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 September 30, 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**	
(Address of principal executive offices)	**KY1-1108** (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 October 31, 2021, 1,219,734,201 ordinary shares, par value $0.0001 per share, were outstanding, of which 978,399,318 ordinary shares were held in the form of 75,261,486 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

TABLE OF CONTENTS

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.
- 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 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.
- 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 September 30, 2021 $ (unaudited)	As of December 31, 2020 $ (audited)
Assets			
Current assets:			
Cash and cash equivalents		1,383,310	1,381,950
Short-term restricted cash	4	330	307
Short-term investments	4	2,533,617	3,268,725
Accounts receivable, net	10	129,584	60,403
Inventories	5	150,979	89,293
Prepaid expenses and other current assets	10	235,015	160,012
Total current assets		4,432,835	4,960,690
Long-term restricted cash	4	6,056	7,748
Property, plant and equipment, net	6	450,788	357,686
Operating lease right-of-use assets		100,585	90,581
Intangible assets, net	8	14,104	5,000
Deferred tax assets	9	106,844	65,962
Other non-current assets	10	175,122	113,090
Total non-current assets		853,499	640,067
Total assets		5,286,334	5,600,757
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		206,203	231,957
Accrued expenses and other payables	10	389,874	346,144
Deferred revenue, current portion	3	72,626	—
Tax payable	9	20,878	20,380
Operating lease liabilities, current portion		18,644	13,895
Research and development cost share liability, current portion	3	153,838	127,808
Short-term debt	11	442,372	335,015
Total current liabilities		1,304,435	1,075,199
Non-current liabilities:			
Long-term bank loans	11	200,906	183,637
Deferred revenue, non-current portion	3	52,272	—
Operating lease liabilities, non-current portion		37,613	29,417
Deferred tax liabilities	9	13,266	10,792
Research and development cost share liability, non-current portion	3	266,163	375,040
Other long-term liabilities	10	54,606	57,429
Total non-current liabilities		624,826	656,315
Total liabilities		1,929,261	1,731,514
Commitments and contingencies	18		
Equity:			
Ordinary shares, US$0.0001 par value per share; 9,500,000,000 shares authorized; 1,213,234,201 and 1,190,821,941 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively		121	118
Additional paid-in capital		7,724,822	7,414,932
Accumulated other comprehensive income	15	12,580	6,942
Accumulated deficit		(4,380,450)	(3,552,749)
Total equity		3,357,073	3,869,243
Total liabilities and equity		5,286,334	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 September 30,		Nine Months Ended September 30,	
		2021	2020	2021	2020
		$	$	$	$
Revenues					
Product revenue, net	12	192,461	91,080	437,202	208,774
Collaboration revenue	3	13,979	—	525,102	—
Total revenues		206,440	91,080	962,304	208,774
Expenses					
Cost of sales - product		47,413	21,123	116,361	49,579
Research and development		351,937	349,070	1,028,754	939,340
Selling, general and administrative		269,227	160,837	683,622	391,967
Amortization of intangible assets		188	187	563	658
Total expenses		668,765	531,217	1,829,300	1,381,544
Loss from operations		(462,325)	(440,137)	(866,996)	(1,172,770)
Interest (expense) income, net		(2,230)	(614)	(11,275)	7,184
Other income, net		31,477	5,711	26,487	29,368
Loss before income taxes		(433,078)	(435,040)	(851,784)	(1,136,218)
Income tax benefit	9	(19,223)	(8,423)	(24,083)	(8,344)
Net loss		(413,855)	(426,617)	(827,701)	(1,127,874)
Less: net loss attributable to noncontrolling interests		—	(1,393)	—	(3,713)
Net loss attributable to BeiGene, Ltd.		(413,855)	(425,224)	(827,701)	(1,124,161)
Loss per share attributable to BeiGene, Ltd.		(0.34)	(0.37)	(0.69)	(1.07)
Weighted-average shares outstanding—basic and diluted		1,205,971,284	1,148,973,077	1,196,391,201	1,052,940,583
Loss per American Depositary Share ("ADS")		(4.46)	(4.81)	(8.99)	(13.88)
Weighted-average ADSs outstanding—basic and diluted		92,767,022	88,382,544	92,030,092	80,995,429

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Net loss	(413,855)	(426,617)	(827,701)	(1,127,874)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	664	10,143	6,528	7,526
Pension liability adjustments	(111)	—	250	—
Unrealized holding (loss) gain, net	(68)	(1,044)	(1,140)	184
Comprehensive loss	(413,370)	(417,518)	(822,063)	(1,120,164)
Less: comprehensive loss attributable to noncontrolling interests	—	(1,174)	—	(3,585)
Comprehensive loss attributable to BeiGene, Ltd.	(413,370)	(416,344)	(822,063)	(1,116,579)

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	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
		$	$
Operating activities:			
Net loss		(827,701)	(1,127,874)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		33,336	23,961
Share-based compensation expenses	14	177,701	134,020
Unrealized gains on equity investments	4	(17,166)	(9,974)
Acquired in-process research and development		53,500	89,500
Amortization of research and development cost share liability	3	(82,846)	(85,296)
Deferred income tax benefits		(38,408)	(8,762)
Other items, net		17,719	(10,163)
Changes in operating assets and liabilities:			
Accounts receivable		(69,174)	10,497
Inventories		(61,686)	(6,972)
Other assets		(92,938)	(58,921)
Accounts payable		(12,376)	21,979
Accrued expenses and other payables		819	103,600
Deferred revenue		124,898	—
Other liabilities		3,438	(26,722)
Net cash used in operating activities		(790,884)	(951,127)
Investing activities:			
Purchases of property, plant and equipment		(147,963)	(82,819)
Purchases of investments		(2,062,879)	(4,879,705)
Proceeds from sale or maturity of investments		2,758,391	1,972,608
Purchase of in-process research and development		(8,500)	(89,500)
Other investing activities		(7,500)	(2,025)
Net cash provided by (used in) investing activities		531,549	(3,081,441)
Financing activities:			
Proceeds from sale of ordinary shares, net of cost	16	50,000	4,232,017
Proceeds from research and development cost share liability		—	616,834
Prepayment to acquire joint venture ("JV") minority interest		—	(28,723)
Proceeds from long-term loan	11	16,838	64,288
Repayment of long-term loan		—	(132,061)
Proceeds from short-term loans	11	143,456	48,983
Repayment of short-term loans		(40,229)	—
Proceeds from option exercises and employee share purchase plan		82,192	75,830
Net cash provided by financing activities		252,257	4,877,168
Effect of foreign exchange rate changes, net		6,769	4,340
Net (decrease) increase in cash, cash equivalents, and restricted cash		(309)	848,940
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		1,389,696	1,469,715
Supplemental cash flow information:			
Cash and cash equivalents		1,383,310	1,464,470
Short-term restricted cash		330	295
Long-term restricted cash		6,056	4,950
Income taxes paid		15,214	10,596
Interest paid		23,398	41,577
Supplemental non-cash information:			
Acquisitions of equipment included in accounts payable		41,897	30,926
Acquired in-process research and development included in accrued expenses		45,000	20,000

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
Use of shares reserved for share option exercises	(1,599,676)	—	—	—	—	—	—	—
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	8,844,082	1	9,846	—	—	9,847	—	9,847
Share-based compensation	—	—	64,791	—	—	64,791	—	64,791
Other comprehensive income	—	—	—	8,891	—	8,891	—	8,891
Net loss	—	—	—	—	(480,341)	(480,341)	—	(480,341)
Balance at June 30, 2021	1,204,567,023	120	7,561,155	12,095	(3,966,595)	3,606,775	—	3,606,775
Proceeds from issuance of ordinary shares, net of cost	2,151,877	—	50,000	—	—	50,000	—	50,000
Use of shares reserved for share option exercises	(3,644,641)	—	—	—	—	—	—	—
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	10,159,942	1	46,590	—	—	46,591	—	46,591
Share-based compensation	—	—	67,077	—	—	67,077	—	67,077
Other comprehensive income	—	—	—	485	—	485	—	485
Net loss	—	—	—	—	(413,855)	(413,855)	—	(413,855)
Balance at September 30, 2021	1,213,234,201	121	7,724,822	12,580	(4,380,450)	3,357,073	—	3,357,073
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
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	10,493,392	1	16,568	—	—	16,569	—	16,569
Use of shares reserved for share option exercises and RSU releases	(3,493,516)	—	—	—	—	—	—	—
Share-based compensation	—	—	45,468	—	—	45,468	—	45,468
Deconsolidation of entity	—	—	—	—	—	—	(3,545)	(3,545)
Other comprehensive loss	—	—	—	(2,751)	—	(2,751)	13	(2,738)
Net loss	—	—	—	—	(335,202)	(335,202)	(1,116)	(336,318)

Balance at June 30, 2020	1,014,976,692	102	5,200,275	(9,299)	(2,654,780)	2,536,298	10,194	2,546,492
Proceeds from issuance of ordinary shares, net of cost	145,838,979	14	2,069,596	—	—	2,069,610	—	2,069,610
Exercise of options, ESPP and release of Restricted Share Units ("RSUs")	16,575,806	1	47,631	—	—	47,632	—	47,632
Use of shares reserved for share option exercises and RSU releases	5,525,182	1	—	—	—	1	—	1
Share-based compensation	—	—	50,297	—	—	50,297	—	50,297
Other comprehensive income	—	—	—	8,880	—	8,880	219	9,099
Net loss	—	—	—	—	(425,224)	(425,224)	(1,393)	(426,617)
Balance at September 30, 2020	1,182,916,659	118	7,367,799	(419)	(3,080,004)	4,287,494	9,020	4,296,514

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 three commercial medicines, BRUKINSA®, a small molecule inhibitor of Bruton’s Tyrosine Kinase (“BTK”) for the treatment of various blood cancers, tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers, and pamiparib, a selective small molecule inhibitor of PARP1 and PARP2. 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 and pamiparib in China, with an established, science-based commercial organization. Additionally, the Company has licensed the China rights to multiple medicines, including Amgen's XGEVA®, BLINCYTO®, and KYPROLIS®; BMS's REVLIMID®, VIDAZA®, and ABRAXANE®; and EUSA Pharma's SYLVANT® and QARZIBA®. The Company has built state-of-the-art biologic and small molecule manufacturing facilities in China to support current and potential future demand of its medicines and plans to build a commercial-stage biologics manufacturing and clinical R&D center in New Jersey. The Company is also constructing a new small molecule manufacturing campus in Suzhou, China. 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 1,800-person global clinical development team that is running more than 90 ongoing or planned clinical trials. This includes more than 30 pivotal or registration-enabling trials for three drug candidates that have enrolled more than 13,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of September 2021. The Company has over 45 medicines and drug candidates in commercial stage or clinical development, including 10 approved medicines, 2 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 over 7,600 employees in 23 countries and regions as of September 30, 2021, including China, the United States, Europe and Australia.

