corresponding to the applicable Development Milestone Event in accordance with Section 8.2.4 (each, a "Development Milestone Payment") in respect of Licensed Products other than BeiGene Anti-PD-L1 Licensed Products and Novartis Anti-PD-1 Licensed Products:

Milestone Event	Milestone Payment
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**
[…*…]**	**[…***…]**

Each Development Milestone Payment shall be payable **[…***…]**.

8.2.2 Partial Milestone Payment. Notwithstanding the foregoing, if (x) **[…***…]**, Novartis shall pay BeiGene **[…***…]** of the applicable Development Milestone Payment set forth above associated with U.S. Regulatory Approval for such Indication in accordance with Section 8.2.1 and (z) **[…***…]**, Novartis shall pay BeiGene **[…***…]** of the

applicable amount set forth above associated with the applicable Development Milestone Event in accordance with Section 8.2.1.

8.2.3 Commercialization Milestones. Upon the first achievement of each milestone event set forth in the table below (each, a "Commercialization Milestone Event"), Novartis shall make the corresponding milestone payment to BeiGene (each, a "Commercialization Milestone Payment") in accordance with Section 8.2.4:

Commercialization Milestone Event	Commercialization Milestone Payment
1. Annual Net Sales of Licensed Product in the Novartis Territory in excess of **[…***…]**	**[…***…]**
2. Annual Net Sales of Licensed Product in the Novartis Territory in excess of **[…***…]**	**[…***…]**
3. Annual Net Sales of Licensed Product in the Novartis Territory in excess of **[…***…]**	**[…***…]**

Each Commercialization Milestone Payment shall be payable **[…***…]**.

8.2.4 Invoice and Payment of Milestone Payments. Following BeiGene's receipt of notice from Novartis that Novartis has achieved any Milestone Event or Milestone Events, BeiGene shall invoice Novartis for the applicable Milestone Payment or Milestone Payments, and Novartis shall pay such Milestone Payment within **[…***…]** after receipt of each such invoice.

8.3 Royalties.

8.3.1 Royalty Rates. Subject to the terms of Section 8.3.6(b), Novartis shall pay BeiGene royalties on Annual Net Sales of the Licensed Product during the applicable Royalty Term, equal to the following portions of Annual Net Sales of the Licensed Product multiplied by the applicable royalty rate set forth below for such portion of Annual Net Sales during the applicable Royalty Term for the Licensed Product, which royalties shall be paid in accordance with Section 8.3.6.

Annual Net Sales in the Novartis Territory for the Licensed Product in a given Calendar Year	Royalty Rate
i. Portion of Annual Net Sales in the Novartis Territory of the Licensed Product in a given Calendar Year up to and including **[…***…]**	**[…***…]**
ii. Portion of Annual Net Sales in the Novartis Territory of the Licensed Product in a given Calendar Year **[…***…]**	**[…***…]**
iii. Portion of Annual Net Sales in the Novartis Territory of the Licensed Product in a given Calendar Year above **[…***…]**	**[…***…]**
iv. Portion of Annual Net Sales in the Novartis Territory of the Licensed Product in a given Calendar Year above **[…***…]**	**[…***…]**
v. Portion of Annual Net Sales in the Novartis Territory of the Licensed Product in a given Calendar Year above **[…***…]**	**[…***…]**
vi. Portion of Annual Net Sales in the Novartis Territory of the Licensed Product in a given Calendar Year above **[…***…]**	**[…***…]**

The applicable royalty rate set forth in the tables above shall apply **[…***…]**.

8.3.2 Royalty Term. Novartis's royalty obligations to BeiGene under Section 8.3.1 shall apply, on a country-by-country basis during the applicable Royalty Term for the Licensed Product in such country. Following the expiration of the applicable Royalty Term for the Licensed Product in a given country: (a) no further royalties shall be payable with respect to sales of the Licensed Product in such country (and no sales of Licensed Products in such country shall be counted for purposes of determining Net Sales for any period commencing on or after the expiration of such Royalty Term); and (b) the license granted to Novartis under this Agreement with respect to the Licensed Product in such country shall become fully paid-up, perpetual, irrevocable, and royalty-free in accordance with Section 15.1.2(a).

8.3.3 Royalty Reductions.

(a) No Valid Claim. For purposes of determining the royalties payable with respect to the Licensed Product pursuant to Section 8.3.1, as may be further reduced pursuant to Section 8.3.3(b) and Section 8.3.4, during any portion of the applicable Royalty Term in which there is not either (i) at least one (1) Valid Claim of a BeiGene Patent that Covers the Licensed Product in such country in the Novartis Territory or (ii) Regulatory Exclusivity of the Licensed Product in such country in the Novartis Territory, Net Sales in such country shall be reduced, on a country-by-country basis, to **[…***…]** of the Net Sales otherwise calculated for such country(ies) during such portion of the Royalty Term.

(b) Biosimilar Products.

(i) If during the portion of the applicable Royalty Term in a particular country in the Novartis Territory, (A) one or more Biosimilar Products with respect to the Licensed Product are being sold in such country, other than any Biosimilar Product that is sold by any Affiliate or Sublicensee of Novartis or Sandoz AG and its Affiliates, (B) the Net Sales of such Licensed Product in that country in any Calendar Year are less than **[…***…]** as compared with the Net Sales of such Licensed Product in that country in the Calendar Year immediately preceding the Calendar Year in which such Biosimilar Product(s) is/are first sold, and (C) the decline in Net Sales of the Licensed Product is reasonably attributable in material part to the marketing or sale in such country of such Biosimilar Products ((A) through (C), a "Loss of Marketing Exclusivity"), then, for purposes of determining the royalties payable with respect to the Licensed Product as set forth in Section 8.3.1, as may be further reduced by Section 8.3.3(a), the Net Sales with respect to the Licensed Product in such country shall be reduced to **[…***…]** of the Net Sales otherwise calculated for such country(ies) during such portion of the Royalty Term for so long as the Loss of Market Exclusivity continues during the Royalty Term for the Licensed Product in such country.

(ii) Novartis will promptly notify BeiGene of the occurrence of Loss of Market Exclusivity, which notice will specify the applicable Biosimilar Product(s), Indication and country in the Novartis Territory, the applicable percentage of market share loss and will include evidence supporting Novartis's determination that the decline in Net Sales of the Licensed Product is reasonably attributable in material part to the marketing or sale in such country of such Biosimilar Product(s).

8.3.4 Royalty Offset for Third Party Payments. If Novartis in its good faith judgment reasonably determines that it is necessary to obtain a license from any Third Party under any Patent in order to Manufacture or Commercialize the Licensed Compound, which Patent would be infringed by the Manufacture or Commercialization of the Licensed Compound (each, a "Third Party Patent"), then Novartis (a) shall have the right to negotiate and execute an agreement for the grant of a license or other similar rights to such Third Party Patent (each, a "Third Party License Agreement") and (b) may deduct from the royalty payments that would otherwise have been due and payable under Section 8.3.1 with respect to the Licensed Product in a particular Calendar Quarter, an amount equal to **[…***…]** of the amount of any royalty payments paid by Novartis or any of its Affiliates or Sublicensees to such Third Party under such Third Party License Agreement for such right or license or the exercise thereof during such Calendar Quarter.

8.3.5 Cumulative Effect of Royalty Reductions and Offsets. In no event shall the royalty reductions or offsets described in Sections 8.3.3(a), 8.3.3(a), and 8.3.4, alone or together, reduce the royalties payable by Novartis for a given Calendar Quarter pursuant to Section 8.3.1 to less than **[…***…]** of the amounts otherwise payable by Novartis for a given Calendar Quarter pursuant to Section 8.3.1; provided, however, that in the event that Novartis is precluded from applying the full amount it would otherwise be entitled to apply in reducing its royalty payments in any Calendar Quarter by virtue of this Section 8.3.5, then it shall be

permitted to apply such unapplied portion to reduce its royalty obligations in the next subsequent Calendar Quarter(s).

8.3.6 Payment of Royalties; Royalty Reports.

(a) For any Calendar Quarter in respect of which royalties are owing by Novartis hereunder, in the event that **[…***…]**, then the aggregate Net Sales for the United States to be included in the Net Sales for such Calendar Quarter for purposes of calculating the royalties owing for such Calendar Quarter shall be **[…***…]**.

(b) Novartis shall within **[…***…]** following the end of each Calendar Quarter in which a royalty payment pursuant to Section 8.3.1 accrues, provide to BeiGene (i) a report specifying, for such Calendar Quarter: (A) **[…***…]** (B) **[…***…]** (C) **[…***…]** (D) **[…***…]** (E) **[…***…]** following Novartis' receipt of a written invoice for the royalty payments specified in such royalty report.

(c) For purposes of calculating Net Sales, **[…***…]**.

8.4 Additional Payment Terms.

8.4.1 Currency. All payments under this Agreement shall be made in US Dollars. Any sales incurred in a currency other than US Dollars shall be converted to the US Dollar equivalent using Novartis' then-current standard exchange rate methodology as applied in its external reporting for the conversion of foreign currency sales into US Dollars.

8.4.2 Taxes.

(a) Generally. Each Party shall be responsible for any Tax obligations of its own due to this Agreement (including income Tax and capital gains Tax). Neither Party shall have any obligation towards the other Party in case the other Party fails to fully comply with its own Tax obligations. Each Party shall bear all Taxes for which it is liable under applicable law incurred in connection with this Agreement. Any indirect tax, other than Value Added Tax (VAT), including but not limited to transfer tax, duties, levies and customs, shall be borne by the payee Party.

(b) Withholding Taxes.

(i) In the event any amount payable hereunder is subject to withholding Tax under Applicable Law, the payor Party shall deduct the respective amount from the amount due and pay the withholding Tax to the relevant Tax authority. The payor Party shall deliver within **[…***…]** to the payee Party proof of such payment. The Parties shall make all reasonable efforts to obtain relief or reduction of withholding tax under the applicable Tax treaties, including but not limited to the submission or issuance of requisite forms and information by the payee Party to the payor Party and the payor Party to the competent Governmental Authorities as the case may be. Any costs incurred as a result of failure to timely obtain such relief or reduction shall be borne by the Party responsible for the relevant effort.

(ii) The payor Party further acknowledges that if the payee Party provides a properly completed form claiming a royalty withholding tax exemption and absent change in Applicable Law or change in facts, the payor Party shall not withhold any Tax under the Applicable Law or any other Governmental Authority with respect to payments made pursuant to Sections 8.1, 8.2 and 8.3 of this Agreement.

(c) Value Added Taxes.

(i) Generally. Each amount stated as payable by either Party under or pursuant to this Agreement is exclusive of VAT, if any. Each Party shall issue all invoices in full compliance with the VAT laws and regulations applicable. If any VAT is payable or chargeable on or in respect of the payments by Novartis pursuant to Section 8.1, 8.2 or 8.3 in respect of the intellectual property rights licensed under this Agreement (the "License"), or any supply of Licensed Product by BeiGene or its Affiliates under this Agreement, Novartis shall pay to BeiGene the amount of that VAT in addition to the amount owed; provided, that, such a payment will only be made by Novartis if BeiGene provides Novartis, prior to the payment, with a valid VAT invoice in the appropriate form and based on local indirect Tax law. For the avoidance of doubt, this Section 8.4.2(c)(i) applies to Royalty payments described in Section 8.3.

(ii) Upfront and Milestone Payments. Novartis and BeiGene agree that, if so allowed under Applicable Law and approved by the Swiss Federal Tax Administration prior to the payment dates set forth in Sections 8.1 and 8.2 (as applicable to payments to be made by Novartis) of this Agreement, such payments by Novartis shall be treated with the notification procedure according to Art. 38 of the Swiss VAT law, and the Parties shall take reasonable steps to achieve such VAT treatment. The Parties will initiate and pursue, in respect of the License, the voluntary notification procedure ("Meldeverfahren") as foreseen in Art.38 Swiss VAT law. At the Execution Date, BeiGene is registered in the UID register under the number CHE-151.848.099 MWST and Novartis under the number CHE 116.268.023 MWST. The Parties shall cooperate with each other and, within the applicable legal deadlines, notify the Swiss Federal Tax Administration of the License, and undertake in a timely manner all steps required by Swiss law in connection with such notification procedure (including the timely filing of the signed form 764). Upon the request from Novartis for purposes of responding to Swiss Federal Tax Administration inquiry related to such notification procedure, BeiGene shall, within a reasonable period of time, provide all information and documentation to Novartis Controlled by BeiGene which is necessary to evidence the previous input VAT deductions and use of goods or services received. Pursuant to the application of the notification procedure, once it is approved, no specific indication of any VAT being due (e.g. "incl. VAT", etc.) shall be made by BeiGene on the relevant invoices, except for the notion that the notification procedure applies. Should, however, VAT be chargeable on the License or any part thereof in Switzerland or abroad, it shall be fully payable by Novartis together with any interest or penalties for late payment of such VAT.

8.5 Records; Audit Rights.

8.5.1 Records. Each Party shall keep complete, true, and accurate books and records in accordance with its Accounting Standards in relation to this Agreement, including: (a)

with respect to Novartis, its Affiliates, and its Sublicensees, in relation to Net Sales, royalties, and Milestone Payments; (b) with respect to BeiGene, in relation to costs incurred which Novartis is obligated to reimburse pursuant to this Agreement; and (c) with respect to both Parties, Shared Development Costs incurred in the conduct of Global Monotherapy Trials. Each Party shall keep such books and records for at least **[…***…]** following the Calendar Year to which they pertain or for such longer period of time as required under any Applicable Law.

8.5.2 Audit Rights. Subject to the other terms of this Section 8.5.2, during the Term, at the request of a Party (the "Auditing Party"), which shall not be made more frequently than **[…***…]** per Calendar Year, upon at least **[…***…]** prior written notice from the Auditing Party, and at the expense of the Auditing Party, the other Party (the "Audited Party") shall permit an independent, internationally nationally-recognized certified public accounting firm selected by the Auditing Party and reasonably acceptable to the Audited Party (the "Auditor") to inspect, during regular business hours, the relevant records required to be maintained by the Audited Party under Section 8.5.1; provided, that such audit right shall not apply to records beyond **[…***…]** from the end of the Calendar Year to which they pertain and no such audit shall cover periods or records previously audited. Prior to its inspection, the Auditor shall enter into a confidentiality agreement with both Parties having obligations of confidentiality and non-use no less restrictive than those set forth in Article 12 and limiting the disclosure and use of such information by such accountant to authorized representatives of the Parties and the purposes germane to Section 8.5.1. The Auditor shall provide its audit report and basis for any determination to the Audited Party at the time such report is provided to the Auditing Party before it is considered final. The Audited Party shall have the right to request a further determination by such Auditor as to matters which the Audited Party reasonably disputes within **[…***…]** following receipt of such report. The Audited Party will provide the Auditing Party and the Auditor with a reasonably detailed statement of the grounds upon which it disputes any findings in the audit report and the Auditor shall undertake to complete such further determination within **[…***…]** after the dispute notice is provided, which determination shall be limited to the disputed matters. Subject to the foregoing, the results of any audit report will be binding on both Parties absent manifest error. Any matter that remains unresolved shall be resolved in accordance with the dispute resolution procedures contained in Section 16.7.2. The accountant shall report to the Auditing Party only whether the particular amount being audited was accurate, and if not, the amount of any discrepancy. The Auditing Party shall treat the results of any such accountant's review of the Audited Party's records as Confidential Information of the Audited Party subject to the terms of Article 12. In the event such audit leads to the discovery of a discrepancy to the Auditing Party's detriment, the Audited Party shall, within **[…***…]** after receipt of such report from the Auditor, pay any undisputed amount of the discrepancy. The Auditing Party shall pay the full cost of the audit unless the underpayment of amounts due to, or overpayment of amounts payable by, the Auditing Party is greater than **[…***…]** of the amount due for the entire period being examined, in which case the Audited Party shall pay the reasonable cost charged by the Auditor for such review. Any undisputed overpayments by the Audited Party revealed by an examination shall be paid by the Auditing Party within **[…***…]** days of the Auditing Party's receipt of the applicable report.