Basis of presentation and consolidation

The accompanying condensed consolidated balance sheet as of September 30, 2021, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, the condensed consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020, and the condensed consolidated statements of shareholders' equity for the three and nine months ended September 30, 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 and nine months ended September 30, 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, 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 nine months ended September 30, 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 September 30, 2021 and December 31, 2020:

As of September 30, 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	237,796	—	—
Money market funds	62,291	—	—
Short-term investment (Note 4):			
U.S. Treasury securities	2,533,617	—	—
Other non-current assets (Note 4):			
Equity securities with readily determinable fair values	29,467	13,650	—
Total	2,863,171	13,650	—

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 and in Leap's underwritten public offering in September 2021. 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 September 30, 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 has entered 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 and nine months ended September 30, 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 and nine months ended September 30, 2020.

The following table summarizes total collaboration revenue recognized for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue from Collaborators	$	$	$	$
License revenue	—	—	484,646	—
Research and development service revenue	13,979	—	40,456	—
Total	13,979	—	525,102	—

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 nine months ended September 30, 2021. As such, the Company recognized the entire amount of the transaction price allocated to the license as collaboration revenue during the nine months ended September 30, 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 $13,979 and $40,456 during the three and nine months ended September 30, 2021, respectively.

In-Licensing Arrangements

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 Macau, 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). In July 2021, KYPROLIS® was conditionally approved in China for injection in combination with dexamethasone for the treatment of adult patients with relapsed or refractory (R/R) 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 LUMAKRAS™ (sotorasib), Amgen's 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 LUMAKRAS).

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 and nine months ended September 30, 2021 and 2020 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Research and development expense	29,710	30,795	85,040	87,498
Amortization of research and development cost share liability	28,943	30,056	82,846	85,296
Total amount due to Amgen for BeiGene's portion of the development funding	58,653	60,851	167,886	172,794

	As of September 30, 2021
Remaining portion of development funding cap	851,124

As of September 30, 2021 and December 31, 2020, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of	
	September 30, 2021	December 31, 2020
	$	$
Research and development cost share liability, current portion	153,838	127,808
Research and development cost share liability, non-current portion	266,163	375,040
Total research and development cost share liability	420,001	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 and nine months ended September 30, 2021 and 2020 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Cost of sales - product	380	(1,023)	1,058	(1,023)
Research and development	(373)	61	(310)	61
Selling, general and administrative	(12,552)	(3,667)	(28,469)	(3,667)
Total	(12,545)	(4,629)	(27,721)	(4,629)

The Company purchases commercial inventory from Amgen to distribute in China. Total inventory purchases amounted to $32,129 and $50,983 during the three and nine months ended September 30, 2021, respectively, and $7,404 during the three and nine months ended September 30, 2020. Net amounts payable to Amgen as of September 30, 2021 and December 31, 2020 were $105,675 and $122,828, respectively.

Shoreline

In June 2021, the Company signed an exclusive worldwide strategic collaboration with Shoreline Biosciences, Inc., to develop and commercialize a portfolio of NK-based based cell therapeutics leveraging Shoreline's iPSC NK cell technology and BeiGene's research and clinical development capabilities for different malignancies.

4. Restricted Cash and Investments

Restricted Cash

The Company's restricted cash balance of $6,386 and $8,055 as of September 30, 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 September 30, 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	2,533,886	—	(269)	2,533,617
Total	2,533,886	—	(269)	2,533,617

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 September 30, 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 September 30, 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. In September 2021, the Company purchased $7,250 of common stock in Leap's underwritten public offering. As of September 30, 2021, the Company's ownership interest in the outstanding common stock of Leap was 8.4% 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 13.2% 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. The Company recorded unrealized gains of $23,764 and $18,388 for the three and nine months ended September 30, 2021, respectively, and unrealized (losses)/gains of $(1,048) and $10,216 for the three and nine months ended September 30, 2020, respectively, in the consolidated statements of operations. As of September 30, 2021 and December 31, 2020, the fair value of the common stock and warrants was as follows:

	As of	
	September 30, 2021	December 31, 2020
	$	$
Fair value of Leap common stock	29,467	10,810
Fair value of Leap warrants	13,650	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 $21,714 and $9,705 in equity securities without readily determinable fair values as of September 30, 2021 and December 31, 2020, respectively. There were no adjustments to the carrying values of these securities for the three and nine months ended September 30, 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 $291 and $763 for the three and nine months ended September 30, 2021, respectively, and losses of $143

and $166 for the three and nine months ended September 30, 2020, respectively. As of September 30, 2021 and December 31, 2020, the carrying amount of the Company's investment in MapKure was $8,746 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 unrealized losses of less than $1 and $56 for the three and nine months ended September 30, 2021, respectively, and losses of $76 for the three and nine months ended September 30, 2020. As of September 30, 2021 and December 31, 2020, the carrying amount of the Company's investment in the fund was $12,286 and $12,189, respectively.

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 nine months ended September 30, 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	
	September 30, 2021	**December 31, 2020**
	$	**$**
Raw materials	54,993	19,330
Work in process	10,397	1,378
Finished goods	85,589	68,585
Total inventories	150,979	89,293

6. Property, plant and equipment

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

	As of	
	September 30, 2021	December 31, 2020
	$	$
Laboratory equipment	109,950	78,640
Leasehold improvements	47,521	37,643
Building	133,478	111,527
Manufacturing equipment	114,408	96,669
Software, electronics and office equipment	26,160	20,782
Property, plant and equipment, at cost	431,517	345,261
Less accumulated depreciation	(110,086)	(73,354)
Construction in progress	129,357	85,779
Property, plant and equipment, net	450,788	357,686

As of September 30, 2021 and December 31, 2020, construction in progress ("CIP") of $129,357 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 was $11,773 and $32,440 for the three and nine months ended September 30, 2021, respectively, and $8,157 and $23,303 for the three and nine months ended September 30, 2020, 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 $15,520 (RMB100,000) of the Related Party Loan as of September 30, 2021. See Note 11 for further discussion of the loans.

8. Intangible Assets

Intangible assets as of September 30, 2021 and December 31, 2020 are summarized as follows:

	As of					
	September 30, 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	(3,063)	4,437	7,500	(2,500)	5,000
Developed product	10,000	(333)	9,667	—	—	—
Trading license	816	(816)	—	816	(816)	—
Total finite-lived intangible assets	18,316	(4,212)	14,104	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, as a single identified asset, over a period of 10 years which is the term of the agreement. Developed product represents the post-approval milestone payments under the license agreement with Merck KGaA that was terminated during the year ended December 31, 2018 and the commercialization agreement with EUSA Pharma. The Company is amortizing the developed product over the remainder of the product patent or the term of the commercialization 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 for developed product is included in cost of sales - product in the accompanying consolidated statements of operations. Amortization expense for product distribution rights and the trading licenses is included in operating expenses in the accompanying consolidated statements of operations. Amortization expense was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Amortization expense - Cost of sales - product	216	—	333	—
Amortization expense - Operating expense	188	187	563	658
Total	404	187	896	658

As of September 30, 2021, expected amortization expense for the unamortized finite-lived intangible assets is approximately $424 for the remainder of 2021, $1,695 in 2022, $1,695 in 2023, $1,695 in 2024, and $8,595 in 2025 and thereafter.

9. Income Taxes

Income tax benefit was $19,223 and $24,083 for the three and nine months ended September 30, 2021, respectively, and was $8,423 and $8,344 for the three and nine months ended September 30, 2020, respectively. The income tax benefit for the three and nine months ended September 30, 2021 and September 30, 2020 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.

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 September 30, 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 September 30, 2021, the Company had gross unrecognized tax benefits of $9,084. 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 $778 and $1,961, respectively, in the three and nine months ended September 30, 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 September 30, 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 September 30, 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 nine months ended September 30, 2021 and 2020 consists of the following activity:

	Nine Months Ended September 30,	
	2021	2020
	$	$
Balance at beginning of the period	112	—
Current period provision for expected credit losses	(7)	114
Amounts written-off	—	—
Exchange rate changes	3	—
Balance at end of the period	108	114

Prepaid expenses and other current assets consist of the following:

	As of	
	September 30, 2021	December 31, 2020
	$	$
Prepaid research and development costs	75,696	71,341
Prepaid manufacturing cost	59,536	25,996
Prepaid taxes	38,438	30,392
Payroll tax receivable	20,911	3,580
Prepaid Commercial	7,646	2,794
Interest receivable	7,223	6,619
Prepaid insurance	4,122	1,347
Income tax receivable	3,016	4,607
Non-trade receivable	2,829	4,464
Other	15,598	8,872
Total	235,015	160,012

Other non-current assets consist of the following:

	As of	
	September 30, 2021	December 31, 2020
	$	$
Goodwill	109	109
Prepayment of property and equipment	34,579	16,984
Prepayment of facility capacity expansion activities (1)	23,816	29,778
Prepaid VAT	21,499	10,913
Rental deposits and other	7,691	5,962
Long-term investments (Note 4)	87,428	49,344
Total	175,122	113,090

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

Accrued expenses and other payables consist of the following:

	As of	
	September 30, 2021	December 31, 2020
	$	$
Compensation related	104,878	106,765
External research and development activities related	163,937	143,302
Commercial activities	67,100	66,131
Employee tax withholdings	27,494	14,373
Sales rebates and returns related	20,190	11,874
Professional fees and other	6,275	3,699
Total	389,874	346,144

Other long-term liabilities consist of the following:

	As of	
	September 30, 2021	December 31, 2020
	$	$
Deferred government grant income	46,672	49,139
Pension liability	7,863	8,113
Other	71	177
Total	54,606	57,429

11. Debt

The following table summarizes the Company's short-term and long-term debt obligations as of September 30, 2021 and December 31, 2020:

Lender	Agreement Date	Line of Credit	Term	Maturity Date	Interest Rate	September 30, 2021		December 31, 2020	
						$	RMB	$	RMB
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	776	5,000	307	2,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	1,164	7,500	—	—
China Minsheng Bank (the "Senior Loan")	September 24, 2020	$200,000		(3)	5.8 %	198,320	1,277,835	198,320	1,294,010
Zhuhai Hillhouse (the "Related Party Loan")	September 24, 2020	RMB500,000		(4)	5.8 %	15,520	100,000	15,326	100,000
Other short-term debt (5)						226,592	1,460,000	121,062	789,918
Total short-term debt						442,372	2,850,335	335,015	2,185,928
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	89,085	574,000	88,584	578,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	53,156	342,500	53,641	350,000
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(6)	58,665	378,000	41,412	270,206
Total long-term bank loans						200,906	1,294,500	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 September 30, 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. The Company repaid $155 (RMB1,000) during the nine months ended September 30, 2021.

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 September 30, 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 September 8, 2022. The Company drew down $143,456 (RMB930,082) during the nine months ended September 30, 2021. The Company repaid $40,074 (RMB260,000) of the short-term loans in the nine months ended September 30, 2021. The weighted average interest rate for the short-term working capital loans was approximately 4.3% as of September 30, 2021. One of the short-term working capital loans outstanding in the amount of $9,312 (RMB60,000) 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 September 30, 2021. The Company drew down $16,838 (RMB107,794) during the nine months ended September 30, 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 and nine months ended September 30, 2021 was $7,609 and $22,186, respectively, among which, $275 and $526 was capitalized, respectively. Interest expense recognized for the three and nine months ended September 30, 2020 was $4,139 and $12,849, respectively, among which, $97 and $214 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 and pamiparib in China; the sale of REVLIMID® and VIDAZA® in China under a license from BMS; and XGEVA® and BLINCYTO® 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 and nine months ended September 30, 2021 and 2020.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Product revenue – gross	206,029	95,333	497,823	216,210
Less: Rebates and sales returns	(13,568)	(4,253)	(60,621)	(7,436)
Product revenue – net	192,461	91,080	437,202	208,774

The following table disaggregates net product sales by product for the three and nine months ended September 30, 2021 and September 30, 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Tislelizumab	76,980	49,934	200,738	99,877
BRUKINSA®	65,832	15,662	130,345	23,353
REVLIMID®	20,209	14,067	46,984	38,914
VIDAZA®	5,810	8,366	12,771	26,198
ABRAXANE®	—	—	—	17,381
XGEVA®	15,699	3,051	33,491	3,051
BLINCYTO®	5,040	—	5,040	—
Pamiparib	1,516	—	3,737	—
Other	1,375	—	4,096	—
Total product revenue – net	192,461	91,080	437,202	208,774

The following table presents the roll-forward of accrued sales rebates and returns for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
	$	$
Balance at beginning of the period	11,874	3,198
Accrual	60,621	7,436
Payments	(52,305)	(3,110)
Balance at end of the period	20,190	7,524

Sales rebates accrued and paid through September 30, 2021 increased as a result of compensating distributors for products previously sold at the pre-NRDL price, which remained in the distribution channel, due to the first inclusion of tislelizumab, BRUKINSA® and XGEVA® in the NRDL.

13. Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Numerator:				
Net loss	(413,855)	(426,617)	(827,701)	(1,127,874)
Less: Net loss attributable to noncontrolling interest	—	(1,393)	—	(3,713)
Net loss attributable to BeiGene, Ltd.	(413,855)	(425,224)	(827,701)	(1,124,161)
Denominator:				
Weighted average shares outstanding—basic and diluted	1,205,971,284	1,148,973,077	1,196,391,201	1,052,940,583

For the three and nine months ended September 30, 2021 and September 30, 2020, the computation of basic loss 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 loss 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 September 30, 2021, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,166,510. 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 nine months ended September 30, 2021, the Company granted options for 6,074,757 ordinary shares and restricted share units for 15,583,295 ordinary shares under the 2016 Plan. As of September 30, 2021, options and restricted share units for ordinary shares outstanding under the 2016 Plan totaled 59,405,189 and 36,239,359, respectively. As of September 30, 2021, share-based awards to acquire 50,670,190 ordinary shares were available for future grant under the 2016 Plan.

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 nine months ended September 30, 2021, the Company did not grant any options or restricted share units under the 2018 Plan. As of September 30, 2021, options and restricted share units for ordinary shares outstanding under the 2018 Plan

totaled 30,901 and 831,116, respectively. As of September 30, 2021, share-based awards to acquire 9,294,440 ordinary shares were available for future grant under the 2018 Plan.

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. In June 2021, the board of directors of the Company adopted the third amended and restated ESPP to include some technical amendments under U.S. tax rules and to consolidate the changes in the prior amendment, to be effective on September 1, 2021. 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.

As of September 30, 2021, 5,194,546 ordinary shares were available for future issuance under the ESPP.

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
August 31, 2021	425,386	$ 308.30	$ 23.72	$ 262.06	$ 20.16	$ 8,575
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 and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
Research and development	31,680	25,410	83,762	69,521
Selling, general and administrative	35,397	24,887	93,939	64,499
Total	67,077	50,297	177,701	134,020

15. Accumulated Other Comprehensive Income

The movement of accumulated other comprehensive income was as follows:

	Foreign Currency Translation Adjustments	Unrealized Gains/(Losses) 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	6,528	(1,078)	250	5,700
Amounts reclassified from accumulated other comprehensive income (1)	—	(62)	—	(62)
Net-current period other comprehensive (loss) income	6,528	(1,140)	250	5,638
Balance as of September 30, 2021	20,712	(269)	(7,863)	12,580

(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

On September 10, 2021, the Company issued an aggregate of 165,529 ADSs, representing 2,151,877 ordinary shares, to Amgen Inc. for a total consideration of $50,000, in a private placement pursuant to a Share Purchase Agreement dated October 31, 2019, as amended on December 6, 2019 and September 24, 2020 by and between Amgen and Company (the "SPA").

On January 2, 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.

Registered Direct Offering

On July 15, 2020, the Company issued 145,838,979 ordinary shares, par value $0.0001, to eight existing investors including entities associated with Hillhouse Capital and Baker Bros. Advisors LP, as well as Amgen, in a registered direct offering under the Company's effective Registration Statement on Form S-3 (File No. 333-238181). Each ordinary share was sold for a purchase price of $14.2308 per share ($185.00 per ADS), resulting in gross proceeds of approximately $2,075,000, and net proceeds, after offering expenses, of approximately $2,069,610. The shares were priced on July 12, 2020, and the last reported sale price of the ADSs on the NASDAQ on July 10, 2020 was $196.03 per ADS. The offering was made without an underwriter or a placement agent, and as a result the Company did not pay any underwriting discounts or commissions in connection with the offering.

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 September 30, 2021 and December 31, 2020, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to $622,761 and $119,776, respectively.

18. Commitments and Contingencies

Purchase Commitments

As of September 30, 2021, the Company had purchase commitments amounting to $268,498, of which $77,601 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $190,897 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 $57,720 for the acquisition of property, plant and equipment as of September 30, 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 September 30, 2021, the Company's remaining co-development funding commitment was $851,124.

Research and Development Commitment

The Company entered into a long-term research and development agreement during the nine months ended September 30, 2021, which includes obligations to make an upfront payment and fixed quarterly payments over the next five years. As of September 30, 2021, the total research and development commitment amounted to $74,392.

Funding Commitment

The Company had committed capital related to an equity method investment in the amount of $15,000. As of September 30, 2021, the remaining capital commitment was $13,500 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 $1,285 per year based on annual funding contributions in effect as of September 30, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	$	$	$	$
PRC	158,775	85,384	377,392	199,301
United States	43,471	5,696	427,280	9,473
Other	4,194	—	157,632	—
Total	206,440	91,080	962,304	208,774

U.S. revenues for the three and nine months ended September 30, 2021 consisted of collaboration revenue of $9,785 and $367,571, respectively, and BRUKINSA® product sales of $33,686 and $59,709, respectively. U.S. revenues for the three and nine months ended September 30, 2020 consisted entirely of BRUKINSA® product sales.

20. Subsequent Events

On October 6, 2021, Celgene delivered a notice to the Company purporting to terminate the License and Supply Agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in the Territory pursuant to Section 2.6 of the License and Supply Agreement. The Company believes that the reasons stated in the termination notice do not provide a valid basis for terminating the agreement with respect to ABRAXANE® and intends to contest the purported termination vigorously.

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; 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 environment and 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 in which we operate; 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, manufacturing, 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.

We have delivered ten molecules into the clinic in our first ten years, including three commercial medicines, BRUKINSA®, a small molecule inhibitor of Bruton's Tyrosine Kinase ("BTK") for the treatment of various blood cancers, tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers, and pamiparib, a selective small molecule inhibitor of PARP1 and PARP2. We are 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 and pamiparib in China, with an established, science-based commercial organization. Additionally, we have licensed the China rights to multiple medicines, including Amgen's XGEVA®, BLINCYTO®, and KYPROLIS®; BMS's ABRAXANE®, REVLIMID®, and VIDAZA®; and EUSA Pharma's SYLVANT® and QARZIBA®. We have built state-of-the-art biologic and small molecule manufacturing facilities in China to support current and potential future demand of our medicines, and plan to build a commercial-stage biologics manufacturing and clinical R&D center in New Jersey. We are also constructing a new small molecule manufacturing campus in Suzhou, China. 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 1,800-person global clinical development team that is running more than 90 ongoing or planned clinical trials. This includes more than 30 pivotal or registration-enabling trials for three drug candidates that have enrolled more than 13,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of September 2021. We have over 45 medicines and drug candidates in commercial stage or clinical development, including 10 approved medicines, 2 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 over 7,600 employees in 23 countries and regions as of September 30, 2021, including China, the United States, Europe and Australia.