8.5.3 Records Final. Upon the expiration of **[…***…]** following the end of a given Calendar Year, the calculation of any amounts payable by a Party to the other Party with respect to such Calendar Year shall be binding and conclusive upon the Parties, such Party and its Affiliates shall be released from any liability or accountability with respect to such payments to the other Party for such Calendar Year. Subject to the foregoing, to the extent that Novartis reasonably determines, from time to time, that it has paid more royalties than were owed to BeiGene for any period, (a) Novartis shall provide BeiGene with written notice, which notice shall include reasonable supporting evidence for its determination, (b) the Parties shall discuss in good faith and use reasonable efforts to confirm Novartis's determination that an excess royalty payment was made, (c) to the extent that the Parties confirm Novartis's determination that an excess royalty payment was made, reasonably agree on the appropriate offset to be made over time with respect to subsequent royalty payments to be made to BeiGene until such excess amount has been recovered by Novartis and (d) to the extent BeiGene reasonably disputes Novartis's determination that an excess royalty payment was made, the matter shall be submitted to Accelerated Arbitration pursuant to Section 16.7.2(i).

ARTICLE 9
LICENSES; EXCLUSIVITY

9.1 Licenses Grants to Novartis.

9.1.1 Exclusive License. Subject to the terms and conditions of this Agreement, BeiGene hereby grants to Novartis (a) an exclusive (even as to BeiGene but subject to BeiGene's retained rights set forth in Section 9.4(b) below), transferrable (pursuant to Section 16.4), license, with the right to grant sublicenses solely in accordance with Section 9.1.3, under the BeiGene Patents and BeiGene's interest in Joint Inventions and Joint Patents and (b) an exclusive (even as to BeiGene but subject to BeiGene's retained rights set forth in Section 9.4(b) below), transferrable (pursuant to Section 16.4), license, with the right to grant sublicenses solely in accordance with Section 9.1.3, under the BeiGene Know-How, in each case, to Develop, Manufacture, conduct Medical Affairs Activities and Commercialize the Licensed Product **[…***…]** in the Field in the Novartis Territory.

9.1.2 Non-exclusive License. Subject to the terms and conditions of this Agreement, BeiGene hereby grants to Novartis a non-exclusive, transferrable (pursuant to Section 16.4), license, with the right to grant sublicenses solely in accordance with Section 9.1.3, under the BeiGene Patents, BeiGene's interest in Joint Inventions and Joint Patents, and the BeiGene Know-How, in each case, to (a) Develop and Manufacture, the Licensed Product **[…***…]** in the Field and in the BeiGene Territory solely for the purposes of further Developing, Commercializing, and conducting Medical Affairs Activities with respect to, the Licensed Compound or Licensed Product in the Novartis Territory, and (b) Develop, Manufacture, conduct Medical Affairs Activities and Commercialize any Combination Regimen in the Field and in the BeiGene Territory.

9.1.3 Right to Sublicense. Subject to the terms and conditions of this Agreement, Novartis shall have the right to grant sublicenses under the license granted to it in Section 9.1.1 through multiple tiers: (a) to its Affiliates, provided that such sublicense shall

automatically terminate if such sublicensee ceases to be an Affiliate of Novartis; (b) subject to Section 9.3, to contract research organizations, distributors and other Third Party subcontractors for the sole purpose of performing Novartis's obligations hereunder with respect to the Development, Manufacture and Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Licensed Compounds and the Licensed Product in the Field in the Novartis Territory; and (c) to any other Third Party with respect to the Development, Manufacture and/or Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Licensed Product in the Field and in the Novartis Territory. The terms of each such sublicense shall not be inconsistent with the terms and conditions of this Agreement, and Novartis shall ensure that its sublicensees comply with the terms and conditions of this Agreement applicable to the Sublicensee. Novartis will remain directly responsible for all of its obligations under this Agreement, regardless of whether any such obligation is delegated, subcontracted or sublicensed to any sublicensees. In the event of any material breach by any such sublicensee of any agreement entered into by Novartis pursuant to Section 9.1.3(b) or (c) that would be a material breach of this Agreement by Novartis, Novartis shall promptly terminate such agreement with such sublicensee if such breach is not cured within **[…***…]** of Novartis becoming aware of such breach. In the event that Novartis grants a Sublicense to a Third Party pursuant to which it permits such Sublicensee to control all material decisions regarding Development or Commercialization of the Licensed Product in a particular country or countries in the Novartis Territory, Novartis shall notify the JSC of such Sublicense and the general scope thereof.

9.1.4 Trademark License.

(a) Subject to the terms and conditions of this Agreement including Section 5.1.2, BeiGene hereby grants to Novartis and its Affiliates (i) an exclusive license, with the right to grant sublicenses, through multiple tiers, to use the BeiGene Trademarks solely in connection with the Commercialization of, and the conduct of Medical Affairs Activities in respect of, the Licensed Product (as a Monotherapy or as part of a Combination Regimen) in the Field in the Novartis Territory, and (ii) a non-exclusive license, with the right to grant sublicenses, through multiple tiers, to use the BeiGene Trademarks solely in connection with the Commercialization of, and the conduct of Medical Affairs Activities in respect of, a Combination Regimen in the Field in the BeiGene Territory (clauses (i) and (ii), the "Trademark License"). Subject to the terms and conditions of this Agreement, BeiGene hereby grants to Novartis an exclusive license, with the right to grant sublicenses, through multiple tiers, to register domain names corresponding to or containing such BeiGene Trademarks in any generic Top Level Domains (gTLDs) and country code Top Level Domain (ccTLDs) in the Novartis Territory.

(b) Acknowledgements and Covenants. Novartis hereby acknowledges BeiGene's ownership of all right, title and interest in and to the BeiGene Trademarks and hereby agrees that it will do nothing inconsistent with such ownership and that all use of the BeiGene Trademarks by Novartis shall inure to the benefit of and be on behalf of BeiGene. Novartis further agrees that (i) nothing in this Agreement shall give Novartis any right, title or interest in the BeiGene Trademarks other than the right to use the BeiGene Trademarks in accordance with this Agreement; (ii) it will not attack or challenge, nor will it assist others in

attacking or challenging, BeiGene's rights in the BeiGene Trademarks; and (iii) if, by virtue of Novartis's use of the BeiGene Trademarks, Novartis acquires any equity, title or other rights in or to the BeiGene Trademarks, Novartis shall and hereby does assign and agrees to assign and transfer same to BeiGene.

(c) Trademark Quality Standards. Novartis agrees that the nature and quality of the Licensed Product Commercialized by it under the BeiGene Trademarks, together with all related advertising, promotional and other related uses of the BeiGene Trademarks by Novartis shall conform in all respects with the trademark guidelines Novartis follows in respect of its own proprietary trademarks. BeiGene will have the right to monitor Novartis's use of the BeiGene Trademarks and to request that Novartis correct any failure to comply with this Section 9.1.4 which BeiGene reasonably determines is likely to adversely affect the strength or value of such trademark, such request not to be unreasonably refused.

(d) Quality Maintenance. Novartis agrees to reasonably cooperate with BeiGene in connection with BeiGene's monitoring of the quality of the Licensed Product with respect to which the BeiGene Trademarks is licensed hereunder. Without limiting the foregoing, Novartis shall provide BeiGene with exemplary specimens of the packaging of a Licensed Product prior to using or otherwise disseminating such materials (each, a "Specimen"). Novartis agrees not to use, distribute or sell the Licensed Product using the BeiGene Trademarks without BeiGene's prior written consent, not to be unreasonably withheld, conditioned or delayed. BeiGene agrees to use reasonable efforts to provide its consent to or rejection of any such proposed use of the BeiGene Trademarks as soon as practicable and in any event within **[…***…]** after receipt of each Specimen from Novartis after which time BeiGene shall be deemed to have consented to such proposed use. In addition, from time to time during the Term (a) Novartis shall, upon the written request of BeiGene and with **[…***…]** prior notice, provide BeiGene with such written assurance as may be reasonably requested by BeiGene that the Licensed Product then being Commercialized is in compliance with the Specimen approved by BeiGene and (b) BeiGene shall have the right, at its sole cost and expense and upon **[…***…]** notice to Novartis, to examine the Licensed Product Commercialized by Novartis, but excluding any Novartis Controlled Compound, to ensure compliance with this Section 9.1.4.

9.1.5 Trademark Prosecution and Maintenance.

(a) BeiGene First Right. BeiGene will have the first right, but not the obligation, using trademark counsel of its choice, to Prosecute and Maintain, at BeiGene's sole cost and expense any BeiGene Trademarks. BeiGene will keep Novartis informed as to material developments with respect to the Prosecution and Maintenance of such BeiGene Trademarks including by providing copies of all substantive office actions, registration and renewal certificates, examination reports, communications or any other substantive documents to or from any trademark office at least **[…***…]** prior to any deadline to take any action, or if there is no such deadline, no later than **[…***…]** after BeiGene receives such materials of communication. BeiGene will also provide Novartis with a reasonable opportunity to comment substantively on the Prosecution and Maintenance of such BeiGene Trademark in the Novartis Territory prior to taking material actions (including the filing of initial applications), and will in good faith

consider any comments made by, and actions recommended by, Novartis and shall pursue in good faith all reasonable claims requested by Novartis; provided, that, Novartis provides its comments in a timely fashion consistent with any applicable filing deadlines.

(b) Novartis Fallback Right. If BeiGene decides not to Prosecute or Maintain a BeiGene Trademark in any country in the Novartis Territory or intends to allow such BeiGene Trademark in the Novartis Territory to lapse or become abandoned without having first filed a substitute, it will notify and consult with Novartis of such decision or intention at least **[…***…]** prior to the date upon which the subject matter of such BeiGene Trademark will lapse or become abandoned, and Novartis will thereupon have the right, but not the obligation, to assume the Prosecution and Maintenance thereof at Novartis's sole cost and expense (each, an "Novartis Assumed Trademark"), through trademark counsel of its choice, (b) BeiGene shall take all actions reasonably necessary to assign and transfer ownership of such Novartis Assumed Trademark to Novartis, and (c) such Novartis Assumed Trademark will no longer deemed to be part of the licenses granted to BeiGene pursuant to this Agreement. To the extent that Novartis assumes such responsibility, BeiGene shall promptly deliver to Novartis copies of all necessary files related to any BeiGene Trademark with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Novartis to assume such activities, at Novartis's request and otherwise provide such cooperation and assistance as Novartis may request following such transfer in connection with Novartis' Prosecution and Maintenance of such Novartis Assumed Trademark.

9.1.6 Trademark Enforcement.

(a) Notice. Each Party shall notify the other Party within **[…***…]** of receipt of any indication or notice of infringement or challenge, including any available evidence relating thereto, by a Third Party of any BeiGene Trademark in the Novartis Territory of which it becomes aware, including any declaratory judgment, opposition, petition for cancellation, or similar action alleging the invalidity, or non-infringement with respect to such BeiGene Trademark or other actual or potential infringement or BeiGene Trademark challenge by a potential competitor anywhere in the Novartis Territory (collectively, a "Competing Trademark Infringement").

(b) Novartis First Right. Subject to the remaining provisions of this Section 9.1, Novartis will have the first right, but not the obligation, at its sole expense, to institute, prosecute, and control any action or proceeding (which may include settlement or otherwise seeking to secure the abatement of such infringement), with respect to any Competing Trademark Infringement of a BeiGene Trademark in the Novartis Territory within the Field by counsel of its own choice, in Novartis's own name (or, if required, under BeiGene's name) and under Novartis's direction and control, including the right to control the defense of any challenges to such Patents as a counterclaim in such infringement proceeding. Novartis shall consider in good faith the interests of BeiGene in such enforcement of any BeiGene Trademark in the Novartis Territory; provided, that, if Novartis does not intend to prosecute or defend a Competing Trademark Infringement, or ceases to diligently pursue an enforcement with respect

to such a Competing Trademark Infringement, it shall promptly inform BeiGene in such a manner that such enforcement will not be prejudiced and Section 9.1.6(c) shall apply.

(c) BeiGene Fallback Right. If Novartis determines not to institute an action or proceeding with respect to a given Competing Trademark Infringement of any BeiGene Trademark pursuant to Section 9.1.6(b) or if Novartis or its designee fails to abate such Competing Trademark Infringement in the Novartis Territory or to file an action to abate such Competing Trademark Infringement in the Novartis Territory within **[…***…]** after a written request from BeiGene to do so, or if Novartis discontinues the prosecution of any such action after filing without abating such Competing Trademark Infringement, then BeiGene shall have the right to enforce such BeiGene Trademark against such Competing Trademark Infringement in the Novartis Territory at its sole expense as it reasonably determines appropriate and shall keep Novartis reasonably informed with respect to any such enforcement action.

(d) Consultation; Cooperation. The enforcing Party will keep the non-enforcing Party regularly informed of the status and progress of such enforcement efforts. The enforcing Party will consult with the non-enforcing Party and will take comments of the non-enforcing Party into good faith consideration with respect to the defense or enforcement of any BeiGene Trademark in the Novartis Territory. The non-enforcing Party will provide to the enforcing Party reasonable cooperation in such enforcement, at such enforcing Party's request and expense.

(e) Settlement. A settlement or consent judgment or other voluntary final disposition of a suit with respect to the BeiGene Trademarks under this Section 9.1.6 may be entered into without the consent of the Party not bringing suit; provided, however, that any such settlement, consent judgment or other disposition of any action or proceeding by a Party under this Section 9.1.6 will not, without the consent of the other Party, (a) impose any liability or obligation on such other Party, (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 subject matter included under the rights and licenses granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect.

(f) Recovery. Except as otherwise set forth in this Section 9.1, each Party will bear all of its own internal and out-of-pocket costs incurred in connection with its activities under this Section 9.1. Any damages or other monetary awards recovered in any action, suit or proceeding brought under this Section 9.1 to the extent related to any BeiGene Trademarks will be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action 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 (b) any remaining proceeds shall be allocated between the Parties as follows:

(i) If Novartis controls enforcement in accordance with this Section 9.1.6, Novartis shall be entitled to receive **[…***…]**; and

(ii) If BeiGene controls enforcement in accordance with this Section 9.1.6, BeiGene shall be entitled to receive **[…***…]**.

9.1.7 Copyright License. Subject to the terms and conditions of this Agreement, BeiGene hereby grants to Novartis a non-exclusive license, with the right to grant sublicenses through multiple tiers, to use the BeiGene Copyrights (i) in connection with the Commercialization of the Licensed Product in accordance with this Agreement in the Field, and (ii) for carrying out Medical Affairs Activities in accordance with this Agreement (clauses (i) and (ii), the "Copyright License").

9.2 Licenses to BeiGene.

9.2.1 Subject to the terms and conditions of this Agreement, Novartis hereby grants to BeiGene a non-exclusive, transferrable (pursuant to Section 16.4), license, with the right to grant sublicenses solely in accordance with Section 9.3.2, under the Novartis Inventions, Novartis Invention Patents and Novartis' interest in Joint Invention and Joint Patents, to (a) perform its obligations under this Agreement; (b) conduct Global Development Activities, Unilateral Studies conducted by BeiGene, Permitted Combination Studies, BeiGene Permitted Commercialization Activities, Medical Affairs Activities and Third Party Permitted Commercialization Activities, in each case, pursuant to and in accordance with this Agreement; (c) Develop, conduct Medical Affairs Activities in respect of, and Commercialize any Combination Regimen or Combination Product in the Field and in the BeiGene Territory, (d) Manufacture the Licensed Compound and the Licensed Product in the BeiGene Territory solely for the BeiGene Territory, and (e) Manufacture the Licensed Compound and the Licensed Product in the Novartis Territory solely for use (i) by Novartis in the Field and in the Novartis Territory and (ii) by BeiGene (A) in the Field and in the BeiGene Territory and (B) to conduct (1) the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan; and (2) Global Development Activities, Unilateral Studies conducted by BeiGene or Permitted Combination Studies pursuant to and in accordance with this Agreement, in each case, whether directly or through its Affiliates or contractors.

9.2.2 Subject to the terms and conditions of this Agreement, including Novartis' retained rights set forth in Section 9.4(c) below, Novartis hereby grants to BeiGene an exclusive, transferrable (pursuant to Section 16.4), license, with the right to grant sublicenses solely in accordance with Section 9.3.2, under the Novartis Inventions, Novartis Invention Patents and Novartis' interest in Joint Inventions and Joint Patents to Develop, Manufacture, conduct Medical Affairs Activities and Commercialize the Licensed Product **[…***…]** in the Field in the BeiGene Territory.

9.3 Subcontracting.

9.3.1 Novartis. Novartis may subcontract to Affiliates or Third Parties the performance of tasks and obligations related to Novartis's Development, Manufacture, and Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Licensed Product under this Agreement as Novartis deems appropriate, which subcontract may include a sublicense of rights necessary for the performance of the subcontract as reasonably required; provided, that Novartis shall remain responsible for the performance of this Agreement and shall cause any such subcontractor to comply with all applicable terms and conditions of this Agreement.

9.3.2 BeiGene. BeiGene may subcontract to Affiliates or Third Parties the performance of BeiGene's tasks and obligations under this Agreement, including under the Development Plan (if any), as BeiGene deems appropriate, which subcontract may include a sublicense of rights necessary for the performance of the subcontract as reasonably required; provided, that BeiGene shall remain responsible for the performance of this Agreement and shall cause any such subcontractor to comply with all applicable terms and conditions of this Agreement.

9.4 Rights Retained by the Parties.

(a) Each Party retains all rights under Patents, Know-How, or other intellectual property rights Controlled by such Party which are not expressly granted to the other Party pursuant to this Agreement.

(b) Without limiting the foregoing and notwithstanding the exclusive licenses granted to Novartis, BeiGene hereby retains the rights to use the BeiGene IP in the Field in the Novartis Territory in order to (i) perform its obligations under this Agreement; (ii) conduct Global Development Activities, Permitted Combination Studies, BeiGene Permitted Commercialization Activities, Medical Affairs Activities in respect of BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan, Global Monotherapy Trials agreed to by the Parties, Unilateral Studies conducted by BeiGene, and Third Party Permitted Commercialization Activities pursuant to and in accordance with this Agreement; (iii) Manufacture the Licensed Compound and the Licensed Product in Novartis Territory for use by Novartis; and (iv) Manufacture and supply by BeiGene of the Licensed Compound and the Licensed Product in the Novartis Territory solely for use by BeiGene, whether directly or through its Affiliates, licensees or contractors, in the conduct of (1) the BeiGene Ongoing Clinical Trials and any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan; (2) any Permitted Combination Studies; and (3) Unilateral Studies conducted by BeiGene and any Global Monotherapy Trial mutually agreed to by the Parties.

(c) Without limiting the foregoing and notwithstanding the exclusive licenses granted to BeiGene hereunder, Novartis hereby retains the rights to use the Novartis IP and Novartis' interest in the Joint Patents in the Field in the BeiGene Territory in order to conduct Permitted Combination Studies, Novartis Permitted Commercialization Activities and Medical Affairs Activities in support of Novartis Permitted Commercialization Activities pursuant to and in accordance with this Agreement.

9.5 No Implied Licenses. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license, or other right in or to any Patents, Know-How, or other intellectual property rights of the other Party, including tangible or intangible items owned, controlled, or developed by the other Party, or provided by the other Party to the receiving Party at any time, in each case, pursuant to this Agreement.

9.6 Exclusivity; Exceptions to Exclusivity; Effect of Certain Third Party Acquisitions and Changes of Control.

9.6.1 In General. Subject to the remainder of this Section 9.6, during the Term, neither Party shall, and shall cause its Affiliates not to, alone or with any Third Party (including through licensing or sublicensing any Third Party), directly or indirectly, Develop, Manufacture, or Commercialize, or conduct Medical Affairs Activities with respect to, any Competing Product for use in the Field.

9.6.2 Exception for Novartis Anti-PD-1.

(a) Notwithstanding anything to the contrary in Section 9.6.1:

(i) Novartis shall have the right to continue to conduct clinical development of the Novartis Anti-PD-1, including the conduct of Clinical Trials with the Novartis Anti-PD-1; provided, that, **[…***…]**; provided, further, that **[…***…]**; and

(ii) Novartis shall not be limited from conducting (A) **[…***…]** or (B) **[…***…]**.

(b) Upon the date of filing of a BLA for the Novartis Anti-PD-1 for any Indication in any country in the Novartis Territory (whether as a Monotherapy or a Combination Regimen), Novartis shall provide written notice to BeiGene (the "Novartis Anti-PD-1 Filing Notice"), together with **[…***…]**. During the period commencing on the date of the delivery of the Novartis Anti-PD-1 Filing Notice and continuing until **[…***…]** following the date of receipt of Regulatory Approval of the Novartis Anti-PD-1 for such Indication, BeiGene will provide Novartis with a written notice (the "BeiGene Anti-PD-1 Election Notice") that it elects or does not elect, in its sole discretion, to have the Novartis Anti-PD-1 be treated as a Licensed Product for purposes of this Agreement. If BeiGene provides in the BeiGene Anti-PD-1 Election Notice that it elects to have the Novartis Anti-PD-1 be treated as a Licensed Product for purposes of this Agreement, then, **[…***…]**.

(c) If BeiGene does not elect to have the Novartis Anti-PD-1 be treated as a Licensed Product for purposes of this Agreement or if BeiGene fails to provide the BeiGene Anti-PD-1 Election Notice within the time period specified in Section 9.6.2(b), **[…***…]**.

(d) If Novartis **[…***…]** or if Novartis fails to provide BeiGene with the Novartis Anti-PD-1 Election Notice **[…***…]** (ii) BeiGene shall have the right to terminate this Agreement pursuant to Section 15.5.

9.6.3 Exception for BeiGene Anti-PD-L1.

(a) Notwithstanding anything to the contrary in Section 9.6.1, (i) BeiGene shall have the right to continue to conduct clinical development of the BeiGene Anti-PD-L1, including the conduct of Clinical Trials with the BeiGene Anti-PD-L1 and (ii) BeiGene shall not be limited from conducting any current or future Clinical Trial of an Other Product (that is not a Competing Product) for a Combination Regimen utilizing a Competing Product solely for comparison purposes or standard of care.

(b) Upon the date of filing of a BLA for the BeiGene Anti-PD-L1 for any Indication in any country in the Novartis Territory (whether as a Monotherapy or a Combination Regimen), BeiGene shall provide written notice to Novartis (the "BeiGene Anti-PD-L1 Filing Notice"), together with **[…***…]**. During the period commencing on the date of the delivery of the BeiGene Anti-PD-L1 Filing Notice and continuing until **[…***…]** following the date of receipt of Regulatory Approval of the BeiGene Anti-PD-L1, Novartis may provide BeiGene with a written notice (the "Novartis Anti-PD-L1 Election Notice") that it elects, in its sole discretion, to have the BeiGene Anti-PD-L1 be treated as a Licensed Product for purposes of this Agreement. If Novartis provides in the Novartis Anti-PD-L1 Election Notice that it elects to have the BeiGene Anti-PD-L1 be treated as a Licensed Product for purposes of this Agreement, then, **[…***…]**.

9.6.4 Exception for Development of **[…***…]**. Notwithstanding anything to the contrary in Section 9.6.1, **[…***…]**.

9.6.5 Exceptions for Certain Third Party Acquisitions.

(a) Notwithstanding Section 9.6.1, if a Party or any of its Affiliates (collectively, the "Acquiring Party") acquires a Third Party or a portion of the business of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of such Third Party or of any operating or business division of such Third Party or similar transaction) (a "Third Party Acquisition") that is, prior to such acquisition, developing, manufacturing, or commercializing a Competing Product for use in the Field, then the Acquiring Party shall not be in breach of Section 9.6.1 as a result of such Third Party Acquisition; provided, that, such Acquiring Party provides written notice to the other Party no later than **[…***…]** following the closing of such Third Party Acquisition that it elects to **[…***…]**. If such Acquiring Party provides such written notice within such **[…***…]**, the Parties shall promptly negotiate in good faith such an amendment for a period up to **[…***…]**. If such Acquiring Party fails to provide such written notice within such **[…***…]** period, then such Acquiring Party shall be deemed to have elected to **[…***…]** in accordance with this Section 9.6.5. Immediately upon execution by the Acquiring Party of a binding agreement to effect the Third Party Acquisition, the Acquiring Party shall have the right, by providing written notice to Novartis, **[…***…]**.

(b) **[…***…]**in accordance with clauses (ii) or (iii) of this Section 9.6.5 then such Acquiring Party shall: **[…***…]**.

9.7 Effect of Change of Control. If either Party enters into an agreement with an Acquiring Person that results or that, if the transaction contemplated thereby is completed would result, in a Change of Control of such Party, the Acquired Party shall provide the other Party with prompt written notice (the "Change of Control Notice") prior to execution of such agreement, if permitted under Applicable Law and not prohibited by the terms of any agreement between such Party and any Third Party, and otherwise as soon as practicable thereafter and, in any event, not later than the date of **[…***…]**. If the Acquiring Person in the Change of Control is developing, manufacturing or commercializing a Competing Product for use in the Field (based on the applicable Regulatory Approval), then the Acquiring Person shall not be in breach of Section 9.6.1 as a result of such Change of Control; provided, that, **[…***…]**. In addition, the other Party, immediately upon the date of receipt by the other Party of the Change of Control Notice, shall have the right, by providing written notice to the Acquired Party, to **[…***…]**.

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 Ownership.

10.1.1 Inventions.

(a) BeiGene IP. BeiGene shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all BeiGene IP and any other Inventions that is conceived or first reduced to practice by employees of, or consultants to, BeiGene, alone or jointly with any Third Party, without the use in any material respect of any Novartis IP or Joint IP.

(b) Novartis IP. Novartis shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Novartis IP and any other Inventions that is conceived or first reduced to practice by employees of, or consultants to, Novartis, alone or jointly with any Third Party, without the use in any material respect of any BeiGene IP or Joint IP.

(c) Joint Inventions. Novartis and BeiGene shall jointly own all Joint Inventions and Joint Patents. Notwithstanding anything to the contrary contained herein or under Applicable Laws, except to the extent exclusively licensed to one Party under this Agreement set forth herein, the Parties hereby agree that, except as prohibited by Article 9, either Party may use or license or sublicense to Affiliates or Third Parties all or any portion of its interest in Joint Inventions and/or Joint Patents for use in connection with any products that are not Competing Products, without the prior written consent of the other Party, without restriction and without the obligation to provide compensation to the other Party.

10.1.2 Results and Data. All Clinical Data shall be owned by the Party that conducts the applicable Clinical Trial. Without limiting the foregoing, any Clinical Data arising

from the BeiGene Ongoing Clinical Trials (the "BeiGene Ongoing Clinical Trial Data") shall be owned by BeiGene and included in BeiGene Know-How and the licenses granted to Novartis pursuant to Section 9.1.

10.2 Prosecution and Maintenance.

10.2.1 BeiGene First Right. BeiGene will have the first right, but not the obligation, using patent counsel of its choice, to Prosecute and Maintain, at BeiGene's sole cost and expense any BeiGene Patents. BeiGene will keep Novartis informed as to material developments with respect to the Prosecution and Maintenance of such BeiGene Patents including by providing copies of all substantive office actions, examination reports, communications or any other substantive documents to or from any patent office, including notice of all interferences, reissues, re-examinations, inter partes reviews, post grant proceedings, oppositions or requests for patent term adjustments, in all cases at least **[…***…]** prior to any deadline to take any action. BeiGene will also provide Novartis with a reasonable opportunity to comment substantively on the Prosecution and Maintenance of such BeiGene Patents in the Novartis Territory prior to taking material actions (including the filing of initial applications), and will in good faith consider any comments made by, and actions recommended by, Novartis and shall pursue in good faith all reasonable claims requested by Novartis; provided, that, Novartis provides its comments in a timely fashion consistent with any applicable filing deadlines.

10.2.2 Novartis Fallback Right. If BeiGene decides not to Prosecute or Maintain a BeiGene Patent in any country in the Novartis Territory or intends to allow such BeiGene Patent in the Novartis Territory to lapse or become abandoned without having first filed a substitute, it will notify and consult with Novartis of such decision or intention at least **[…***…]** days prior to the date upon which the subject matter of such BeiGene Patent will become unpatentable or will lapse or become abandoned, and Novartis will thereupon have the right, but not the obligation, to assume the Prosecution and Maintenance thereof at Novartis's sole cost and expense (each, an "Novartis Assumed Patent"), through patent counsel or agents of its choice, and such Novartis Assumed Patent will no longer deemed to be part of the licenses granted to BeiGene pursuant to this Agreement. To the extent that Novartis assumes such responsibility, BeiGene shall promptly deliver to Novartis copies of all necessary files related to any BeiGene Patents with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Novartis to assume such activities, at Novartis's request.

10.2.3 Novartis First Right. Novartis will have the first right, but not the obligation, using patent counsel of its choice, to Prosecute and Maintain, at Novartis's sole cost and expense (a) the Joint Patents (which will be in the names of both BeiGene and Novartis) and (b) the Novartis Patents (collectively, the "Novartis Controlled Patents"). Novartis will keep BeiGene informed as to material developments with respect to the Prosecution and Maintenance of such Novartis Controlled Patents including by providing copies of all substantive office actions, examination reports, communications or any other substantive documents to or from any patent office, including notice of all interferences, reissues, re-examinations, inter partes reviews,

post grant proceedings, oppositions or requests for patent term extensions or Supplemental Protection Certificates, in all cases at least **[…***…]** prior to any deadline to take any action. Novartis will also provide BeiGene with a reasonable opportunity to comment substantively on the Prosecution and Maintenance of such Novartis Controlled Patents prior to taking material actions (including the filing of initial applications), and will in good faith consider any comments made by, and actions recommended by, BeiGene and shall pursue in good faith all reasonable claims requested by BeiGene; provided, that, BeiGene provides its comments in a timely fashion consistent with any applicable filing deadlines.

10.2.4 BeiGene Fallback Right. If Novartis decides not to Prosecute or Maintain a Joint Patent in any country or intends to allow such Joint Patent to lapse or become abandoned without having first filed a substitute, it will notify and consult with BeiGene of such decision or intention in at least **[…***…]** prior to the date upon which the subject matter of such Joint Patent will become unpatentable or will lapse or become abandoned, and (a) BeiGene will thereupon have the right, but not the obligation, to assume the Prosecution and Maintenance thereof at BeiGene's sole cost and expense (each, an "BeiGene Assumed Patent") (in both Parties' names), through patent counsel or agents of its choice and (b) such BeiGene Assumed Patent will no longer deemed to be part of the licenses granted to Novartis pursuant to this Agreement, although Novartis shall retain its rights as an owner of such Joint Patent. To the extent that BeiGene assumes such responsibility, Novartis shall promptly deliver to BeiGene copies of all necessary files related to any BeiGene Assumed Patents with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for BeiGene to assume such activities, at BeiGene's request.

10.2.5 Cooperation in Prosecution and Maintenance. The Parties will reasonably cooperate with one another with respect to the Prosecution and Maintenance of the BeiGene Patents and Joint Patents for which either Party is responsible for Prosecution and Maintenance pursuant to this Section 10.2. Such responsible Party shall make its employees, agents and consultants reasonably available to the other Party (and the other Party's authorized attorneys, agents or representatives) to enable the other Party to undertake Prosecution and Maintenance provided in this Section 10.2, and will reasonably assist in any license registration processes with applicable Governmental Authorities that may be available for the protection of the other Party's interests in this Agreement. In addition, the responsible Party will (and will cause its employees, agents and consultants to) provide reasonable assistance to the other Party (and to the other Party's authorized attorneys, agents or representatives) to enable the other Party to undertake such Prosecution and Maintenance, including by executing powers of attorney and other agreements for the other Party to undertake such Prosecution and Maintenance.

10.2.6 Cost of Prosecution and Maintenance. Except as otherwise expressly set forth in this Section 10.2, each Party will be responsible for all costs and expenses associated with its Prosecution and Maintenance activities under this Section 10.2 with respect to BeiGene Patents and Joint Patents for which it is responsible pursuant to Sections 10.2.1, 10.2.2 or 10.2.3 as applicable.

10.2.7 Patent Prosecution Conferences. Each Party shall cause its patent counsel to confer no less frequently than once each calendar quarter regarding the status of all Patent Applications and Patents for which it is responsible under this Section 10.2, and whether and in which countries foreign counterparts of such Patent Applications and Patents shall be filed and any subject matter claimed in each. The Parties shall set the location, date, time and type of meeting (either in person, by teleconference, or by videoconference) so as to be mutually agreeable to the patent counsel of each Party.