Recent Developments

Recent Business Developments

On October 20, 2021, we and Nanolek, a biopharmaceutical company specializing in the production of import-substituting and innovative drugs in Russia, announced that BRUKINSA® (zanubrutinib) received approval from the Russia Ministry of Health for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. BeiGene and Nanolek entered into an exclusive distribution agreement for Nanolek to commercialize BRUKINSA® in the Russian Federation.

On October 10, 2021, we announced that BRUKINSA® (zanubrutinib) was approved in Australia for the treatment of adult patients with MCL who have received at least one prior therapy.

On October 7, 2021, we announced that BRUKINSA® was approved in Australia for the treatment of adult patients with Waldenström’s macroglobulinemia (WM) who have received at least one prior therapy or in first line treatment for patients unsuitable for chemo-immunotherapy. Following registration of BRUKINSA® with the Therapeutic Goods Administration (TGA), these patients now have immediate access to BRUKINSA® through our sponsored post-approval, pre-reimbursement access program.

On October 6, 2021, BMS-Celgene delivered a notice to us, which we dispute, purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license agreement with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS-Celgene to reduce its damages in the on-going arbitration proceedings described in Part II-Item 1. Legal Proceedings. We intend to contest the purported termination vigorously.

On September 17, 2021, we announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending approval of BRUKINSA® for the treatment of adult patients with WM who have received at least one prior therapy or first-line treatment for patients unsuitable for chemo-immunotherapy.

On September 15, 2021, we announced that BRUKINSA® received accelerated approval from the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed or refractory (R/R) marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

On September 13, 2021, we announced that the FDA accepted for review a Biologics License Application (BLA) for our anti-PD-1 antibody tislelizumab as a treatment for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) target action date is July 12, 2022.

On September 1, 2021, we announced that BRUKINSA® received approval from the FDA for the treatment of adult patients with WM.

On August 22, 2021, we announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) accepted a supplemental Biologics License Application (sBLA) for anti-PD-1 antibody tislelizumab in combination with chemotherapy as a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC).

On August 18, 2021, we announced that Swissmedic accepted the marketing authorization application (MAA) for BRUKINSA, a treatment option for adult patients with WM. Swissmedic has started the formal review of the MAA. BRUKINSA has already been granted orphan drug status by Swissmedic.

On August 16, 2021, we announced that the NMPA granted QARZIBA® (dinutuximab beta) conditional approval for the treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of R/R neuroblastoma with or without residual disease. Dinutuximab beta is a targeted immunotherapy approved by the EMA.

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. We launched our third internally developed medicine, pamiparib, in China in May 2021. 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 received approval for KYPROLIS® in China in July 2021, and plan to launch additional in-licensed products from our collaborations, 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 costs to manufacture our internally developed commercial products, as well as costs to purchase tislelizumab from Boehringer Ingelheim Biopharmaceuticals (China) Ltd. Additionally, cost of sales included the cost of products purchased from Amgen and BMS. 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, a selective small molecule inhibitor of PARP1 and PARP2;
- ociperlimab, 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;
- BGB-A445, an investigational non-ligand competing OX40 monoclonal antibody;
- BGB-16673, an investigational Chimeric Degradation Activating Compound, or CDAC, targeting BTK; 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");
- 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"). The license rights of the candidate outside of the U.S. and the development rights of the candidate in the U.S. have been returned to Singlomics under a reversion agreement signed by the parties, with us retaining U.S. commercial rights.

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 and maintaining 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 for our approved medicines, 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 Income, Net

Other 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 and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2021	2020	$	%	2021	2020	$	%
	(dollars in thousands)							
Revenues								
Product revenue, net	$ 192,461	$ 91,080	$ 101,381	111.3 %	$ 437,202	$ 208,774	$ 228,428	109.4 %
Collaboration revenue	13,979	—	13,979	NM	525,102	—	525,102	NM
Total revenues	206,440	91,080	115,360	126.7 %	962,304	208,774	753,530	360.9 %
Expenses								
Cost of sales - product	47,413	21,123	26,290	124.5 %	116,361	49,579	66,782	134.7 %
Research and development	351,937	349,070	2,867	0.8 %	1,028,754	939,340	89,414	9.5 %
Selling, general and administrative	269,227	160,837	108,390	67.4 %	683,622	391,967	291,655	74.4 %
Amortization of intangible assets	188	187	1	0.5 %	563	658	(95)	(14.4)%
Total expenses	668,765	531,217	137,548	25.9 %	1,829,300	1,381,544	447,756	32.4 %
Loss from operations	(462,325)	(440,137)	(22,188)	5.0 %	(866,996)	(1,172,770)	305,774	(26.1)%
Interest (expense) income, net	(2,230)	(614)	(1,616)	263.2 %	(11,275)	7,184	(18,459)	(256.9)%
Other income, net	31,477	5,711	25,766	451.2 %	26,487	29,368	(2,881)	(9.8)%
Loss before income taxes	(433,078)	(435,040)	1,962	(0.5)%	(851,784)	(1,136,218)	284,434	(25.0)%
Income tax benefit	(19,223)	(8,423)	(10,800)	128.2 %	(24,083)	(8,344)	(15,739)	188.6 %
Net loss	(413,855)	(426,617)	12,762	(3.0)%	(827,701)	(1,127,874)	300,173	(26.6)%
Less: Net loss attributable to noncontrolling interest	—	(1,393)	1,393	(100.0)%	—	(3,713)	3,713	(100.0)%
Net loss attributable to BeiGene, Ltd.	$ (413,855)	$ (425,224)	$ 11,369	(2.7)%	$ (827,701)	$ (1,124,161)	$ 296,460	(26.4)%

Comparison of the Three Months Ended September 30, 2021 and 2020

Revenue

Total revenue increased to $206.4 million for the three months ended September 30, 2021, from $91.1 million for the three months ended September 30, 2020, primarily due to continued sales increases of our internally developed products and our in-licensed products from Amgen.

The following table summarizes the components of revenue for the three months ended September 30, 2021 and 2020, respectively:

	Three Months Ended September 30,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
Product revenue	$ 192,461	$ 91,080	$ 101,381	111.3 %
Collaboration revenue:				
Research and development service revenue	13,979	—	13,979	NM
Total collaboration revenue	13,979	—	13,979	NM
Total Revenue	$ 206,440	$ 91,080	$ 115,360	126.7 %

Net product revenues consisted of the following:

	Three Months Ended September 30,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
Tislelizumab	$ 76,980	$ 49,934	$ 27,046	54.2 %
BRUKINSA®	65,832	15,662	50,170	320.3 %
REVLIMID®	20,209	14,067	6,142	43.7 %
VIDAZA®	5,810	8,366	(2,556)	(30.6)%
XGEVA®	15,699	3,051	12,648	414.6 %
BLINCYTO®	5,040	—	5,040	NM
Pamiparib	1,516	—	1,516	NM
Other	1,375	—	1,375	NM
Total product revenue	$ 192,461	$ 91,080	$ 101,381	111.3 %

Net product revenue increased 111.3% to $192.5 million for the three months ended September 30, 2021, compared to $91.1 million in the prior year period, primarily due to continued increases in sales of tislelizumab in China and BRUKINSA® in the United States and China, as well as sales of pamiparib, which we began selling in China in May 2021, partially offset by decreased sales of the BMS products distributed in China. In addition, product revenues in the third quarter of 2021 were positively impacted by sales of Amgen's XGEVA® and BLINCYTO® in China, which we began distributing in July 2020 and August 2021, respectively.

Global sales of BRUKINSA® totaled $65.8 million in the third quarter, representing a 320% increase compared to the prior year period; U.S. sales of BRUKINSA® totaled $33.7 million in the third quarter compared to $5.7 million in the comparable prior year period. U.S. sales continued to accelerate in the quarter, driven by continued uptake in MCL and the recent FDA approvals in WM and MZL. BRUKINSA® sales in China totaled $32.1 million in the third quarter, representing growth of 223% compared to the prior year period, driven by a significant increase in all approved indications, including CLL. Additionally, we expect approval of our marketing authorization application for BRUKINSA® in WM in the European Union in the fourth quarter of 2021 and are expanding our commercial presence there in anticipation of launch.

Sales of tislelizumab in China totaled $77.0 million in the third quarter, representing a 54% increase compared to the prior year period. In the third quarter, new patient demand from broader reimbursement and further expansion of our salesforce and hospital listings continued to drive increased market penetration and market share for tislelizumab. We believe that our strategy during 2021 of expanding our salesforce and hospital listings and continuing to seek expanded labels in broad indications will allow us to increase our market share during the remainder of 2021 and into 2022.

We are preparing for the upcoming NRDL negotiations in China for our eligible medicines, including tislelizumab in first-line non-squamous non-small cell lung cancer (NSCLC), first-line squamous NSCLC and second- or third-line hepatocellular carcinoma (HCC), BRUKINSA® in WM, and pamiparib in germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy. We expect the NRDL negotiations to be completed in the fourth quarter of 2021. The inclusion of new indications or medicines may impact pricing and result in distributor compensation, which could affect revenue in the short term; however, we continue to believe in the opportunity for our medicines in China, including tislelizumab, and that reimbursement of broader indications will enable us to have further penetration and help many more patients, given our established commercial infrastructure in the core and broad markets.