10.3 Enforcement.

10.3.1 Notice. Each Party shall notify the other Party within **[…***…]** of receipt of any indication or notice of infringement or Patent challenge by a Third Party of any BeiGene Patent in the Novartis Territory consisting solely of claims that Cover the composition, formulation, a method of use or a method of making the Licensed Compound or the Licensed Product ("BeiGene Core Patent"), Novartis Patent or Joint Patent in the Novartis Territory of which it becomes aware, including any declaratory judgment, opposition, post grant review, inter partes review, or similar action alleging the invalidity, unenforceability, unpatentability, or non-infringement with respect to such BeiGene Core Patent, Novartis Patent or Joint Patent, including with respect to any Abbreviated Biologics License Application or Biologics License Application (each, as defined in the Federal Food, Drug, and Cosmetic Act, Biologics Price Competition and Innovation Act of 2009, or United States Patient Protection and Affordable Care Act) filing, any regulatory filing based on Section 351(k) of the Public Health Service Act (42 U.S.C. § 262), or ARTICLE 10(4) of the Directive 2001/83/EC, or any other similar regulation promulgated by the FDA, EMA, MHLW, or by other applicable similar Governmental Authority or other actual or potential infringement or Patent challenge by a biosimilar, or potential biosimilar competitor anywhere in the Novartis Territory (collectively, a "Competing Infringement").

10.3.2 Novartis First Right. Subject to the remaining provisions of this Section 10.3, Novartis will have the first right, but not the obligation, at its sole expense, to institute, prosecute, and control any action or proceeding (which may include settlement or otherwise seeking to secure the abatement of such infringement), with respect to any Competing Infringement of a BeiGene Core Patent, Joint Patent, Novartis Controlled Patent or Novartis Patent in the Novartis Territory within the Field by counsel of its own choice, in Novartis's own name (or, if required, under BeiGene's name) and under Novartis's direction and control, including the right to control the defense of any challenges to such Patents as a counterclaim in such infringement proceeding. Novartis shall consider in good faith the interests of BeiGene in such enforcement of any Novartis Controlled Patent; provided, that, if Novartis does not intend to prosecute or defend a Competing Infringement, or ceases to diligently pursue an enforcement with respect to such a Competing Infringement, it shall promptly inform BeiGene in such a manner that such enforcement will not be prejudiced and Section 10.3.3 shall apply.

10.3.3 BeiGene Fallback Right. If Novartis determines not to institute an action or proceeding with respect to a given Competing Infringement of any BeiGene Core Patent or Joint Patent pursuant to Section 10.3.2 or if Novartis or its designee fails to abate such

Competing Infringement in the Novartis Territory or to file an action to abate such Competing Infringement in the Novartis Territory within **[…***…]** after a written request from BeiGene to do so, or if Novartis discontinues the prosecution of any such action after filing without abating such Competing Infringement, then BeiGene shall have the right to enforce such BeiGene Core Patent or Joint Patent as applicable, against such Competing Infringement in the Novartis Territory at its sole expense as it reasonably determines appropriate and shall keep Novartis reasonably informed with respect to any such enforcement action. Notwithstanding the foregoing, BeiGene shall only have the right to enforce a Joint Patent if it determines in good faith after consultation with outside patent counsel mutually acceptable to the Parties and with Novartis, subject to entering into a common interest agreement pursuant to Section 10.3, that there is a good faith basis to enforce the Joint Patent.

10.3.4 BeiGene First Right. BeiGene will have the first right, but not the obligation, at its sole expense, to institute, prosecute, and control any action or proceeding (which may include settlement or otherwise seeking to secure the abatement of such infringement) in the Novartis Territory, with respect to any Competing Infringement of any BeiGene Patent that is not a BeiGene Core Patent as well as any BeiGene Assumed Patent by counsel of its own choice, in BeiGene's own name (or, if required, under Novartis's name upon written authorization from Novartis) and under BeiGene's direction and control, including the right to control the defense of any challenges to such Patents as a counterclaim in such infringement proceeding.

10.3.5 Right to Participate; Joinder. In the case of any enforcement action or proceeding with respect to Joint Patents as set forth in Sections 10.3.2, the other Party (or its Affiliate, as applicable) will join any such action or proceeding as a party, at the enforcing Party's expense, if doing so is necessary for the purposes of establishing standing or is otherwise required by Applicable Law to pursue such action or proceeding. The non-enforcing Party in relation to any enforcement action or proceeding with respect to Joint Patents as set forth in Sections 10.3.2, as applicable, will have the right, at its own expense and by counsel of its choice, to be represented in any such action or proceeding. In the case of any enforcement action or proceeding with respect to BeiGene Patents controlled by Novartis as set forth in Section 10.3.2, BeiGene (or its Affiliate, as applicable) will join any such action or proceeding as a party, at Novartis's expense, if doing so is necessary for the purposes of establishing standing or is otherwise required by Applicable Law to pursue such action or proceeding. In the case of any enforcement action or proceeding with respect to BeiGene Patents controlled by BeiGene as set forth in Section 10.3.3, BeiGene will bear its own costs and expenses arising out of such enforcement action or proceeding, and Novartis may, at its option, participate in such enforcement action or proceeding at its own expense. To the extent that Novartis is required to join any enforcement action or proceeding with respect to Joint Patents controlled by BeiGene as set forth in Section 10.3.3, then BeiGene will reimburse Novartis for its reasonable costs and expenses in connection therewith.

10.3.6 Consultation; Cooperation. The enforcing Party will keep the non-enforcing Party regularly informed of the status and progress of such enforcement efforts. The enforcing Party will consult with the non-enforcing Party and will take comments of the non-

enforcing Party into good faith consideration with respect to the infringement or claim construction of any claim in any BeiGene Patent or Joint Patent. The non-enforcing Party will provide to the enforcing Party reasonable cooperation in such enforcement, at such enforcing Party's request and expense.

10.3.7 Settlement. A settlement or consent judgment or other voluntary final disposition of a suit with respect to the BeiGene Patents or Joint Patents under this Section 10.3 may be entered into without the consent of the Party not bringing suit; provided, however, that any such settlement, consent judgment or other disposition of any action or proceeding by a Party under this Section 10.3 will not, without the consent of the other Party, (a) impose any liability or obligation on such other Party, (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 subject matter included under the rights and licenses granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect.

10.3.8 Recovery. Except as otherwise set forth in this Section 10.3, each Party will bear all of its own internal and out-of-pocket costs incurred in connection with its activities under this Section 10.3. Any damages or other monetary awards recovered in any action, suit or proceeding brought under this Section 10.3 to the extent related to any BeiGene Patents, Novartis Patents or Joint Patents will be shared as follows: (a) the amount of such recovery actually received by the Party controlling such action 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 (b) any remaining proceeds shall be allocated between the Parties as follows:

(i) if Novartis controls enforcement in accordance with this Section 10.3, with respect to the Licensed Product, BeiGene shall be entitled to a payment **[…***…]**, and any remaining amounts **[…***…]** to Novartis to the extent such proceeds relate to infringement of the Novartis Controlled Patents; and

(ii) If BeiGene controls enforcement in accordance with this Section 10.3, with respect to the Licensed Products, BeiGene shall be entitled to receive **[…***…]** of all remaining proceeds.

10.4 Common Interest Agreement. At the request of either Party, the Parties will negotiate in good faith to enter into a common interest agreement with respect to the subject matter of this Article 10. 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.

10.5 Defense.

10.5.1 Notice. Each Party shall promptly notify the other Party of any claim alleging that the Development, Manufacture, or Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Licensed Product in the Novartis Territory infringes, misappropriates, or otherwise violates any Patents, Know-How, or other intellectual property rights of any Third Party ("Third Party Infringement"). In any such instance, the Parties shall as soon as practicable thereafter discuss in good faith the best response to such notice of Third Party Infringement.

10.5.2 Novartis Right to Defend. Novartis shall have the first right, but not the obligation, to defend, and take other actions (including to settle) with respect to, any such claim of Third Party Infringement, at Novartis's sole discretion, cost, and expense; provided, that, (a) Novartis will discuss in good faith and coordinate with BeiGene in connection therewith and Novartis will consider in good faith and reasonably address BeiGene's input and comments with respect thereto and (b) Novartis will not, without the prior written consent of BeiGene, enter into any settlement, consent judgment or other disposition of any action or proceeding that would (i) impose any liability or obligation on BeiGene (including pursuant to the final sentence of this Section 10.5.2), (ii) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and licenses granted to BeiGene under this Agreement, or (iii) otherwise adversely affect the licenses or other rights granted to BeiGene hereunder in any respect. BeiGene shall have the right to be represented in any such action by counsel of its own choice at BeiGene's sole cost and expense. Subject to the foregoing, if Novartis enters into any settlement of any such Third Party Infringement, Novartis may deduct from the royalty payments that would otherwise have been due and payable to BeiGene under Section 8.3.1 an amount equal to **[…***…]** of any payments made by Novartis or any of its Affiliates or Sublicensees to such Third Party under such settlement agreement.

10.5.3 BeiGene Fallback Right. If Novartis determines not to institute an action or proceeding with respect to a given Third Party Infringement pursuant to Section 10.5.2 or if Novartis or its designee fails to defend such Third Party Infringement in the Novartis Territory or to file an action to defend such Third Party Infringement in the Novartis Territory within **[…***…]** after a written request from BeiGene to do so, or if Novartis discontinues the defense of any such action after filing without abating such Third Party Infringement, then BeiGene shall have the right to right, but not the obligation, to defend, and take other actions (including to settle) with respect to, any such claim of Third Party Infringement, at BeiGene's sole discretion, cost, and expense and shall keep Novartis reasonably informed with respect to any such enforcement action; provided, that, BeiGene shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Novartis Controlled Patents without the prior written consent of Novartis, which consent shall not be unreasonably withheld, delayed or conditioned.

10.6 Novartis Trademarks. Novartis and its Affiliates shall have the exclusive right, but not the obligation, to brand the Licensed Products using trademarks and trade names it determines appropriate for the Licensed Products, which may vary for different countries (the "Novartis Trademarks"). Novartis shall exclusively own all rights in and goodwill associated with the Novartis Trademarks and shall register, maintain and defend the Novartis Trademarks at

its sole cost and expense. The benefit of the Novartis Trademarks shall inure entirely to Novartis.

10.7 Patent Extensions. BeiGene will reasonably cooperate with Novartis, including providing reasonable assistance to Novartis (including executing any documents as may reasonably be required), in efforts to seek and obtain patent term restoration or supplemental protection certificates or the like or their equivalents in any country in the Novartis Territory, where applicable to BeiGene Patents or Joint Patents or any other applicable Patents, 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 the 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 are to be made in connection therewith, the Parties will mutually agree upon the election.

10.8 Orange Book and Purple Book Listings. The Parties will reasonably agree upon the listings to be made with the applicable Regulatory Authorities in the Novartis Territory for all applicable Patents (including any BeiGene Patents) for the Licensed Product, including all so-called "Orange Book" and "Purple Book" listings required under the U.S. Public Health Service Act, and all similar listings in any other relevant countries. If the Parties are unable to agree, Novartis will retain final decision-making authority with respect to the listing of any applicable Patents for the Licensed Product, regardless of which Party owns such Patent; provided, that, Novartis shall reasonably consider BeiGene's position in connection therewith.

ARTICLE 11
ANTITRUST LAW COMPLIANCE

11.1 Filings. Each of BeiGene and Novartis shall, no later **[…***…]** after the Execution Date, file with the U.S. Federal Trade Commission (the "FTC") and the Antitrust Division of the U.S. Department of Justice (the "DOJ") HSR Filings with respect to the transactions contemplated by this Agreement. The Parties shall cooperate with one another to the extent necessary in the preparation of such HSR Filings. Each Party shall be responsible for **[…***…]** of the filing fees associated with such HSR Filings.

11.2 Information Exchange. Each Party shall, in connection with the HSR Filings: (a) use reasonable efforts to make, or cause or be made, all filings and submissions required under the HSR Act and use reasonable efforts to obtain, or cause to be obtained, all consents, authorizations, orders and approvals from the FTC and the DOJ that are, in any case, required and/or otherwise necessary for the execution and delivery by such Party of this Agreement and the performance of its obligations pursuant to this Agreement; (b) use reasonable efforts to, and reasonably cooperate with the other Party in connection with any communication, filing, submission, investigation, or other inquiry (including any proceeding initiated by a private party) and shall not willfully take any action that will have the effect of delaying, impairing or impeding the receipt of any such required consents, authorizations, orders and approvals; (c) respond promptly to any inquiries by the FTC or the DOJ regarding antitrust or other matters with respect to the transactions contemplated by this Agreement; (d) keep the other Party or its

counsel reasonably informed of any communication received by such Party from, or given by such Party to, the FTC or the DOJ (including any communication received or given in connection with any proceeding by a private party), in each case, regarding the transactions contemplated by this Agreement; (e) consult with the other Party in advance of any meeting or conference with the FTC or the DOJ (or, in connection with any proceeding by a private party, with such private party), and to the extent permitted by the FTC or the DOJ (or such private party), give the other Party or their counsel the opportunity to attend and participate in such meetings and conferences, at the other Party's cost and expense; and (f) permit the other Party or its counsel to review in advance any submission, filing, or communication (and documents submitted therewith) intended to be given by it to the FTC or the DOJ (or, in connection with any proceeding by a private party, to such private party). BeiGene and Novartis, as each deems advisable and necessary, may reasonably designate any competitively sensitive material to be provided to the other under this Section 11.2 as "Antitrust Counsel Only Material." Such materials and the information contained therein shall be given only to the outside antitrust counsel of the recipient and shall not be disclosed by such outside counsel to employees, officers, or directors of the recipient Party unless express permission is obtained in advance from the source of the materials or the applicable Party's legal counsel. To the extent that any antitrust agency other than the FTC or DOJ decides to review the transactions contemplated by this Agreement, the provisions of this Section 11.2 will apply for the purposes of such review with equivalent effect.

ARTICLE 12
CONFIDENTIALITY

12.1 Nondisclosure. Each Party agrees that a Party (the "Receiving Party") which receives any Confidential Information of the other Party (the "Disclosing Party") pursuant to this Agreement shall: (a) maintain in confidence such Confidential Information using not less than the efforts that such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of efforts; (b) not disclose such Confidential Information to any Third Party without first obtaining the prior written consent of the Disclosing Party, except for disclosures expressly permitted pursuant to this Article 12; and (c) not use such Confidential Information for any purpose except those permitted under this Agreement, including, in the case of each Party, the exercise of the rights and licenses granted to such Party hereunder. The obligations of confidentiality, non-disclosure, and non-use under this Section 12.1 shall be in full force and effect from the Execution Date until the **[…***…]** of the termination or expiration of this Agreement. The Receiving Party shall return all copies of or destroy the Confidential Information of the Disclosing Party disclosed or transferred to it by the other Party pursuant to this Agreement, within **[…***…]** after the expiration or termination of this Agreement; provided, that, a Party may retain: (i) Confidential Information of the other Party to exercise rights and licenses which expressly survive such termination or expiration pursuant to this Agreement; and (ii) one (1) copy of all other Confidential Information in archives solely for the purpose of establishing the contents thereof.