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. In addition, BMS provided notice to us, which we dispute, purporting to terminate the License and Supply Agreement entered into by us and Celgene in July 2017 with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the License and Supply Agreement. We also expect revenues to be impacted by increased competition from generic products for REVLIMID® and the loss of volume-based procurement ("VBP") bidding for VIDAZA®. We do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE®, qualified drug is manufactured and available for sale in China, and the dispute regarding the termination notice is resolved. 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®.

Although the impact of COVID-19 on commercial activities in China lessened in the second half of 2020 and in the first nine months of 2021, there is continued uncertainty regarding the future potential impact of the pandemic both in China and the United States, as well as globally.

Collaboration revenue totaled $14.0 million for the three months ended September 30, 2021, which was recognized from deferred revenue for R&D services performed during the three months ended September 30, 2021 (see Footnote 3). We did not have any collaboration revenue during the three months ended September 30, 2020.

Cost of Sales

Cost of sales increased to $47.4 million for the three months ended September 30, 2021 from $21.1 million for the three months ended September 30, 2020, primarily due to increased product sales of tislelizumab, BRUKINSA®, and XGEVA®.

Gross Margin

Gross margin on global product sales increased to $145.0 million for the three months ended September 30, 2021, compared to $70.0 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 75.4% for the three months ended September 30, 2021, from 76.8% in the comparable period of the prior year. The decrease is primarily due to the lower price resulting from the listing of tislelizumab on the NRDL in March 2021 and was partially offset by a proportionally higher sales mix of global BRUKINSA® and tislelizumab compared to lower margin sales of in-licensed products. Pre-launch inventory carried at zero or low cost consumed during the three months ended September 30, 2021 and September 30, 2020 was immaterial and did not have a significant impact on our gross margin.

Research and Development Expense

Research and development expense increased by $2.9 million, or 0.8%, to $351.9 million for the three months ended September 30, 2021 from $349.1 million for the three months ended September 30, 2020. The following table summarizes external clinical, external non-clinical and internal research and development expense for the three months ended September 30, 2021 and 2020, respectively:

	Three Months Ended September 30,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 117,131	$ 111,037	$ 6,094	5.5 %
Upfront license fees	—	66,500	(66,500)	(100.0)%
Amgen co-development expense[1]	29,710	30,795	(1,085)	(3.5)%
Total external research and development expenses	146,841	208,332	(61,491)	(29.5)%
Internal research and development expenses	205,096	140,738	64,358	45.7 %
Total research and development expenses	$ 351,937	$ 349,070	$ 2,867	0.8 %

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended September 30, 2021 totaled $58.7 million, of which $29.7 million was recorded as R&D expense. The remaining $28.9 million was recorded as a reduction of the R&D cost share liability.

The decrease in external research and development expenses in the third quarter was primarily attributable to a decrease of $66.5 million related to upfront license fees under collaboration agreements as well as decreased spending on clinical trials related to BRUKINSA®, which were partially offset by milestone payments related to collaboration deals, as well as increased spending related to our early stage programs.

Internal research and development expense increased $64.4 million, or 45.7%, to $205.1 million, and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, as well as our continued efforts to internalize research and clinical trial activities, and included the following:

- $31.6 million increase of employee salary and benefits, primarily attributable to hiring more research and development personnel to support our expanding research and development activities;

- $18.4 million increase of facilities, depreciation, office expense, rental fees, and other expenses to support the growth of our organization;
- $5.5 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;
- $6.3 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
- $2.6 million increase of materials and reagent expenses, primarily in connection with the in-house manufacturing of drug candidates used for clinical purposes.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $108.4 million, or 67.4%, to $269.2 million for the three months ended September 30, 2021, from $160.8 million for the three months ended September 30, 2020. The increase was primarily attributable to the following:

- $50.9 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 emerging markets, and the hiring of more personnel to support our growing business;
- $32.2 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;
- $14.8 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, the United States and Europe; and
- $10.5 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, Net

Interest expense, net increased by $1.6 million, or 263.2%, to $2.2 million for the three months ended September 30, 2021, from $0.6 million for three months ended September 30, 2020. The increase in interest expense, net, was primarily attributable to decreased interest income resulting from lower interest rates, as well as increased interest expense resulting from increased debt balances.

Other Income, Net

Other income, net increased to $31.5 million for the three months ended September 30, 2021, from $5.7 million for the three months ended September 30, 2020. The increase was primarily attributable to the unrealized gain on our equity investment in Leap Therapeutics.

Income Tax Benefit

Income tax benefit was $19.2 million for the three months ended September 30, 2021, as compared to $8.4 million for the three months ended September 30, 2020. The income tax benefit for three months ended September 30, 2021 and September 30, 2020 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.

Comparison of the Nine Months Ended September 30, 2021 and 2020

Revenue

Total revenue increased to $962.3 million, or 360.9%, for the nine months ended September 30, 2021, from $208.8 million for the nine months ended September 30, 2020, primarily due to collaboration revenue from the Novartis arrangement,

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 nine months ended September 30, 2021 and 2020, respectively:

	Nine Months Ended September 30,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
Product revenue	$ 437,202	$ 208,774	$ 228,428	109.4 %
Collaboration revenue:				
License revenue	484,646	—	484,646	NM
Research and development service revenue	40,456	—	40,456	NM
Total collaboration revenue	525,102	—	525,102	NM
Total Revenue	$ 962,304	$ 208,774	$ 753,530	360.9 %

Net product revenues consisted of the following:

	Nine Months Ended September 30,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
Tislelizumab	$ 200,738	$ 99,877	$ 100,861	101.0 %
BRUKINSA®	130,345	23,353	106,992	458.2 %
REVLIMID®	46,984	38,914	8,070	20.7 %
VIDAZA®	12,771	26,198	(13,427)	(51.3)%
ABRAXANE®	—	17,381	(17,381)	(100.0)%
XGEVA®	33,491	3,051	30,440	997.7 %
BLINCYTO®	5,040	—	5,040	NM
Pamiparib	3,737	—	3,737	NM
Other	4,096	—	4,096	NM
Total product revenue	$ 437,202	$ 208,774	$ 228,428	109.4 %

Net product revenue increased 109.4% to $437.2 million for the nine months ended September 30, 2021, compared to $208.8 million in the prior year period, primarily due to increased sales of tislelizumab in China and BRUKINSA® in the United States and China, as well as sales of pamiparib, which we began selling in China in May 2021, partially offset by decreased sales of the BMS products distributed in China. In addition, product revenues in the nine months ended September 30, 2021 were positively impacted by sales of Amgen's XGEVA® and BLINCYTO® in China, which we began distributing in July 2020 and August 2021, respectively.

Product revenues in the nine months ended September 30, 2021 were negatively impacted by an adjustment of $28.1 million as a result of compensating distributors for products that remained in the distribution channel which were sold during the first 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 nine months ended September 30, 2021, 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.

Global sales of BRUKINSA® totaled $130.3 million in the nine months ended September 30, 2021, representing a 458% increase compared to the prior year period; U.S. sales of BRUKINSA® totaled $59.8 million in the nine months ended September 30, 2021 compared to $9.5 million in the comparable prior year period. U.S. sales continued to accelerate in the period, driven by continued uptake in MCL and the recent FDA approvals in WM and MZL. BRUKINSA® sales in China totaled $70.5 million in the nine months ended September 30, 2021, representing growth of 408% compared to the prior year period, driven by a significant increase in all approved indications, including CLL.

Sales of tislelizumab in China totaled $200.7 million in the nine months ended September 30, 2021, representing a 101% increase compared to the prior year period. In the nine months ended September 30, 2021, new patient demand from broader reimbursement and further expansion of our salesforce and hospital listings continued to drive increased market penetration and market share for tislelizumab.

Collaboration revenue totaled $525.1 million for the nine months ended September 30, 2021. $484.6 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 $40.5 million was recognized from deferred revenue for R&D services performed during the nine months ended September 30, 2021 (see Footnote 3). We did not have any collaboration revenue during the nine months ended September 30, 2020.

Cost of Sales

Cost of sales increased to $116.4 million for the nine months ended September 30, 2021 from $49.6 million for the nine months ended September 30, 2020, primarily due to increased product sales of tislelizumab, BRUKINSA®, and Amgen products, and were partially offset by lower sales of BMS in-licensed products.

Gross Margin

Gross margin on global product sales increased to $320.8 million for the nine months ended September 30, 2021, compared to $159.2 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 73.4% for the nine months ended September 30, 2021, from 76.3% in the comparable period of the prior year. The decrease is primarily due to the impact of the accrued compensation in the first quarter of 2021 to customers for sales of tislelizumab, BRUKINSA®, and XGEVA® that remained in the channel and were sold at the pre-NRDL price, as well as the ongoing lower prices resulting from the listing on the NRDL. These negative impacts to our gross margin were partially offset by a proportionally higher sales mix of global BRUKINSA® sales compared to lower margin sales of in-licensed products. Pre-launch inventory carried at zero or low cost consumed during the nine months ended September 30, 2021 and September 30, 2020 was immaterial and did not have a significant impact on our gross margin.

Research and Development Expense

Research and development expense increased by $89.4 million, or 9.5%, to $1,028.8 million for the nine months ended September 30, 2021 from $939.3 million for the nine months ended September 30, 2020. The following table summarizes external clinical, external non-clinical and internal research and development expense for the nine months ended September 30, 2021 and 2020, respectively:

	Nine Months Ended September 30,		Changes	
	2021	2020	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 336,564	$ 353,953	$ (17,389)	(4.9)%
Upfront license fees	53,500	109,500	(56,000)	(51.1)%
Amgen co-development expense[1]	85,040	87,498	(2,458)	(2.8)%
Total external research and development expenses	475,104	550,951	(75,847)	(13.8)%
Internal research and development expenses	553,650	388,389	165,261	42.6 %
Total research and development expenses	$ 1,028,754	$ 939,340	$ 89,414	9.5 %

1 Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the nine months ended September 30, 2021 totaled $167.9 million, of which $85.0 million was recorded as R&D expense. The remaining $82.8 million was recorded as a reduction of the R&D cost share liability.

The decrease in external research and development expenses in the nine months ended September 30, 2021 was primarily attributable to a decrease of $56.0 million related to upfront license fees under collaboration agreements, decreases in external spending for BRUKINSA® and pamiparib, and a decrease in the expense recognized on co-development fees to Amgen.

Internal research and development expense increased $165.3 million, or 42.6%, to $553.7 million and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, as well as our continued efforts to internalize research and clinical trial activities, and included the following:

- $84.1 million increase of employee salary and benefits, primarily attributable to hiring more research and development personnel to support our expanding research and development activities;
- $39.2 million increase of facilities, depreciation, office expense, rental fees, and other expenses to support the growth of our organization;
- $19.2 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;
- $14.2 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
- $8.4 million increase of materials and reagent expenses, primarily in connection with the in-house manufacturing of drug candidates used for clinical purposes.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by $291.7 million, or 74.4%, to $683.6 million, for the nine months ended September 30, 2021, from $392.0 million for the nine months ended September 30, 2020. The increase was primarily attributable to the following:

- $128.4 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 emerging markets, and the hiring of more personnel to support our growing business;
- $99.1 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;
- $34.7 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, the United States and Europe; and
- $29.4 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 $18.5 million, or 256.9%, to $11.3 million of net interest expense for the nine months ended September 30, 2021, from $7.2 million of net interest income for nine months ended September 30, 2020. The decrease in interest income, net, was primarily attributable to decreased interest income, as a result of lower interest rates, as well as increased interest expense, resulting from higher debt balances.

Other Income, Net

Other income, net decreased to $26.5 million for the nine months ended September 30, 2021, from $29.4 million for the nine months ended September 30, 2020. The income in the current year period was primarily due to the unrealized gain on our investment in Leap Therapeutics. The income in the prior year period resulted from unrealized gains on equity investments, as well as a gain recognized in conjunction with the deconsolidation of MapKure.

Income Tax Benefit

Income tax benefit was $24.1 million for the nine months ended September 30, 2021, as compared to $8.3 million for the nine months ended September 30, 2020. The income tax benefit for nine months ended September 30, 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.

Liquidity and Capital Resources

The following table represents our cash, short-term investments, and debt balances as of September 30, 2021 and December 31, 2020:

	As of	
	September 30, 2021	December 31, 2020
	(dollars in thousands)	
Cash, cash equivalents and restricted cash	$ 1,389,696	$ 1,390,005
Short-term investments	$ 2,533,617	$ 3,268,725
Total debt	$ 643,278	$ 518,652

With the exception of the periods in which we received 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 losses of $413.9 million and $827.7 million, respectively, for the three and nine months ended September 30, 2021, and net losses of $426.6 million and $1.1 billion, respectively, for the three and nine months ended September 30, 2020. As of September 30, 2021, we had an accumulated deficit of $4.4 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 September 30, 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.

On June 28, 2021, the Listing Committee of the Science and Technology Innovation Board (the “STAR Market") of the Shanghai Stock Exchange (the "SSE") approved the listing application which we submitted in January 2021 to the SSE for a proposed public offering of our ordinary shares and listing of such shares on 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. On July 28, 2021, we filed a registration application for the STAR Offering with the China Securities Regulatory Commission ("CSRC"), including an updated prospectus. The consummation of STAR Offering is subject to, among other things, market conditions and additional regulatory approvals, including registration granted by the China Securities Regulatory Commission.

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 nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
	(dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 1,390,005	$ 620,775
Net cash used in operating activities	(790,884)	(951,127)
Net cash provided by (used in) investing activities	531,549	(3,081,441)
Net cash provided by financing activities	252,257	4,877,168
Net effect of foreign exchange rate changes	6,769	4,340
Net (decrease) increase in cash, cash equivalents, and restricted cash	(309)	848,940
Cash, cash equivalents and restricted cash at end of period	$ 1,389,696	$ 1,469,715

Operating Activities

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

Operating activities used $790.9 million of cash in the nine months ended September 30, 2021, which resulted principally from our net loss of $827.7 million and an increase in our net operating assets and liabilities of $107.0 million, partially offset by non-cash charges of $143.8 million. The non-cash charges were primarily driven by share-based compensation expense, charges for acquired in-process research and development costs, and depreciation and amortization expense, offset by amortization of the research and development cost share liability and deferred income tax benefits. The increase in working capital was driven largely by increases in accounts receivable, inventory and prepaid expenses, and a decrease in accounts payable and accrued expenses, partially offset by an increase in deferred revenue resulting from the upfront payment from Novartis.

Operating activities used $951.1 million of cash in the nine months ended September 30, 2020, which resulted principally from our net loss of $1.1 billion, partially offset by non-cash charges of $133.3 million and a decrease in our net operating assets and liabilities of $43.5 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 primarily by an increase in accounts payable and accrued expenses and a decrease in accounts receivable, partially offset by increases in inventories and other assets and a decrease in other long-term 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 $531.5 million of cash in the nine months ended September 30, 2021, consisting of sales and maturities of investment securities of $2.8 billion, offset by $2.1 billion in purchases of investment securities, capital expenditures of $148.0 million, $8.5 million of acquired in-process research and development, and a $7.5 million collaboration milestone payment.

Investing activities used $3.1 billion of cash in the nine months ended September 30, 2020, consisting of $4.9 billion in purchases of investment securities, $89.5 million of acquired in-process research and development, capital expenditures of $82.8 million, and cash outflows for the deconsolidation of a subsidiary of $2.0 million, all of which were offset by sales and maturities of investment securities of $2.0 billion.

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 $252.3 million of cash in the nine months ended September 30, 2021, consisting primarily of $143.5 million from proceeds of short-term bank loans, $82.2 million from the exercise of employee share options and proceeds from the issuance of shares through our employee share purchase plan, $50.0 million from the sale of our shares to Amgen, and

$16.8 million from proceeds of long-term bank loans. These inflows were partially offset by $40.2 million of repayment of short-term bank loans.

Financing activities provided $4.9 billion of cash in the nine months ended September 30, 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 $2.1 billion from a registered direct offering of ordinary shares to certain existing investors, $75.8 million from the exercise of employee share options and proceeds issuance of shares through our employee share purchase plan, $64.3 million from proceeds of a long-term bank loan, and $49.0 million from proceeds of short-term bank loans. These inflows were partially offset by the repayment of the Shareholder Loan principal with GET and the prepayment $28.7 million of the remaining 5% minority interest in BeiGene Biologics. On October 9, 2020, the Company drew down $198.3 million of additional debt related to the JV share repurchase and Shareholder Loan repayment.

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 September 30, 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	$ 61,174	$ 4,859	$ 37,007	$ 18,000	$ 1,308
Purchase commitments	268,498	190,897	33,184	30,757	13,660
Debt obligations	643,278	442,372	35,873	75,234	89,799
Interest on debt	71,513	36,592	17,390	12,162	5,369
Co-development funding commitment	851,124	311,750	539,374	—	—
Funding commitment	13,500	4,500	4,500	4,500	—
Research and development commitment	74,392	50,617	11,744	12,031	—
Pension plan	7,863	1,285	2,570	2,570	1,438
Capital commitments	57,720	57,720	—	—	—
Total	$ 2,049,062	$ 1,100,592	$ 681,642	$ 155,254	$ 111,574

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 office facilities 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 September 30, 2021, purchase commitments amounted to $268.5 million, of which $77.6 million related to minimum purchase requirements for supply purchased from contract manufacturers and $190.9 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 September 30, 2021 (amounts in thousands, except for percentage data):

Lender	Agreement Date	Line of Credit	Term	Maturity Date	Interest Rate	September 30, 2021	
						$	RMB
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	776	5,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	1,164	7,500
China Minsheng Bank (the "Senior Loan")	September 24, 2020	$200,000		(3)	5.8 %	198,320	1,277,835
Zhuhai Hillhouse (the "Related Party Loan")	September 24, 2020	RMB500,000		(4)	5.8 %	15,520	100,000
Other short-term debt (5)						226,592	1,460,000
Total short-term debt						442,372	2,850,335
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	89,085	574,000
China Merchants Bank	January 22, 2020	(2)	9-year	January 20, 2029	(2)	53,156	342,500
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(6)	58,665	378,000
Total long-term bank loans						200,906	1,294,500

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 September 30, 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. The Company repaid $155 (RMB1,000) during the nine months ended September 30, 2021.

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 September 30, 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 September 8, 2022. The Company drew down $143,456 (RMB930,082) during the nine months ended September 30, 2021. The Company repaid $40,074 (RMB260,000) of the short-term loans in the nine months ended September 30, 2021. The weighted average interest rate for the short-term working capital loans was approximately 4.3% as of September 30, 2021. One of the short-term working capital loans outstanding in the amount of $9,312 (RMB60,000) 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 September 30, 2021. The Company drew down $16,838 (RMB107,794) during the nine months ended September 30, 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 September 30, 2021, our remaining co-development funding commitment was $0.85 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 September 30, 2021, our remaining capital commitment was $13.5 million and is expected to be paid from time to time over the investment period.

Research and Development Commitment

We entered into a long-term research and development agreement during the three months ended September 30, 2021, which includes obligations to make an upfront payment and fixed quarterly payments over the next five years. As of September 30, 2021, the total research and development commitment amounted to $74.4 million.

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 September 30, 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 $57.7 million for the acquisition of property, plant and equipment as of September 30, 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 contract research organizations to provide research and development services. These contracts are generally cancellable 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 and nine months ended September 30, 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 and nine months ended September 30, 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 $1.4 billion and $1.4 billion, restricted cash of $6.4 million and $8.1 million, and short-term investments of $2.5 billion and $3.3 billion at September 30, 2021 and December 31, 2020, respectively. At September 30, 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 September 30, 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 $19.6 million or an increase of $3.2 million, respectively, as of September 30, 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 appreciated approximately 0.3% in the nine months ended September 30, 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 nine months ended September 30, 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 September 30, 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 September 30, 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, "BMS-Celgene"), we initiated an arbitration proceeding at the International Chamber of Commerce (the "ICC") against BMS-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 BMS-Celgene in July 2017 and a related quality agreement (collectively, the "BMS-Celgene License"). Under the BMS-Celgene License, we allege that BMS-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 (i) a declaration that BMS-Celgene was and is in breach of the Agreement, (ii) a declaration that BMS-Celgene acted with gross negligence and/or willful misconduct, (iii) an award of damages, and (iv) such other relief as the arbitrators deem appropriate. BMS-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. On October 6, 2021, BMS-Celgene delivered a notice to us purporting to terminate the BMS-Celgene License with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the BMS-Celgene License. We believe that the reasons stated in the notice do not provide a valid basis for terminating the BMS-Celgene License with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS-Celgene to reduce its damages in the on-going arbitration proceedings described above. We intend to contest the purported termination vigorously.