12.2 Exceptions.

12.2.1 General. Section 12.1 shall not apply with respect to any portion of the Confidential Information of the Disclosing Party to the extent that such Confidential Information:

(a) was known to the Receiving Party or any of its Affiliates, as evidenced by written records, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(b) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

(c) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party, without any breach by the Receiving Party of its obligations hereunder; or

(d) is independently developed by or for the Receiving Party or any of its Affiliates, as evidenced by contemporaneous written records, without reference to or reliance upon the Disclosing Party's Confidential Information.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

12.3 Authorized Disclosure.

12.3.1 Disclosure. Notwithstanding Section 12.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party in the following instances:

(a) subject to Section 12.5, to comply with Applicable Law (including the rules and regulations of the U.S. Securities and Exchange Commission or any national securities exchange in any jurisdiction in the Novartis Territory) (collectively, the "Securities Regulators") or with judicial process (including prosecution or defense of litigation), if, in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance or for such judicial process (including prosecution or defense of litigation);

(b) disclosure to governmental or other regulatory agencies in order to obtain Patents, to obtain or maintain approval to conduct Clinical Trials, or to market the Licensed Products under this Agreement, in each case, in accordance with this Agreement; provided, that, reasonable steps are taken to ensure confidential treatment of such Confidential Information to the extent available;

(c) disclosure to any of its or its Affiliates' officers, employees, directors, consultants, agents, or Affiliates, including: (i) in the case of Novartis, any actual or

potential collaborators, licensees, or Sublicensees; (ii) in the case of either Party, to such Party's permitted subcontractors for purpose of such subcontractors performing obligations of such Party under this Agreement as it deems necessary or advisable in the course of conducting activities in accordance with this Agreement in order to carry out its responsibilities or exercise its rights under this Agreement (including the exercise of the rights and licenses granted to the relevant Party under this Agreement); and (iii) in the case of either Party, to such Party's actual or potential acquirers, investment bankers or other financial advisors, or actual or potential investors, lenders or other financial partners; provided, that, prior to any such disclosure, each such disclosee is bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than the obligations set forth in this Article 12 to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement; provided, that, in each of the above situations in this Section 12.3.1(c), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this Section 12.3.1(c) to treat such Confidential Information as required under this Article 12;

(d) disclosure to its advisors (including attorneys and accountants) in connection with activities under this Agreement; provided, that, prior to any such disclosure, each such disclose is bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than the obligations set forth in this Article 12 (provided, that, in the case of legal advisors and accountants, no written agreement shall be required), to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement; provided, that, in each of the above situations in this Section 12.3.1(d), the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this Section 12.3.1(d) to treat such Confidential Information as required under this Article 12; and

(e) disclosure of any pharmacovigilance information originating from a Party its Affiliates, or the other Party to Regulatory Authorities, investigators, ethical committees and internal review boards, and any other Third Parties that have a need to know such information according to each Party's risk management and adverse event reporting policies and requirements.

12.3.2 Terms of Disclosure. If and whenever any Confidential Information is disclosed in accordance with this Section 12.3, such disclosure shall not cause any such information to cease to be Confidential Information, except to the extent that such disclosure results in a public disclosure of such information other than by breach of this Agreement. Subject to Section 12.6, the Receiving Party will notify the Disclosing Party of the Receiving Party's intent to make any disclosures pursuant to Section 12.3.1(a) sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information, and the Receiving Party will provide reasonable assistance to the Disclosing Party with respect thereto; provided that, in such event, the Receiving Party will use reasonable measures to ensure confidential treatment of such information and will only disclose such Confidential Information of the Disclosing Party as is necessary for the purposes of Section 12.3.1(a).

12.4 Terms of this Agreement. The Parties agree that this Agreement shall be deemed to be Confidential Information of both BeiGene and Novartis, and each Party agrees not to disclose this Agreement or any terms hereof without obtaining the prior written consent of the other Party; provided, that each Party may disclose this Agreement or any terms hereof in accordance with the provisions of Sections 12.3 or 12.5, as applicable.

12.5 Securities Filings; Disclosure under Applicable Law. Each Party acknowledges and agrees that the other Party may submit this Agreement to, or file this Agreement with, the Securities Regulators or to other Persons as may be required by Applicable Law, and if a Party submits this Agreement to, or files this Agreement with, any Securities Regulator or other Person as may be required by Applicable Law, such Party agrees to consult with the other Party with respect to the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party is required by any Securities Regulator or other Person as may be required by Applicable Law to make a disclosure of the terms of this Agreement in a filing or other submission as required by such Securities Regulator or such other Person, and such Party has: (a) provided copies of the disclosure to the other Party reasonably in advance under the circumstances of such filing or other disclosure; (b) promptly notified the other Party in writing of such requirement and any respective timing constraints; and (c) given the other Party reasonable time under the circumstances from the date of provision of a copy of such disclosure to comment upon and request confidential treatment for such disclosure, then such Party shall have the right to make such disclosure at the time and in the manner reasonably determined by its counsel to be required by the Securities Regulator or the other Person. Notwithstanding the foregoing, if a Party seeks to make a disclosure as required by a Securities Regulator or other Person as may be required by Applicable Law as set forth in this Section 12.5 and the other Party provides comments in accordance with this Section 12.5, the Party seeking to make such disclosure or its counsel, as the case may be, shall use good-faith efforts to consider the incorporation of such comments.

12.6 Publicity.

12.6.1 Press Releases; Publications; Public Statements.

(a) Press Release. The Parties agree to issue press releases in the forms attached hereto as Exhibit C-1 (Novartis) and Exhibit C-2 (BeiGene) promptly after execution of this Agreement. In all other cases, subject to this Section 12.6.1, each Party agrees not to, and agrees to cause its Affiliates not to, issue any press release or other public statement disclosing the activities hereunder, or the transactions contemplated hereby, unless such press release or other public statement is approved by the other Party in writing. For any press releases made by a Party, the Party issuing the press release shall provide the other Party with a copy of the press release for review and comment at least **[…***…]** before the proposed release. Notwithstanding the foregoing, each Party will be authorized to make any disclosure, without the approval of the other Party, that is required by Applicable Law (including the U.S. Securities Act of 1933, as amended, and the U.S. Securities Exchange Act of 1934, as amended) or the rules of any Securities Regulator, or by judicial process, subject to and in accordance with Section 12.5.

(b) Additional Restrictions on Public Disclosure. Without limiting any other restrictions on disclosure set forth in this Article 12, with respect to any press release or other public statement proposed to be made by a Party, including a filing contemplated by Section 12.5, if a press release or public statement discloses any information with respect to the development of a Licensed Compound or Licensed Product, including any information related to Clinical Trials with respect thereto, such press release or other public statement may not be issued without the other Party's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, except, for such disclosures by a Party as required by Applicable Law (solely and to the extent such Party's counsel determines such disclosure is required to be disclosed by Applicable Law); provided, that, in such case the disclosing Party will use reasonable efforts to afford the other Party a reasonable period of time (not less than **[…***…])** to review any such disclosure and any comments made by the other Party will be incorporated in good faith. In the event a Party proposes that the disclosing Party use specific wording or language with respect thereto, the disclosing Party will either incorporate such wording or language or provide a reasoned explanation of why it disagrees with the proposed wording or language.

(c) Previously Issued Public Statements. The contents of any press release or other public statement that has been reviewed and approved by a reviewing Party may be re-released by such reviewing Party or publishing Party without a requirement for re-approval.

12.7 Publication of Results.

12.7.1 Publications Committee. Neither Party nor its Affiliates nor Sublicensees may make any publications or presentations with respect to the results of the Development of the Licensed Compounds or Licensed Products without prior consultation with the other Party via a publications committee (the "Publications Committee") to be nominated by the JSC promptly after formation of the JSC. The Publications Committee will discuss and issue a joint publications charter (the "Publications Charter") to set out the ground rules and procedures for review of all such publications, with the objective of protecting each Party's Confidential Information and providing at least **[…***…]** for patent prosecution prior to publication, while facilitating publication activities by the Parties as are customary for companies that develop and commercialize proprietary therapeutic products.

12.7.2 Presentations at Scientific Meetings. Unless otherwise set forth in the Publications Charter, with at least **[…***…]** prior notice to the other Party, each Party may present findings with respect to the Licensed Product at symposia and other meetings of healthcare professionals, and congresses, conferences or meetings organized by a professional society or organization (any such occasion, a "Scientific Meeting"); provided, that, unless otherwise agreed by the Parties, that (a) the Party presenting at any such Scientific Meeting shall have complied with the Publications Charter with respect to such presentation, and, with respect to any such Scientific Meeting at which a Party is presenting, such presenting Party shall inform the other Party of such Scientific Meeting and where invitation is required, invite the other Party to attend such Scientific Meeting; and (b) a Party shall not organize or sponsor any satellite

symposia in a country outside its territory without the other Party's prior written consent, not to be unreasonably withheld.

12.7.3 Publication in Medical Journals. Unless otherwise set forth in the Publications Charter, each Party with at least **[…***…]** prior notice to the other Party may publish in medical or scientific journals ("Medical Journals") articles and papers, including primary reports of clinical data, secondary or pooled analyses, and review papers concerning the Licensed Product which have been prepared by or on behalf of such Party, for publication in the Novartis Territory or in the BeiGene Territory and related to studies conducted after the Effective Date concerning the Licensed Product (each a "Scientific Paper"); provided, that, the Party proposing to publish such Scientific Paper shall have complied with the Publications Charter with respect to such Scientific Paper.

12.7.4 Disclosure of Clinical Data. Unless otherwise set forth in the Publications Charter, each Party may disclose any clinical data generated by such Party concerning the Licensed Product in clinical trial registries; provided, that, the Party proposing to make such disclosure shall have provided the other Party with at least **[…***…]** notice to the other Party prior to such disclosure, a detailed description of the proposed disclosure and shall have, in good faith, considered the comments made by the other Party.

12.7.5 Scientific Papers. Each Party, through the Publications Committee, shall provide to the other, with at least **[…***…]** notice to the other Party prior to submission of any Scientific Paper primarily related to the use of a Licensed Product as a monotherapy (a "Monotherapy Scientific Paper") to a Medical Journal, a draft of such Scientific Paper. Commencing with the receipt of such draft Monotherapy Scientific Paper, the receiving Party shall have **[…***…]** to notify the sending Party of its observations and suggestions with respect thereto; it being understood that, during such **[…***…]** period, no submission for publication thereof shall take place and the Parties shall discuss these suggestions if requested by either Party. The Party proposing to publish such Monotherapy Scientific Paper shall, in good faith, consider the comments made by the other Party, and will not publish if disclosure would be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not publish or present any Confidential Information of the other Party (whether in a Monotherapy Scientific Paper or otherwise) without such other Party's prior written consent, not to be unreasonably withheld or delayed. The sending Party shall provide to the receiving Party copies of any final Scientific Paper (including any Scientific Paper that is not a Monotherapy Scientific Paper) accepted by a Medical Journal, not less than **[…***…]** or as soon as practicable prior to the planned publication thereof (upon availability and distribution of such information).

12.7.6 Abstracts and Posters. Each Party shall provide to the other, at least **[…***…]** prior to submission or presentation, as the case may be, copies of (a) all abstracts that will be submitted to any Scientific Meeting in the Novartis Territory or in the BeiGene Territory, as the case may be, and (b) all posters and other materials (such as slides) that will be presented at such Scientific Meeting, in each case, related to the use of a Licensed Product as a monotherapy, which have been prepared by or on behalf of one of the Parties, for submission or presentation outside or in the Territory. Commencing with the receipt of any such abstract or poster or oral

presentation materials the receiving Party shall have **[…***…]** to inform the sending Party of its observations and suggestions with respect thereto; it being understood that, during such **[…***…]** period, no submission or presentation thereof shall take place and the Parties shall discuss these suggestions, if requested by either Party. The Party proposing to publish such an abstract or make such a presentation shall, in good faith, consider the comments made by the other Party, particularly if disclosure may be prejudicial to the other Party's opportunity to obtain any patent rights. A Party will not submit in any abstract or present in any poster, other written materials or oral presentation any Confidential Information of the other Party without such other Party's prior written consent. The sending Party shall provide to the receiving Party copies of all final abstracts as submitted and all final posters to be presented no later than **[…***…]** after submission or presentation.

12.8 Use of Names. Except as otherwise expressly set forth herein, neither Party (or any of its respective Affiliates) shall use the name, trademark, trade name, or logo of the other Party or any of its Affiliates, or its or their respective employees, in any publicity, promotion, news release, or other public disclosure relating to this Agreement or its subject matter, without first obtaining the prior written consent of the other Party; provided, that, such consent shall not be required to the extent use thereof may be required by Applicable Law, including the rules of any securities exchange or market on which a Party's or its Affiliate's securities are listed or traded.

12.9 Relationship to Existing Confidentiality Agreement. This Agreement supersedes the Prior CDA; provided, that, all "Confidential Information" disclosed by the "Disclosing Party" thereunder will be deemed Confidential Information of the Disclosing Party hereunder and will be subject to the terms and conditions of this Agreement and the "Receiving Party" will be bound by and obligated to comply with such terms and conditions as if they were the Receiving Party hereunder. The foregoing will not be interpreted as a waiver of any remedies available to the "Disclosing Party" as a result of any breach, prior to the Execution Date, by the "Receiving Party", of its obligations pursuant to the Prior CDA.

ARTICLE 13
REPRESENTATIONS AND WARRANTIES; COVENANTS

13.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party, as of the Execution Date and the Effective Date, that:

(a) such Party is duly organized, validly existing, and in good standing under the Applicable Law of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) such Party has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation, enforceable against it in

accordance with its terms, except to the extent that enforcement of the rights and remedies created hereby is subject to: (i) bankruptcy, insolvency, reorganization, moratorium, and other similar laws of general application affecting the rights and remedies of creditors; or (ii) laws governing specific performance, injunctive relief, and other equitable remedies;

(d) the execution, delivery, and performance of this Agreement by such Party does not breach or conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which such Party (or any of its Affiliates) is a party or by which such Party (or any of its Affiliates) is bound, nor violate any Applicable Law of any Governmental Authority having jurisdiction over such Party (or any of its Affiliates);

(e) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency, or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or shall be necessary for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except: (i) as may be required to conduct Clinical Trials or to seek or obtain Regulatory Approvals or applicable Regulatory Materials; or (ii) as set forth in Article 11; and

(f) it has obtained all necessary authorizations, consents, and approvals of any Third Party that is required to be obtained by it for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement, except: (i) as may be required to conduct Clinical Trials or to seek or obtain Regulatory Approvals or applicable Regulatory Materials; or (ii) as set forth in Article 11.

13.2 Representations and Warranties of BeiGene. BeiGene hereby represents and warrants to Novartis, as of the Execution Date and the Effective Date, that:

(a) Schedule 1.18 sets forth a complete and accurate list of all BeiGene Patents.

(b) BeiGene has Prosecuted and Maintained each of the BeiGene Patents set forth on Schedule 1.18 in good faith and complied with all duties of disclosure with respect thereto, and, to BeiGene's Knowledge, BeiGene has submitted all material prior art with respect to the BeiGene Patents to the appropriate patent authority in each jurisdiction;

(c) All BeiGene Patents (i) are subsisting and, to BeiGene's Knowledge, are not invalid or unenforceable, in whole or in part, (ii) are being diligently prosecuted in the respective patent offices in accordance with Applicable Law, and (iii) have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment. No claim has been issued or served, and BeiGene has not received any written threat of a claim or litigation made by any Person, against BeiGene or any of its Affiliates that alleges that any BeiGene Patent is invalid or unenforceable.

(d) As of the Execution Date and the Effective Date, BeiGene has the full right and authority to grant all of the rights and licenses granted to Novartis (or purported to

be granted to Novartis) hereunder, and neither BeiGene nor its Affiliates have granted any right or license to any Third Party relating to any of the BeiGene IP that would conflict with or limit the scope of any of the rights or licenses granted to Novartis hereunder.

(e) Except as set forth on Schedule 1.18 BeiGene or its Affiliate is the sole and exclusive owner of BeiGene Patents. Neither BeiGene nor any of its Affiliates has granted any mortgage, pledge, claim, security interest, lien, or other charge of any kind on the BeiGene IP, and the BeiGene IP is free and clear of any mortgage, pledge, claim, security interest, lien, or charge of any kind.

(f) (i) BeiGene and its Affiliates have obtained from all individuals who participated in any respect in the invention or authorship of any BeiGene IP effective assignments of all ownership rights of such individuals in such BeiGene IP, either pursuant to written agreement or by operation of law and (ii) no Person who claims to be an inventor of an invention claimed in a BeiGene Patent is not identified as an inventor of such invention in the filed patent documents for such BeiGene Patent.

(g) Neither BeiGene nor its Affiliates have received any written notice of any claim that any Patent or Know-How (including any trade secret right) owned or controlled by a Third Party would be infringed or misappropriated by the Development, Manufacture, or Commercialization of, or the conduct of Medical Affairs Activities with respect to, the Licensed Products.