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®, BLINCYTO® and KYPROLIS® were first approved in China in May 2019, December 2020 and July 2021, respectively.

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"), which was later approved in the United States for additional indications for the treatment of certain patients with WM (September 2021) and relapsed or refractory (R/R) marginal zone lymphoma (MZL) (September 2021). We also 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 Waldenström's macroglobulinemia (WM) (June 2021). Additionally, we received approvals for BRUKINSA in Canada, Australia, and other markets for certain indications. For tislelizumab, we received approval 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), squamous non-small cell lung cancer ("NSCLC") (January 2021), advanced non-squamous NSCLC (June 2021), and hepatocellular carcinoma ("HCC") (June 2021). For pamiparib, we received approval in China for the treatment of certain patients with ovarian, fallopian tube, or primary peritoneal cancer (May 2021).

We continue to build our salesforce in the United States, China, Europe, and other countries and regions 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.

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 comprehensive 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 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 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, BRUKINSA®, tislelizumab and pamiparib 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.

****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, zanubrutinib and pamiparib at our own manufacturing facilities in China, we are planning to build a commercial-stage biologics manufacturing and clinical R&D center in New Jersey and we are constructing a new small molecule manufacturing campus in Suzhou, 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 become 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 had been working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at its current manufacturing site and/or 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®. On August 16, 2021, BMS informed us that it planned to file a supplementary application in the fourth quarter of 2021 to register a new facility as the manufacturing site for ABRAXANE® for the China market, with an initial projection that the application could be approved by the NMPA in the fourth quarter of 2022. On October 6, 2021, BMS delivered a notice to us purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license agreement with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS to reduce its damages in the on-going arbitration proceedings described in Item 1, Legal Proceedings, above. We intend to contest the purported termination vigorously. We do not know when the NMPA suspension of ABRAXANE® will be lifted, or if 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®, qualified drug is manufactured and available for sale in China and the dispute regarding the termination notice is resolved.

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 the demand for these medicines has increased after inclusion in the NDRL, there can be no assurance that demand will continue to increase and 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. In addition, we are preparing for the upcoming NRDL negotiations in China for our eligible medicines, including tislelizumab in NSCLC and HCC, BRUKINSA® in WM, and pamiparib. We expect the NRDL negotiations to be completed in the fourth quarter of 2021. If any of these medicines are not included in the NRDL, the revenues for such medicines could be limited, which could have a material adverse effect on our business, financial condition and results of operations. Even if such medicines are included in the NRDL, they may be included at prices that are significantly lower than our current prices, reducing our margins, which could have a material adverse effect on our business, financial condition and results of operations. We expect annual NRDL negotiations to recommence in 2022.

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 Europe, 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 ("GDPR"), the Data Security Law of the PRC, and the Personal Information Protection Law of the PRC.

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, Canada, 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 or actions taken by U.S. or China governmental authorities on companies with significant operations in the U.S. and China, such as us;
- 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 or obtain reimbursement at a commercially viable level 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 had been working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and/or 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®. On August 16, 2021, BMS informed us that it planned to file a supplementary application in the fourth quarter of 2021 to register a new facility as the manufacturing site for ABRAXANE® for the China market, with an initial projection that the application could be approved by the NMPA in the fourth quarter of 2022. On October 6, 2021, BMS delivered a notice to us purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license agreement with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS to reduce its damages in the on-going arbitration proceedings described in Item 1, Legal Proceedings, above. We intend to contest the purported termination vigorously. 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 May 2021, 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. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily suspended. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021, announced plans to continue progress toward resuming standard operation levels. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

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 had been working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and/or application to qualify an alternative manufacturing site for China supply. On August 16, 2021, BMS informed us that it planned to file a supplementary application in the fourth quarter of 2021 to register a new facility as the manufacturing site for ABRAXANE® for the China market, with an initial projection that the application could be approved by the NMPA in the fourth quarter of 2022. On October 6, 2021, BMS delivered a notice to us purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license agreement with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS to reduce its damages in the on-going arbitration proceedings described in Item 1, Legal Proceedings, above. We intend to contest the purported termination vigorously.

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 medicine's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the medicine 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 accelerated approval of BRUKINSA® in the United States and China and certain approvals of tislelizumab, pamiparib, XGEVA®, BLINCYTO®, KYPROLIS® and QARZIBA® 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 Europe do not follow price structures of the U.S. and generally prices tend to be significantly lower. Countries in Europe provide options 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. Countries 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 continues to be scrutiny from federal and state governments over the way drug manufacturers set prices for their marketed products. For example, there are ongoing Congressional investigations, legislation, and regulations to, among other things, bring more transparency to drug pricing, set patient spending caps for Medicare beneficiaries , reduce the cost of

prescription drugs under Medicare, review the relationship between pricing and manufacturer's patient programs, reform federal and state government program reimbursement methodologies for drug products, allow importation of lower-priced drugs from Canada, and set prices based on international reference pricing in other countries. While some of these measures can be done through agency rulemaking, most will require statutory changes by Congress. While addressing drug pricing and patient affordability remains a top priority for Congress, it remains to be seen if any agreement can be reached on a legislative solution. It is therefore unclear if any regulations or legislation will be enacted to implement changes to drug pricing or federal and state government reimbursement programs 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 Europe, 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 data exclusivity (referred to as regulatory data protection) are still developing. The PRC Patent Law (as amended in 2020, the "Amended PRC Patent Law"), which became effective on June 1, 2021, contains both patent term extension and a mechanism for early resolution of patent disputes. Accordingly, NMPA and NIPA jointly issued the Implementation Measures for the Early Settlement Mechanism of Drug Patent Disputes (for Trial Implementation), which became effective on July 4, 2021. However, the provisions for patent term extension 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 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 medicine;

- regulatory authorities may withdraw approvals or revoke licenses of the medicine, 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, Europe 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. On June 17, 2021, the U.S. Supreme Court upheld the validity 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.

On July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition.

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 September 30, 2021 and December 31, 2020, we had an accumulated deficit of $4.4 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 used $790.9 million and $951.1 million of net cash during the nine months ended September 30, 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 $1.4 billion, $1.4 billion and $618.0 million, restricted cash of $6.4 million, $8.1 million and $2.8 million and short-term investments of $2.5 billion, $3.3 billion and $364.7 million as of September 30, 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 September 30, 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, Europe 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, medicines, 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; 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; and the use of PD-L1/PD-1/PD-2 binding antagonist and TIGIT antagonist to treat cancers that are relevant to ociperlimab for which patents are expected to expire in 2034. 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.***

We currently have manufacturing facilities that are used for clinical-scale and commercial-scale manufacturing and processing, we plan to build a commercial-stage biologics manufacturing and clinical R&D center in New Jersey, and we are also constructing a new small molecule manufacturing campus in Suzhou, China. However, 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®, BLINCYTO® and KYPROLIS® 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 2018 and 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 had been working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and/or 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®. On August 16, 2021, BMS informed us that it planned to file a supplementary application in the fourth quarter of 2021 to register a new facility as the manufacturing site for ABRAXANE® for the China market, with an initial projection that the application could be approved by the NMPA in the fourth quarter of 2022. On October 6, 2021, BMS delivered a notice to us purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS to reduce its damages in the on-going arbitration proceedings described in Item 1, Legal Proceedings, above. We intend to contest the purported termination vigorously. 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 is expected to 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, or if 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®, qualified drug is manufactured and available for sale in China and the dispute regarding the termination notice is resolved.

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. Vaccines for COVID-19 have been approved by the FDA and more vaccines or treatments are likely to be authorized. The resultant demand for vaccines and treatments 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 had been working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and/or 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®. On August 16, 2021, BMS informed us that it planned to file a supplementary application in the fourth quarter of 2021 to register a new facility as the manufacturing site for ABRAXANE® for the China market, with an initial projection that the application could be approved by the NMPA in the fourth quarter of 2022. On

October 6, 2021, BMS delivered a notice to us purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license agreement with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS to reduce its damages in the on-going arbitration proceedings described in Item 1, Legal Proceeding, above. We intend to contest the purported termination vigorously. 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, qualified drug is manufactured and available for sale in China and the dispute regarding the termination notice is resolved, 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 had been 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®. On October 6, 2021, BMS delivered a notice to us purporting to terminate the license agreement with respect to ABRAXANE® and providing 180-days' notice that it was withdrawing ABRAXANE® from the range of products for sale or distribution in China pursuant to Section 2.6 of the license agreement. We believe that the reasons stated in the notice do not provide a valid basis for terminating the license agreement with respect to ABRAXANE®, and that the notice is a tactical maneuver on the part of BMS to reduce its damages in the on-going arbitration proceedings described in Item 1, Legal Proceedings, above. We intend to contest the purported termination vigorously. 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 license agreement 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 license agreement, 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;
- 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 LUMAKRAS™ (sotorasib), a first-in-class 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 to some extent upon third-party CROs to monitor and manage data and provide other services 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 September 30, 2021, we had over 7,600 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.

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 play a critical role in the Company's operation and development. 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 and plan to build a commercial-stage biologics manufacturing and clinical R&D center in New Jersey, United States. We are also constructing a new small molecule manufacturing campus in 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. For example, we may not be able to complete the construction and validation of and obtain regulatory approval for the new manufacturing and clinical R&D center in New Jersey and the new manufacturing campus in Suzhou in a timely or economic manner.