(h) Except (i) with respect to published Patents or published Patent applications, as disclosed orally by BeiGene's patent counsel to Novartis's patent counsel, or (ii) with respect to published Patents or published Patent applications, as expressly identified in BeiGene's public filings under United States securities laws, to BeiGene's Knowledge, the Development and Manufacture of the Licensed Compound, as conducted by or on behalf of BeiGene or its Affiliates, has not violated, infringed, or misappropriated any intellectual property or proprietary right of any Third Party.

(i) There are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, or legal, administrative or other proceedings, or governmental investigations pending or, to BeiGene's Knowledge, threatened against BeiGene or its Affiliates which could reasonably be expected to adversely affect or restrict the ability of BeiGene to consummate or perform the transactions contemplated under this Agreement, or which would affect the BeiGene IP or BeiGene's Control thereof, the Licensed Compound or the Licensed Product.

(j) Neither BeiGene nor any of its Affiliates has made a claim against a Third Party alleging that a Third Party is violating or has violated, is infringing or has infringed, or is misappropriating or has misappropriated any BeiGene IP, and, to the Knowledge of BeiGene, no BeiGene IP is being violated, infringed, or misappropriated by any Third Party.

(k) Neither BeiGene nor any of its Affiliates has employed, or otherwise used in any capacity, the services of any Person suspended, proposed for debarment, or

debarred under United States law, including under 21 U.S.C. § 335a, or any foreign equivalent thereof, with respect to the Licensed Product. All Development and Manufacturing activities (including non-clinical studies and Clinical Trials) related to the Licensed Product conducted by or on behalf of BeiGene or its Affiliates have been conducted in accordance with all Applicable Law (including, to the extent applicable, GCP, GLP, and GMP).

(l) BeiGene has disclosed or made available to Novartis: (i) all material correspondence sent to or received from any Regulatory Authority; and (ii) any material information and data in the possession or control of BeiGene or its Affiliates, in each case, related to the Licensed Compound.

(m) No funding, facilities, or personnel of any Governmental Authority or any public or private educational or research institutions were used to develop or create any BeiGene IP, and neither BeiGene nor any of its Affiliates has entered into a government funding relationship that would result in rights to the Licensed Product residing in the U.S. Government, the National Institutes of Health, the National Institute for Drug Abuse, or other agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in Public Law 96-517 (35 U.S.C. §§ 200-204), or any similar obligations under the laws of any other country in the Novartis Territory.

(n) **[…***…]**, there exists no Know-How or Materials owned, controlled or possessed by the BeiGene Manufacturer or any other Third Party that BeiGene does not Control and that is necessary, as of the Execution Date, or that will be necessary, as of the Effective Date, for BeiGene's or Novartis' performance of its obligations pursuant to Sections 7.3(a) or 7.4 hereof or pursuant to the terms of the Supply Agreement that are set forth in Schedule 7.3(a) hereto.

(o) All Development and Manufacturing operations conducted by or for the benefit of BeiGene and its Affiliates, including, to BeiGene's Knowledge, by the BeiGene Manufacturer, with respect to the Licensed Compound and the Licensed Product, have been and are being conducted in all material respects in compliance with all Applicable Laws. To BeiGene's Knowledge, the BeiGene Manufacturer has complied with Applicable Law in connection with its Manufacture of the Licensed Compound and the Licensed Product pursuant to the BeiGene Supply Agreements. To BeiGene's Knowledge, neither the BeiGene Manufacturer, nor any other contract manufacturer of BeiGene or its Affiliate with respect to the Licensed Compound or Licensed Product has received any written communication from any governmental authority that alleges that BeiGene, its Affiliates or the BeiGene Manufacturer is, with respect to the Licensed Compound or Licensed Product, in violation of any Applicable Law in with connection with its Manufacture of the Licensed Compound and the Licensed Product pursuant to the BeiGene Supply Agreements.

13.3 Representations and Warranties of Novartis. Novartis hereby represents and warrants to BeiGene, as of the Execution Date and the Effective Date, that it has received no notice of any claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, or legal, administrative, or other proceedings or governmental investigations pending or, to the knowledge of Novartis, none of the foregoing is threatened against Novartis which would

reasonably be expected to adversely affect or restrict the ability of Novartis to consummate or perform the transactions contemplated under this Agreement.

13.4 Covenants.

13.4.1 Mutual Covenants. Each Party hereby covenants to the other Party that: (a) all employees of such Party or its Affiliates or Third Party subcontractors working under this Agreement will be under appropriate confidentiality provisions at least as protective as those contained in this Agreement and, to the extent permitted under Applicable Law, the obligation to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof; (b) to its knowledge, such Party will not (i) employ or use, nor hire or use any contractor or consultant that employs or uses, any individual or entity, including a clinical investigator, institution or institutional review board, debarred or disqualified by the FDA (or subject to a similar sanction by any Regulatory Authority outside the United States) or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States); (c) such Party shall pay any inventor of a Joint Invention that is directly or indirectly employed or engaged as a consultant by such Party or its Affiliates or Sublicensees to perform activities under this Agreement any and all payments owing by such Party or any of its Affiliates to any such inventor that is required in connection with the creation or exploitation of or transfer of rights to such Joint Invention; and (d) such Party and its Affiliates shall perform its activities pursuant to this Agreement in compliance (and shall ensure compliance by any of its subcontractors) in all material respects with all Applicable Law, including GCP, GLP and cGMP as applicable and with respect to the conduct of research, Development, Manufacturing and Commercialization activities or the conduct of Medical Affairs Activities contemplated hereunder.

13.4.2 Additional Covenants of BeiGene.

(a) BeiGene shall not, and shall cause its Affiliates not to: (i) grant any license or other interest to any Third Party under the BeiGene Patents or BeiGene Know-How that is inconsistent with the licenses granted to Novartis hereunder; or (ii) incur or permit to exist any lien, security interest or other encumbrance, other than licenses entered into in the ordinary course of business, on the BeiGene Patents or BeiGene Know-How unless, in each case, such lien, security interest or other encumbrance is subject to the terms of this Agreement (including Novartis' licenses hereunder).

(b) BeiGene shall, and shall cause its Affiliates to, use reasonable precautions to preserve the confidentiality of the BeiGene Know-How.

(c) BeiGene shall make any and all payments owing by BeiGene or any of its Affiliates to any inventor of any BeiGene Know-How or BeiGene Patents (other than Joint Inventions and Joint Patents) owned by BeiGene or such Affiliate that is required in connection with the creation or exploitation of or transfer of rights to such BeiGene Know-How or BeiGene Patents;

(d) BeiGene shall provide Novartis with a list from time to time that reflects any Patents that become BeiGene Patents during the Term.

(e) With respect to any BeiGene Upstream License Agreement, BeiGene shall, and shall cause its Affiliates to: (i) not materially breach such BeiGene Upstream License Agreement in a manner that would permit the counterparty thereto to terminate such BeiGene Upstream License Agreement or otherwise diminish the scope or exclusivity of the sublicenses granted to Novartis under applicable BeiGene Know-How or BeiGene Patents; and (ii) not terminate such BeiGene Upstream License Agreement in a manner that would terminate rights that are sublicensed to Novartis or otherwise diminish the scope or exclusivity of the sublicenses granted to Novartis under the applicable BeiGene Know-How or BeiGene Patents. In the event that BeiGene or any of its Affiliates receives notice of an alleged breach by BeiGene or any of its Affiliates under any such BeiGene Upstream License Agreement, where termination of such BeiGene Upstream License Agreement or any diminishment of the scope or exclusivity of the sublicenses granted to Novartis under the applicable Licensed Technology is being or could be sought by the counterparty, then BeiGene shall promptly, but in no event less than **[…***…]** thereafter, provide written notice thereof to Novartis and discuss with Novartis in good faith any proposals Novartis may have regarding ways to cure or alleviate such breach. BeiGene shall not, and shall cause its Affiliates not to, amend any BeiGene Upstream License Agreement in any manner that adversely affects Novartis' rights pursuant to this Agreement without first obtaining Novartis' prior written consent.

(f) To the extent requested by Novartis, BeiGene will use reasonable best efforts to obtain from the licensor under any BeiGene Upstream License Agreement a written agreement providing for the right to grant to Novartis a sublicense and for any BeiGene Upstream License Agreement that includes the right to grant sublicenses, for Novartis to grant further sublicenses (through multiple tiers) under the licenses granted pursuant to such BeiGene Upstream License Agreement to the extent such right is not expressly provided for in such BeiGene Upstream License Agreement.

(g) During the Term of this Agreement, **[…***…]**.

13.4.3 Notice. Immediately prior to the Effective Date, each Party shall notify the other Party in writing if it or any of its Affiliates becomes aware that the representations and warranties made by it pursuant to this Article 13 as of the Execution Date are not true and correct in any material respects on and as of the Effective Date as though made on and as of the Effective Date; provided, that, solely with respect to representations and warranties that are not expressly stated to be made as of the Effective Date, that such notification shall not imply that any such representation or warranty is made as of the Effective Date.

13.4.4 Additional Covenant of Novartis.

(a) Novartis shall and shall cause its Affiliates not to sue for infringement of the Patent Family: (i) BeiGene, its Affiliates, and its or their Third Party subcontractors and service providers, and (ii) BeiGene's and its Affiliates' collaboration partners and licensees, to which BeiGene or its Affiliate has granted rights to research, develop,

manufacture or commercialize a product Controlled by BeiGene (other than a Licensed Product), including, for example, **[…***…]**.

(b) Upon request of BeiGene, Novartis will provide to BeiGene, a letter confirming the covenant not to sue under Section 13.4.4(a).

13.5 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NON-INFRINGEMENT OF ANY THIRD PARTY PATENT OR OTHER INTELLECTUAL PROPERTY RIGHT. WITHOUT LIMITING THE FOREGOING, THE PARTIES AGREE THAT THE MILESTONE EVENTS, ROYALTY TIERS AND NET SALES LEVELS SET FORTH IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS, AND ROYALTY OBLIGATIONS IF SUCH MILESTONE EVENTS OR NET SALES LEVELS ARE ACHIEVED. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP, MANUFACTURE, OR COMMERCIALIZE ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

ARTICLE 14
INDEMNIFICATION; INSURANCE

14.1 Indemnification by Novartis. Novartis shall indemnify, defend, and hold harmless BeiGene, its Affiliates, and its and their respective directors, officers, employees, agents, successors, and assigns (collectively, the "BeiGene Indemnitees") from and against any and all Damages to the extent arising out of or relating to, directly or indirectly, any Third Party Claim based upon:

(a) the Development, Manufacture, or Commercialization of, and the conduct of Medical Affairs Activities with respect to, the Licensed Compound and/or the Licensed Product in the Field in the Novartis Territory by Novartis, its Affiliates, or its Sublicensees;

(b) the conduct by Novartis of any Permitted Combination Studies;

(c) the gross negligence or willful misconduct of Novartis or its Affiliates or Sublicensees or its or their respective directors, officers, employees, or agents, in connection with Novartis's performance of its obligations under this Agreement; or

(d) any material breach by Novartis of any of its representations, warranties, covenants, agreements, or obligations under this Agreement;

provided, that, in each case ((a)-(c)), such indemnity shall not apply to the extent BeiGene has an indemnification obligation pursuant to Sections 14.2(a), 14.2(b), or 14.2(c) for such Damages.

14.2 Indemnification by BeiGene. BeiGene shall indemnify and hold harmless Novartis, its Affiliates, and its and their respective directors, officers, employees, agents, successors, and assigns (collectively, the "Novartis Indemnitees"), from and against any and all Damages to the extent arising out of or relating to, directly or indirectly, any Third Party Claim based upon:

(a) the conduct by or on behalf of BeiGene of the BeiGene Ongoing Clinical Trials any other Clinical Trial included as a BeiGene responsibility as part of the Initial Global Development Plan;

(b) the Development, Manufacture, or Commercialization of, and the conduct of Medical Affairs Activities with respect to, the Licensed Compound and/or the Licensed Product in the Field in the BeiGene Territory by BeiGene, its Affiliates, or its sublicensees

(c) the conduct by BeiGene of any Permitted Combination Studies;

(d) the conduct by BeiGene of any Permitted Commercialization Activities in the Novartis Territory;

(e) the gross negligence or willful misconduct of BeiGene or its Affiliates or its or their respective directors, officers, employees, or agents, in connection with BeiGene's performance of its obligations under this Agreement; or

(f) any material breach by BeiGene of any of its representations, warranties, covenants, agreements, or obligations under this Agreement;

provided, that, in each case ((a)-(e)), such indemnity shall not apply to the extent Novartis has an indemnification obligation pursuant to Sections 14.1(a), 14.1(b), or 14.1(c) for such Damages.

14.3 Procedure.

14.3.1 If a Party is seeking indemnification under Section 14.1 or Section 14.2, as applicable (the "Indemnitee"), it shall inform the other Party (the "Indemnitor") of the claim giving rise to the obligation to indemnify pursuant to Section 14.1 or Section 14.2, as applicable, as soon as reasonably practicable after receiving notice of the claim (an "Indemnification Claim Notice"); provided, that, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnitee's rights to indemnification under Section 14.1 or Section 14.2, as applicable, except to the extent that such delay or failure materially prejudices the Indemnitor's ability to defend against the relevant claims.

14.3.2 The Indemnitor shall have the right, upon written notice given to the Indemnitee within **[…***…]** after receipt of the Indemnification Claim Notice, to assume the defense of any such claim for which the Indemnitee is seeking indemnification pursuant to Section 14.1 or Section 14.2, as applicable. The Indemnitee shall cooperate with the Indemnitor and the Indemnitor's insurer as the Indemnitor may reasonably request, and at the Indemnitor's cost and expense. The Indemnitee shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnitor.

14.3.3 The Indemnitor shall not settle any claim without first obtaining the prior written consent of the Indemnitee, not to be unreasonably withheld, conditioned, or delayed; provided, that, the Indemnitor shall not be required to obtain such consent if the settlement: (a) involves only the payment of money and shall not result in the Indemnitee (or other BeiGene Indemnitees or Novartis Indemnitees, as applicable) becoming subject to injunctive or other similar type of relief; (b) does not require an admission by the Indemnitee (or other BeiGene Indemnitees or Novartis Indemnitees, as applicable); and (c) does not adversely affect the rights or licenses granted to the Indemnitee (or its Affiliate) under this Agreement. The Indemnitee shall not settle or compromise any such claim without first obtaining the prior written consent of the Indemnitor.

14.3.4 If the Parties cannot agree as to the application of Section 14.1 or Section 14.2, as applicable, to any claim, pending the resolution of the dispute pursuant to Section 16.7, 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 14.1 or Section 14.2, as applicable, upon resolution of the underlying claim. In each case, the Indemnitee shall reasonably cooperate with the Indemnitor and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 12.

14.4 Insurance. During the Term and for a period of **[…***…]** thereafter, each Party shall maintain, at its cost, a program of insurance (or self-insurance) against liability and other risks associated with its activities and obligations under this Agreement (including with respect to its Clinical Trials), and its indemnification obligations hereunder, in such amounts, subject to such deductibles and on such terms as are customary for such Party for the activities to be conducted by it under this Agreement. Such insurance shall not be construed to create a limit on either Party's liability with respect to its indemnification obligations under this Article 14, or otherwise.

14.5 LIMITATION OF LIABILITY. NEITHER PARTY NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES UNDER OR IN CONNECTION WITH THIS AGREEMENT FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES), WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY, CONTRIBUTION, OR OTHERWISE, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY

REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 14.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT: (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 14.1 OR 14.2, AS APPLICABLE, IN CONNECTION WITH ANY THIRD PARTY CLAIMS; (B) THE LIABILITY OF EITHER PARTY FOR BREACH OF ITS EXCLUSIVITY OBLIGATIONS UNDER SECTION 9.6; OR (C) DAMAGES AVAILABLE FOR A PARTY'S GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD OR BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER Article 12.

ARTICLE 15
TERM AND TERMINATION

15.1 Term; Expiration.

15.1.1 Term. Except for the terms and conditions of Article 11, Article 12, and Article 13 and all other provisions of this Agreement that contemplate effectiveness or performance prior to the Effective Date (all of which shall become effective on the Execution Date), this Agreement shall become effective on the date on which the applicable waiting period under the HSR Act with respect to the transactions contemplated by this Agreement expires or is terminated (the "Effective Date"); provided, that, this Agreement shall terminate immediately, upon written notice by a Party to the other Party, if the Effective Date has not occurred on or prior to the first anniversary of the Execution Date. Unless earlier terminated in accordance with this Article 15, this Agreement shall remain in effect until it expires as follows (the "Term"):

(a) on a country-by-country basis, this Agreement shall expire on the date of the expiration of the Royalty Term with respect to the Licensed Product in such country; and

(b) this Agreement shall expire in its entirety upon the expiration of all applicable Royalty Terms under this Agreement with respect to the Licensed Product in all countries in the Novartis Territory.

15.1.2 Effect of Expiration. Upon the expiration of the Term pursuant to Section 15.1.1, the following terms shall apply:

(a) Licenses after Licensed Product Expiration. Upon the expiration of the Term with respect to the Licensed Product in a given country pursuant to Section 15.1.1(a), the licenses set forth in Section 9.1 with respect to the Licensed Product in such country shall become fully paid-up, perpetual, irrevocable and royalty-free.

(b) Licenses after Expiration of Agreement. Upon the expiration of the Term with respect to this Agreement in its entirety pursuant to Section 15.1.1(b), the licenses set forth in Section 9.1 with respect to all Licensed Products in all countries in the Novartis Territory shall become fully paid-up, perpetual, irrevocable, and royalty-free.

15.2 Termination for Material Breach.

15.2.1 Material Breach. This Agreement may be terminated in its entirety by a Party for the material breach by the other Party of this Agreement; provided, that, the breaching Party has not cured such breach within **[…***…]** (or **[…***…]** for failure to make payment) after the date of written notice to the breaching Party of such breach (the "Cure Period"), which notice shall describe such breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement. Notwithstanding the foregoing, if such material breach, by its nature cannot be cured within the foregoing cure period or is incurable, but the consequences of such breach can be reasonably alleviated but not within the foregoing Cure Period, then such cure period shall be extended if, prior to the end of the initial **[…***…]** Cure Period, the non-terminating Party provides a reasonable written plan for curing or reasonably alleviating the consequences of such material breach and thereafter uses Commercially Reasonable Efforts to cure or alleviate such material breach in accordance with such written plan. Notwithstanding the foregoing, in no event shall such Cure Period extend for more than **[…***…]** after the breaching Party provides such written plan to the other Party, subject to Section 15.2.2.

15.2.2 Disagreement as to Material Breach. Notwithstanding Section 15.2.1, if the Parties in good faith disagree as to whether there has been a material breach of this Agreement, then: (a) the Party that disputes whether there has been a material breach may contest the allegation by referring such matter, within **[…***…]** following its receipt of notice of alleged material breach, for resolution in accordance with Section 16.7.2; (b) the relevant Cure Period with respect to such alleged material breach shall be tolled from the date on which the Party that disputes whether there has been a material breach notifies the other Party of such dispute and through the resolution of such dispute in accordance with the applicable provisions of this Agreement; and (c) during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

15.3 Termination at Will. Novartis may terminate this Agreement at will, in its sole discretion, in its entirety at any time during the Term upon one hundred twenty (120) days' prior written notice to BeiGene, to the extent the notice of termination is delivered prior to the date of First Commercial Sale of the Licensed Product and upon one hundred eighty (180) days' prior written notice to BeiGene, to the extent the notice of termination is delivered on and after the date of First Commercial Sale of the Licensed Product.

15.4 Termination for Challenge. Except to the extent the following is unenforceable under the Applicable Law of a particular jurisdiction where a patent application within the BeiGene Patents is pending or a patent within the BeiGene Patents issued, BeiGene may terminate this Agreement in its entirety upon written notice if Novartis or any of its Affiliates, Sublicensees or distributors Challenges any BeiGene Patents or Assists a Third Party in initiating a Challenge of any BeiGene Patents. For the sake of clarity, compliance with orders from a Governmental Authority shall not be deemed a Challenge of, or Assisting a Third Party to Challenge, any BeiGene Patent.

15.5 Termination under BeiGene Election Notice. BeiGene may terminate this Agreement in its entirety immediately upon providing a written notice to Novartis if (i) Novartis elects pursuant to Section 9.6.2(c) to Divest the Novartis Anti-PD-1 but has not completed such Divestiture within the **[…***…]** period specified in Section 9.6.2(c) or (ii) pursuant to Section 9.6.2(d), at any time following BeiGene's receipt of a Novartis Anti-PD-1 Election Notice stating that it does not elect to Divest the Novartis Anti-PD-1 or following the last date on which Novartis was entitled to deliver a Novartis Anti-PD-1 Election Notice pursuant to Section 9.6.2(c) if it fails to deliver such Novartis Anti-PD-1 Election Notice prior to such date.

15.6 Termination for Bankruptcy.

15.6.1 If either Party makes a general assignment for the benefit of, or an arrangement or composition generally with, its creditors, appoints or suffers appointment of an examiner or of a receiver or trustee over all or substantially all of its property, passes a resolution for its winding up, or files a petition under any bankruptcy or insolvency act or law or has any such petition filed against it which is not dismissed, discharged, bonded, or stayed within **[…***…]** after the filing thereof (each, an "Insolvency Event"), the other Party may terminate this Agreement in its entirety, effective immediately upon written notice to such Party.

15.6.2 If this Agreement is terminated due to the rejection of this Agreement by or on behalf of BeiGene due to an Insolvency Event, all licenses and rights to licenses granted under or pursuant to this Agreement by BeiGene to Novartis are and shall otherwise be deemed to be licenses of rights to "intellectual property." The Parties agree that Novartis, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under any applicable insolvency statute, and that upon commencement of an Insolvency Event by or against BeiGene, Novartis shall be entitled to a complete duplicate of or complete access to (as Novartis deems appropriate) any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Novartis: (a) upon any such commencement of a bankruptcy proceeding (or other Insolvency Event) upon written request therefore by Novartis, unless BeiGene elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered pursuant to (a) above, upon the rejection of this Agreement by or on behalf of BeiGene, then upon written request therefore by Novartis. The provisions of this Section 15.6.2 shall be: (i) without prejudice to any rights Novartis may have arising under any applicable insolvency statute or other Applicable Law; and (ii) effective only to the extent permitted by Applicable Law.

15.7 Effects of Termination.

15.7.1 Termination by Novartis for Convenience or by BeiGene for Material Breach or Bankruptcy, or by BeiGene for Challenge or BeiGene Election. Upon termination of this Agreement: (a) by Novartis, in accordance with Section 15.3 or (b) by BeiGene, in accordance with Section 15.2, Section 15.5 or Section 15.6:

(a) all licenses granted by BeiGene to Novartis shall terminate and Novartis shall not have any rights to use or exercise any rights under the BeiGene IP;

(b) Novartis shall be released from its Development, Manufacturing, and Commercialization obligations and/or its obligations to conduct Medical Affairs Activities under this Agreement, including with respect to Section 3.5;

(c) upon BeiGene's request, which will be provided within **[…***…]** of the date of issuance of the notice of termination, the Parties will agree and implement a plan for the orderly transition of Development and Commercialization activities and Medical Affairs Activities in the Novartis Territory from Novartis to BeiGene in a manner consistent with Applicable Law and standards of ethical conduct of human Clinical Trials (each a "Transition Plan") pursuant to which Novartis shall:

(i) promptly transfer and assign to BeiGene all of Novartis's and its Affiliates' rights, title, and interests in and to trademarks (but not any Novartis house marks) owned by Novartis and used solely in connection with the Commercialization of the Licensed Product in the Novartis Territory;

(ii) subject to any limitations pursuant to Applicable Law or Novartis' or its Affiliates' obligations to Third Parties, as soon as reasonably practicable, transfer to BeiGene all Clinical Data Controlled by Novartis or its Affiliates to the extent related to the Licensed Product;

(iii) subject to any limitations pursuant to Applicable Law or Novartis' or its Affiliates' obligations to Third Parties, as soon as reasonably practicable (A) transfer and assign (to the extent permitted) to BeiGene all Regulatory Materials and other documented technical and other information or materials owned and controlled by Novartis or its Affiliates, in each case, to the extent solely related to the Licensed Product and necessary for Developing, Manufacturing, or Commercializing the Licensed Product in the Field in the Novartis Territory; provided, that Novartis may retain a copy of such items for its records; and (B) notify the applicable Regulatory Authorities in the Novartis Territory and take any other actions reasonably necessary to effect the transfer in subsection (A) above, including upon BeiGene's request, providing a right of reference to any Regulatory Filings, or Regulatory Approvals Controlled by Novartis on the effective date of termination, solely to the extent necessary for BeiGene to Develop and Commercialize the Licensed Products in the Novartis Territory;

(iv) unless expressly prohibited by any Regulatory Authority or Applicable Law, as soon as reasonably practicable, at BeiGene's cost and expense (A) transfer sponsorship and control to BeiGene of all Clinical Trials of Licensed Product being conducted by Novartis or its Affiliate in the Novartis Territory as of the effective date of termination and (B) continue to conduct such Clinical Trials after the effective date of termination, at BeiGene's sole cost and expense, to enable such transfer to be completed without interruption of any such Clinical Trial for up to **[…***…]** from the effective date of termination, with the cost of the conduct of such Clinical Trials until the completion of transfer being reimbursed by BeiGene;

(v) use Commercially Reasonable Efforts to assign or amend, as appropriate, any agreements with Third Parties which Novartis has in place solely relating to

the conduct of Clinical Trials for Licensed Products or the Manufacture of Licensed Products (including agreements with contract manufacturing organizations, contract research organizations, clinical sites and investigators), or, to the extent any such Third Party agreement is not assignable to BeiGene, to cooperate with BeiGene, at BeiGene's request and expense, to arrange to continue to provide such services for a reasonable time after termination and to facilitate BeiGene's entry into a replacement agreement with such Third Party for such services;

(vi) if Novartis is Manufacturing or is having Manufactured Licensed Products and supplying BeiGene with such Licensed Product as of the effective date of termination, continue to Manufacture or have Manufactured and supply BeiGene with its requirements of such Licensed Product at the supply price contemplated by Section 7.5 and in accordance with the terms of the applicable supply agreement between BeiGene and Novartis or its Affiliate; and

(vii) if Novartis is Manufacturing or is having Manufactured Licensed Products or any intermediate of such Licensed Products as of the date of termination, Novartis has Manufactured, is Manufacturing or is having Manufactured Licensed Products or any intermediate of such Licensed Products as of the date of termination, Novartis shall use Commercially Reasonable Efforts to (A) transfer copies of any documents and materials Controlled by Novartis and embodying Novartis Know-How and/or Novartis Patent Rights that are at the time of such termination being used by Novartis or its Third Party manufacturers to Manufacture any Licensed Products, including but not limited to all suppliers, analytical methods, quality standards, specifications, commercial active pharmaceutical ingredient formula, process chemistry, Manufacturing process descriptions, process flows, cycle times, process parameters, process equipment type and sizes, cleaning methods, commercial active pharmaceutical ingredient samples, master safety data sheets, and stability reports (the "Novartis Manufacturing Know-How") to enable the Manufacture of any Licensed Products by BeiGene, its Affiliates or any Third Party manufacturer of BeiGene, in each case to the extent that such Novartis Manufacturing Know-How was not transferred to Novartis or such Third Party(ies) by BeiGene or its Affiliates or their respective Third Party manufacturers or is otherwise already known to BeiGene, its Affiliate or their respective Third Party manufacturers; and (B) promptly make available to BeiGene or any such Third Party manufacturer a reasonable number of appropriately trained personnel to provide, on a mutually convenient timetable, technical assistance in the transfer of Novartis Manufacturing Know-How to BeiGene.

(d) The provisions of Article 10 (other than Section 10.1) shall be terminated with respect to the Licensed Product and BeiGene shall have the right to assume all Prosecution and Maintenance and enforcement activities under Article 10 with respect to BeiGene Patent Rights as to which Novartis has assumed the right and authority to Prosecute and Maintain or enforce and Novartis will cooperate with BeiGene and provide BeiGene with reasonable assistance in connection with the transfer of such Prosecution and Maintenance and enforcement activities with respect to such BeiGene Patent Rights.

(e) Novartis shall grant, and hereby does grant, to BeiGene, effective as of the effective date of such termination, a non-exclusive, transferable, fully paid-up, royalty-

free, perpetual sublicenseable license in the Field and in the Novartis Territory to Novartis IP that is necessary or reasonably useful to Develop and Commercialize the Licensed Product and an exclusive option to negotiate in good faith an exclusive, royalty-bearing, sublicenseable license under the Novartis IP that is necessary or reasonably useful to Develop and Commercialize Licensed Products in the Field in the Novartis Territory.

(f) Any and all sublicense agreements entered into by Novartis or any of its Affiliates with a Sublicensee pursuant to this Agreement shall survive such termination of this Agreement, except to the extent that: (i) any such Sublicensee is in material breach of this Agreement or such sublicense; or (ii) BeiGene elects to grant such Sublicensee a direct license of the sublicensed rights on the same terms applicable to Novartis under this Agreement. Novartis shall, upon the written request of BeiGene, assign any such sublicense (to the extent not terminated pursuant to the preceding sentence) to BeiGene or its Affiliates and, upon such assignment, BeiGene or its Affiliates, as applicable, shall assume such sublicense.

(g) Solely to the extent that this Agreement is terminated by BeiGene in accordance with Section 15.5, Novartis will make a one-time payment to BeiGene in the aggregate amount of **[…***…]** (the "Termination Payment") within **[…***…]** of the date of delivery by BeiGene of the notice of termination. The Termination Payment shall be paid by Novartis by transfer of immediately available funds in accordance with the wire transfer instructions provided in writing by BeiGene to Novartis prior to the effective date of termination.

15.7.2 Termination by Novartis for Material Breach or Bankruptcy. Upon termination of this Agreement by Novartis in accordance with Section 15.2 or Section 15.6, subject to Section 15.8:

(a) Novartis shall be released from its Development, Manufacturing, and Commercialization obligations and its obligations to conduct Medical Affairs Activities under this Agreement with respect to the Licensed Product, including with respect to Section 3.5;

(b) the licenses set forth in Section 9.1 with respect to all Licensed Products in all countries in the Novartis Territory shall remain in effect; subject to the terms of this Agreement, as adjusted by the provisions of this Section 15.7.2 and subject to Section 15.8;

(c) the provisions of ARTICLE 10 shall remain in effect; provided, however, BeiGene's rights in respect of Joint Patents in the Novartis Territory shall terminate and Novartis shall have the right to assume all Prosecution and Maintenance and enforcement activities under ARTICLE 10 with respect to Joint Patents as to which BeiGene has assumed the right and authority to Prosecute and Maintain or enforce;

(d) to the extent not completed prior thereto, BeiGene shall remain obligated to perform its obligations pursuant to Section 4.2.2 and Article 7;

(e) **[…***…]**; and

(f) in Novartis's sole discretion, upon Novartis' notice to BeiGene, the licensed granted by Novartis to BeiGene pursuant to Article 9 hereof shall terminate.

15.7.3 Milestone Payments. No Milestone Payments shall be owing by Novartis based on any Milestone Event occurring following the expiration of the Term in respect of the Licensed Product in respect of which such Milestone Event is achieved. In the event of any termination of this Agreement by either Party pursuant to Section 15.2, 15.4, 15.5 or 15.6, Novartis shall not be obligated to make any Milestone Payment that would otherwise be owing in respect of any Milestone Event achieved after the terminating Party notifies the other Party in writing of its intention to so terminate; provided, however, that if this Agreement is not ultimately terminated pursuant to such notice, any such Milestone Payments that would have become due following such notice shall be due and payable at such time as it is determined that such termination shall not occur.

15.8 Surviving Provisions.

15.8.1 Accrued Rights; Remedies. The expiration or termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such expiration or termination, and any and all damages or remedies (whether at law or in equity) arising from any breach hereunder, each of which shall survive expiration or termination of this Agreement. Such expiration or termination shall not relieve any Party from obligations which are expressly indicated to survive expiration or termination of this Agreement. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Article 15 are in addition to any other relief and remedies available to either Party under this Agreement, at law, or in equity; provided, however, that in the event of a termination of this Agreement by Novartis pursuant to Section 15.2 the reduction in royalties owing by Novartis to BeiGene may be taken into account in determining any damages that may be recovered by Novartis in any action in respect of the breach by BeiGene giving rise to such termination.