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. We have also applied to conduct a public offering of our ordinary shares and initial listing of such shares on the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange ("SSE"). 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, SSE if we complete our listing on the STAR Market, 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 U.S. 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 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. The Data Security Law of the PRC became effective on September 1, 2021. One of this law's primary goals is to ensure data security by establishing an overarching regulatory regime over data processors who process "important data" in China and subjecting such processors to a number of regulatory obligations, *e.g.*, such a processor shall have dedicated personnel and internal policies and procedures to ensure compliance. The term "data" is broadly defined under this law to include "any records of information that are in electronic or other forms," however, the scope of "important data" remains unclear, and the Chinese regulatory authorities are expected to issue a separate Catalogue of Important Data in the near future. Further, this law also expressly and plainly prohibits entities in China from transferring "any data that is stored in China" to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. At this point, it is still unclear how this seemingly categorical prohibition will be enforced, but given its broad scope and impact it may have if enforced as is, it is expected that the State Council and relevant Chinese regulators will enact implementing rules to further clarify the scope and application of such requirement. The Personal Information Protection Law of the PRC became effective on November 1, 2021, which further specifies the conditions for providing personal information to overseas recipients, including conducting security assessment and personal information protection certification as well as entering into contractual arrangements with overseas information recipients.

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, despite progress in vaccination efforts, 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. The extent to which such measures are removed or new measures are put in place will depend upon how the pandemic evolves, as well as the distribution of available vaccines, the rates at which they are administered and the emergence of new variants of the virus. 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, including the continued emergence of new variants, developments or perceptions regarding the safety of vaccines, or any additional preventative and protective actions taken to contain the pandemic or treat its impact, 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. We will continue to monitor the latest disruptions and uncertainties relating to the COVID-19 pandemic, including the pace of vaccinations and the emergence of new and more contagious strains of the virus, and any resulting impact on our business, financial condition, results of operations and prospects. Any resulting financial impact cannot be reasonably estimated at this time and may have a material adverse impact on our business, financial condition and results of operations.

Environmental regulation of our business, as a response to climate change, could adversely impact us by increasing our compliance costs and could have a material adverse effect on our results and financial condition.

There has been a broad range of proposed and promulgated state, national and international regulation aimed at reducing the effects of climate change. Such regulations apply or could apply in countries where we have interests or could have interests in the future. Such regulation could result in additional costs in the form of taxes and investments of capital to maintain compliance with laws and regulations.

Climate change regulations continue to evolve, and while it is not possible to accurately estimate either a timetable for implementation or our future compliance costs relating to implementation, it is possible that such regulation could have a material effect in the foreseeable future on our business, results of operations, capital expenditures or financial position.

Our financial and operating performance may be adversely affected by adverse weather conditions, natural disasters and other catastrophes.

We have manufacturing facilities in Suzhou and Guangzhou, China. A significant disruption at these facilities, even on a short-term basis, could impair our ability to timely produce products, which could have a material adverse effect on our business, financial position and results of operations. Our manufacturing operations are vulnerable to interruption and damage from natural and other types of disasters, including earthquake, fire, floods, environmental accidents, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously impaired. For example, our Guangzhou manufacturing facility was hit by a typhoon in 2019, but the typhoon did not cause material damage to the facility. However, the boundary area and the adjacent land were flooded, causing a power outage for a few days. Afterwards, we built a gutter along the boundary and installed waterproof electricity cables to fortify the facility and to help prevent future interruptions.

In addition, we do not maintain any insurance other than property insurance for some of our buildings, vehicles and equipment. Accordingly, unexpected business interruptions resulting from disasters could disrupt our operations and thereby result in substantial costs and diversion of resources. Our production process requires a continuous supply of electricity. We have encountered power shortages historically in China due to restricted power supply to industrial users during summers when the usage of electricity is high and supply is limited or as a result of damage to the electricity supply network. Because the duration of those power shortages was brief, they had no material impact on our operations. Longer interruptions of electricity supply could result in lengthy production shutdowns, increased costs associated with restarting production and the loss of production in progress. Any major suspension or termination of electricity or other unexpected business interruptions could have a material adverse impact on our business, financial condition and results of operations.

Climate change manifesting as physical or transition risks could have a material adverse impact on our business operations, clients and customers.

The long-term effects of climate change are difficult to assess and predict. Our business and the activities of our clients and customers could be impacted by climate change. Climate change could manifest as a financial risk either through changes in the physical climate or from the process of transitioning to a low-carbon economy, including changes in climate policy or in the regulation of companies with respect to risks posed by climate change.

The physical impacts of climate change may include physical risks (such as rising sea levels or frequency and severity of extreme weather conditions), social and human effects (such as population dislocations or harm to health and well-being), compliance costs and transition risks (such as regulatory or technology changes) and other adverse effects. The effects could impair, for example, the availability and cost of certain products, commodities and energy (including utilities), which in turn may impact our ability to procure goods or services required for the operation of our business at the quantities and levels we require. We bear losses incurred as a result of, for example, physical damage to or destruction of our facilities, loss or spoilage

of inventory, and business interruption due to weather events that may be attributable to climate change could materially adversely affect our business operations, financial position or results of operation.

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. In July 2021, the PRC government provided new guidance on China-based companies raising capital outside of China, including through arrangements called variable interest entities (VIEs). In light of such developments, the SEC has imposed enhanced disclosure requirements on China-based companies seeking to register securities with the SEC. Although we do not have a VIE structure, due to our extensive operations in China and stock listings outside of China, any future PRC, US or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could 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.

In recent years, U.S. regulatory authorities have continued to express their concerns about challenges in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. More recently, 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, the United States enacted the Holding Foreign Companies Accountable Act (the "HFCA Act") 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, which became effective on May 5, 2021. The interim final rule applies 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. On May 13, 2021, the PCAOB issued proposed PCAOB Rule 6100 Board Determinations Under the Holding Foreign Companies Accountable Act for public comment. The proposed rule provides a framework for making determinations as to whether PCAOB is unable to inspect an audit firm in a foreign jurisdiction, including the timing, factors, bases, publication and revocation or modification of such determinations, and such determinations will be made on a jurisdiction-wide basis in a consistent manner applicable to all firms headquartered in the jurisdiction. Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act (the "AHFCA Act"), which if enacted into law would amend the HFCA Act and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three. 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 or two years if the AHFCA Act is enacted, 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 have evaluated, designed and are implementing additional business processes and control changes 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 prior to the three-year (or two-year under AHFCA Act) deadline of the HFCA Act. 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."

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.

In addition, the PRC government has recently announced its plans to enhance its regulatory oversight of China-based companies listed overseas and cross-border law enforcement cooperation. The Opinions on Intensifying Crack Down on Illegal Securities Activities issued on July 6, 2021 called for:

- tightening oversight of data security, cross-border data flow and administration of classified information, as well as amendments to relevant regulation to specify responsibilities of overseas listed China-based companies with respect to data security and information security;
- enhanced oversight of overseas listed companies as well as overseas equity fundraising and listing by China-based companies; and
- extraterritorial application of China's securities laws.

As the Opinions on Intensifying Crack Down on Illegal Securities Activities were recently issued, there are great uncertainties with respect to the interpretation and implementation. The PRC government may promulgate laws, rules and regulations to impose additional and significant obligations and liabilities on overseas listed China-based companies regarding data security, cross-border data flow, and compliance with China's securities laws. As a company with extensive operations in China and stock listings outside of China, it is uncertain whether or how the new laws, rules and regulations and the interpretation and implementation may affect us. However, among other things, our ability to obtain external financing through the issuance of equity securities overseas could be adversely affected if restrictions on overseas fundraising are imposed on companies like us.

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 September 30, 2021 and December 31, 2020, these restricted assets totaled $622.8 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 reduced withholding rate arrangement and such non-PRC resident enterprises constitute the beneficiary of such income.

Pursuant to an arrangement between Mainland China and the Hong Kong Special Administrative Region (the "Hong Kong Tax Treaty") and relevant tax regulations of the PRC, subject to certain conditions, a reduced withholding tax rate of 5% 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." We own the PRC subsidiaries through BeiGene HK. 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 October 31, 2021, 1,219,734,201 ordinary shares, par value $0.0001 per share, were outstanding, of which 978,399,318 ordinary shares were held in the form of 75,261,486 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 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 SSE. In June 2021, the Listing Committee of the STAR Market approved the listing application. 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, and additional regulatory approvals, including registration granted by the CSRC. 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 litigation 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, our shareholders approved the Sixth Amended and Restated Memorandum and Articles of Association, which will become effective and will be filed with the Cayman Islands Registrar of Companies conditioned on and subject to the listing of the RMB Shares on the STAR Market. The Sixth Amended and Restated Memorandum and Articles of Association 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 Sixth Amended and Restated Memorandum and Articles of Association 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 59% of our outstanding ordinary shares as of October 31, 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.

On September 10, 2021, we issued an aggregate of 165,529 ADSs, representing 2,151,877 ordinary shares, to Amgen Inc. for total consideration of approximately $50 million, in a private placement pursuant to a Share Purchase Agreement dated October 31, 2019, as amended on December 6, 2019 and September 24, 2020, by and between Amgen and us. The securities were issued in a private placement in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), for transactions by an issuer not involving a public offering, and/or Regulation D under the Securities Act. All certificates evidencing the shares will bear a standard restrictive legend under the Securities Act.

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
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			

*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: November 4, 2021

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

Date: November 4, 2021

By: /s/ Julia Wang
Julia Wang
Chief Financial Officer
(Principal Financial and Accounting Officer)

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: November 4, 2021

/s/ JOHN V. OYLER

John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Julia Wang, 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: November 4, 2021

/s/ JULIA WANG

Julia Wang
Chief Financial 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 September 30, 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.

Date: November 4, 2021

/s/ JOHN V. OYLER

John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: November 4, 2021

/s/ JULIA WANG

Julia Wang
Chief Financial Officer
(Principal Financial and Accounting Officer)