15.8.2 Survival. Without limiting the provisions of Section 15.8.1, the rights and obligations of the Parties set forth in the following Sections and Articles of this Agreement shall survive the expiration or termination of this Agreement, in addition to those other terms and conditions that are expressly stated to survive termination or expiration of this Agreement: Article 1 (to the extent the definitions are used in other surviving provisions), ARTICLE 14, ARTICLE 16, Section 8.4, Section 8.5, Section 9.1 (solely to the extent the licenses contemplated therein survive pursuant to Section 8.3.2 or Section 15.7), Section 10.2 (solely in respect of Joint Patents), Section 10.3 (solely in respect of Joint Patents), Sections 12.1 through Section 12.5, Section 12.9, Section 15.1.2, Section 15.7, and Section 15.8.

ARTICLE 16
MISCELLANEOUS

16.1 Severability. If one (1) or more of the terms or provisions of this Agreement is held by a court of competent jurisdiction to be void, invalid, or unenforceable in any situation in any jurisdiction, such holding shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the void, invalid, or unenforceable

term or provision in any other situation or in any other jurisdiction, and the term or provision shall be considered severed from this Agreement solely for such situation and solely in such jurisdiction, unless the void, invalid, or unenforceable term or provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the void, invalid, or unenforceable term or provision. If the final judgment of such court declares that any term or provision hereof is void, invalid, or unenforceable, the Parties agree to: (a) reduce the scope, duration, area, or applicability of the term or provision or to delete specific words or phrases to the minimum extent necessary to cause such term or provision as so reduced or amended to be enforceable; and (b) make a good-faith effort to replace any void, invalid, or unenforceable term or provision with a valid and enforceable term or provision such that the objectives contemplated by the Parties when entering this Agreement may be realized.

16.2 Notices. Any notice required or permitted to be given by this Agreement shall be in writing and in English and shall be: (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered, or certified mail; or (c) delivered by electronic mail followed by delivery via either of the methods set forth in Sections 16.2(a) and (b), in each case, addressed as set forth below unless changed by notice so given:

If to Novartis:

Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel, Switzerland
Attention: Head of BD&L

With copies to:

Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel, Switzerland
Attention: General Counsel

Novartis Pharmaceuticals Corporation
1 Health Plaza
East Hanover, NJ 07936
Attention: Global Oncology General Counsel

Mayer Brown LLP
1221 Avenue of the Americas
New York, NY 10020
Attention: **[…***…]**

If to BeiGene:

BeiGene Switzerland GmbH
c/o VISCHER AG
Aeschenvorstadt 4
4051 Basel, Switzerland
Attention: Managing Director

With copies to:

BeiGene USA, Inc.
55 Cambridge Parkway
Suite 700W
Cambridge, MA, 02142
Attention: General Counsel
Facsimile: **[…***…]**

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: **[…***…]**
Facsimile: **[…***…]**

Any such notice shall be deemed given on the date received, except any notice received after 5:30 p.m. (in the time zone of the receiving Party) on a Business Day or received on a non-Business Day shall be deemed to have been received on the next Business Day. A Party may add, delete, or change the person or address to which notices should be sent at any time upon written notice delivered to the other Parties in accordance with this Section 16.2.

16.3 Force Majeure. A Party shall not be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to a cause beyond the reasonable control of such Party, including acts of God, fires, earthquakes, acts of war, terrorism, or civil unrest, epidemics, pandemics, quarantines, hurricane or other inclement weather; provided, that the affected Party: (a) promptly notifies the other Party; and (b) shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance in accordance with the terms of this Agreement whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

16.4 Assignment. Except as expressly permitted herein, this Agreement may not be assigned or transferred by any Party, nor may any Party assign or transfer any rights or obligations created by this Agreement, except as expressly permitted hereunder without first obtaining the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned, or delayed. Notwithstanding the limitations in this Section 16.4, either Party may assign or transfer this Agreement, or any rights or obligations hereunder in whole or in part, to: (a) one (1) or more of its Affiliates; provided, that, such assigning Party shall remain

fully and unconditionally liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate; or (b) its successor in interest in connection with its merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement. The terms of this Agreement shall be binding upon and shall inure to the benefit of the successors, heirs, administrators, and permitted assigns of the applicable Party. Any purported assignment in violation of this Section 16.4 shall be null and void *ab initio*. **[…***…]**.

16.5 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release, or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by the Parties.

16.6 WAIVER OF JURY TRIAL. EXCEPT AS LIMITED BY APPLICABLE LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, SUIT, PROCEEDING, OR COUNTERCLAIM (WHETHER BASED IN CONTRACT, TORT, OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE, AND ENFORCEMENT HEREOF. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT BETWEEN THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY ACTION, SUIT, PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT SHALL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

16.7 Choice of Law; Dispute Resolution; Jurisdiction.

16.7.1 Choice of Law. This Agreement shall be governed by, enforced, and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws and excluding the United Nations Convention on Contracts for the International Sales of Goods.

16.7.2 Dispute Resolution.

(a) Disputes. The Parties agree that the procedures set forth in this Section 16.7.2 shall be the exclusive mechanism for resolving any dispute (whether in contract, tort, or otherwise), controversy, or claim between the Parties arising out of or in connection with this Agreement, any Party's rights or obligations under this Agreement, breach of this Agreement, or the transactions contemplated by this Agreement (each, a "Dispute").

(b) Selection of Arbitrators. Any Dispute shall be resolved by final and binding arbitration before a panel of three (3) arbitrators in accordance with the rules of the American Arbitration Association ("AAA") in effect at the time the proceeding is initiated. In

any such arbitration, (a) the panel will be comprised of one arbitrator chosen by BeiGene, one by Novartis and the third, who shall act as the chairman of the panel, by the two co-arbitrators; and (b) if either Party fails or both Parties fail to choose an arbitrator or arbitrators within **[…***…]** after receiving notice of commencement of arbitration or if the two arbitrators fail to choose a third arbitrator within **[…***…]** after their appointment, then either or both Parties shall immediately request that the AAA select the remaining number of arbitrators to be selected, which arbitrator(s) shall have the requisite scientific background, experience and expertise.

(c) Conduct of Arbitration. The place of arbitration shall be New York, New York. The language of the arbitration shall be English. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration decision is rendered or the Dispute is otherwise resolved. Either Party also may, without waiving any right or remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending resolution of the Dispute pursuant to this Section 16.7. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. The award of the arbitrators shall be final and binding on the Parties (except for those remedies expressly set forth in this Agreement). The award rendered by the arbitrators may be entered and enforced in any court having jurisdiction thereof. Notwithstanding anything in this Section 16.7 to the contrary, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in order to enforce the instituting Party's rights hereunder through specific performance, injunction or similar equitable relief.

(d) Costs of Arbitration. Each Party shall bear its own costs and expenses and attorneys' fees in connection with any such arbitration; provided, that, the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to the prevailing Party reimbursement for its reasonable attorneys' fees, costs and expenses (including, for example, expert witness fees and expenses, photocopy charges and travel expenses).

(e) Exceptions to Arbitration. Unless otherwise agreed by the Parties, Disputes relating to Patents and non-disclosure, non-use and maintenance of Confidential Information shall not be subject to arbitration, and shall be submitted to a court of competent jurisdiction.

(f) Confidentiality. The arbitration shall be confidential. Except as may be required by Applicable Law or as necessary to pursue a legal right, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration without the prior written consent of both Parties.

(g) Notwithstanding the provisions of this Section 16.7.2, either Party may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any equitable relief, including any injunctive or provisional relief and specific performance to protect the rights or property of that Party. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or in equity. In addition, notwithstanding the provisions of this Section 16.7.2, either Party

may bring an action in any court having jurisdiction to enforce an award rendered pursuant to this Section 16.7.2.

(h) Until final resolution of the dispute through judicial determination: (i) this Agreement shall remain in full force and effect; and (ii) the time periods for cure as to any termination shall be tolled. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the Dispute shall be refunded if a court determines that such payments are not due.

(i) Any disputed matter that the JSC is unable to resolve under Section 2.1.3(c) that is referred for resolution by either Party shall be resolved as follows:

(i) If such dispute involves a Pricing Reference Standard Change, such dispute shall be submitted to a Third Party expert (a "Third Party Expert") mutually acceptable to the Parties having relevant expertise with respect to the disputed matter and who has not had any material business relationship with either Party in the **[…***…]** prior to appointment. The Parties shall use reasonable efforts to mutually agree on the Third Party Expert within **[…***…]** after either Party designates the disputed matter for arbitration. Within **[…***…]** of the selection of the Third Party Expert, each Party will deliver to both the Third Party Expert and the other Party a detailed written proposal setting forth its proposed terms for the resolution of the disputed matter (the "Proposed Terms") and a memorandum (the "Support Memorandum") in support thereof, not exceeding five (5) pages in length. The Parties will also provide the Third Party Expert with a copy of this Agreement, as amended through such date. Within **[…***…]** after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the Third Party Expert (with a copy to the other Party) a response to the other Party's Proposed Terms and Support Memorandum, such response not exceeding five (5) pages in length. Neither Party may have any other communications (either written or oral) with the Third Party Expert; provided that the Third Party Expert may, in its discretion, convene a hearing to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms and Support Memorandum, at which time each Party shall have an agreed upon time to argue and present witnesses in support of its Proposed Terms. Within **[…***…]** after the Third Party Expert is appointed, the Third Party Expert shall select one of the two Proposed Terms (without modification) provided by the Parties which most closely reflects a commercially reasonable interpretation of the terms of this Agreement. In making its selection, (i) the Third Party Expert shall not modify the terms or conditions of either Party's Proposed Terms nor shall the Third Party Expert combine provisions from both Proposed Terms and (ii) the Third Party Expert shall consider the terms and conditions of this Agreement, the relative merits of the Proposed Terms, the Support Memorandums and, if applicable, the oral arguments of the Parties. The Third Party Expert shall make its decision known to both Parties as promptly as possible by delivering written notice to both Parties. The decision of the Third Party Expert shall be final and binding on the Parties, and specific performance may be ordered by any court of competent jurisdiction; or

(ii) If such dispute relates to any other matter, such dispute shall be resolved by a single Third Party expert (each, an "Accelerated Arbitration Expert") in

accordance with the International Expedited Arbitration Procedures of the AAA. The Accelerated Arbitration Expert shall have relevant expertise with respect to the applicable Accelerated Arbitration Matter, and shall not have had any material business relationship with either Party in the **[…***…]** prior to appointment unless the Parties agree in writing to waive this requirement. All proceedings and decisions of the Accelerated Arbitration Expert under this Section 16.7.2(i)(i) shall be deemed Confidential Information of both Parties.

16.8 Relationship of the Parties. BeiGene and Novartis are independent contractors under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute either Party as a partner, agent, or joint venturer of the other Party. No Party will incur any debts or make any commitments for the other Party, except to the extent, if at all, specifically provided therein. Neither BeiGene nor Novartis, respectively, shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of BeiGene and Novartis, respectively, or to bind BeiGene and Novartis, respectively, to any contract, agreement, or undertaking with any Third Party.

16.9 Fees and Expenses. Except as otherwise specified in this Agreement, each Party shall bear its own costs and expenses (including investment banking and legal fees and expenses) incurred in connection with this Agreement.

16.10 Third Party Beneficiaries. There are no express or implied Third Party beneficiaries hereunder. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party, except for the indemnification rights of the BeiGene Indemnitees pursuant to Sections 14.1 and 14.3 and the Novartis Indemnitees pursuant to Sections 14.2 and 14.3.

16.11 Entire Agreement. This Agreement, together with the attached Exhibits and Schedules, contains the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior express or implied agreements, understandings, and representations, either oral or written, which may have related to the subject matter hereof in any way, including any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date; provided, that, this Agreement shall not supersede the terms and provisions of the Prior CDA applicable to any period prior to the Effective Date.

16.12 Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together, and shall constitute one (1) and the same instrument. Any such counterpart, to the extent delivered by means of facsimile by .pdf, .tif, .gif, .jpeg, or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party hereto shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of

Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.

16.13 Equitable Relief; Cumulative Remedies. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or in equity. The Parties further agree not to raise as a defense or objection to the request or granting of such relief that any breach of this Agreement is or would be compensable by an award of money damages. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.

16.14 Interpretation.

16.14.1 Generally. This Agreement has been diligently reviewed by and negotiated by and between the Parties, and in such negotiations each of the Parties has been represented by competent (in-house or external) counsel, and the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

16.14.2 Definitions; Interpretation.

(a) The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined and, where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning.

(b) Whenever the context may require, any pronoun shall include the corresponding masculine, feminine, and neuter forms.

(c) The word “will” shall be construed to have the same meaning and effect as the word “shall.”

(d) The words “including,” “includes,” “include,” “for example,” and “*e.g.*,” and words of similar import, shall be deemed to be followed by the words “without limitation.”

(e) The word “or” shall be interpreted to mean “and/or,” unless the context requires otherwise.

(f) The words “hereof,” “herein,” and “herewith,” and words of similar import, shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement.

(g) Unless the context requires otherwise or otherwise specifically provided: (i) all references herein to Articles, Sections, Schedules, or Exhibits shall be construed to refer to Articles, Sections, Schedules, and Exhibits of this Agreement; and (ii) reference in any Section to any subclauses are references to such subclauses of such Section.

16.14.3 Subsequent Events. Unless the context requires otherwise: (a) any definition of or reference to any agreement, instrument, or other document herein shall be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein); (b) any reference to any Applicable Law herein shall be construed as referring to such Applicable Law as from time to time enacted, repealed, or amended; and (c) subject to Section 16.4, any reference herein to any Person shall be construed to include the Person’s successors and assigns.

16.14.4 Headings. Headings, captions, and the table of contents are for convenience only and shall not be used in the interpretation or construction of this Agreement.

16.14.5 Prior Drafts. No prior draft of this Agreement shall be used in the interpretation or construction of this Agreement.

16.14.6 Independent Significance. Although the same or similar subject matter may be addressed in different provisions of this Agreement, the Parties intend that, except as reasonably apparent on the face of the Agreement or as expressly provided in this Agreement, each such provision shall be read separately, be given independent significance, and not be construed as limiting any other provision of this Agreement (whether or not more general or more specific in scope, substance, or content).

16.15 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instruments, and do all such other ministerial, administrative, or similar acts, as may be reasonably necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

[*Signature Pages Follow*]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Execution Date.

BEIGENE SWITZERLAND GMBH

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Managing Director

NOVARTIS PHARMA AG

By: /s/ Susanne Schaffert
Name: Dr. Susanne Schaffert
Title: President, Novartis Oncology

By: /s/ Teresa Jose
Name: Teresa Jose
Title: CFO, Novartis Oncology

Schedules and Exhibits Omitted from Collaboration and License Agreement

Pursuant to Regulation S-K, Item 601(a)(5), the schedules and exhibits to the Collaboration and License Agreement, as listed below, have not been filed. The Registrant agrees to furnish supplementally a copy of any omitted schedules or exhibits to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

SCHEDULES

Schedule 1.9	BeiGene Anti-PD-L1
Schedule 1.17	BeiGene Ongoing Clinical Trials
Schedule 1.18	BeiGene Patents
Schedule 1.21	BeiGene Trademarks
Schedule 1.58	Existing IND
Schedule 1.82	Individuals with Knowledge
Schedule 1.83	Licensed Compound
Schedule 1.101	Novartis Anti-PD-1
Schedule 5.7	Regional Marketing Managers Responsibilities
Schedule 5.8	Annual Compliance Certification
Schedule 7.3(a)	Terms of Supply

EXHIBITS

Exhibit A:	Initial Global Development Plan
Exhibit B:	Additional Global Development Plan
Exhibit C-1:	Form of Press Release (Novartis)
Exhibit C-2:	Form of Press Release (BeiGene)

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, John V. Oyler, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BeiGene, Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

/s/ JOHN V. OYLER

John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Howard Liang, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BeiGene, Ltd.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

/s/ HOWARD LIANG

Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of BeiGene, Ltd., an exempted company incorporated in the Cayman Islands with limited liability (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the three months ended March 31, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 6, 2021

/s/ JOHN V. OYLER

John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Dated: May 6, 2021

/s/ HOWARD LIANG

Howard Liang
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)