UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 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: 001-35966

bluebird bio, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-3680878**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
60 Binney Street Cambridge , Massachusetts	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

(339) 499-9300

(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
Common Stock, $0.01 par value per share	BLUE	The NASDAQ Stock Market LLC

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

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

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

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

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

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

As of August 3, 2021, there were 67,578,549 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical studies;
- our ability to advance our viral vector and drug product manufacturing capabilities, and to ensure adequate supply of our viral vectors and drug products;
- the timing or likelihood of regulatory filings and approvals for our betibeglogene autotemcel (beti-cel), elivaldogene autotemcel (eli-cel), LentiGlobin for SCD, and our oncology product candidates;
- the timing or success of commercialization of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained;
- our ability to obtain adequate pricing and reimbursement of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our approved product, product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations and licenses;
- developments relating to our competitors and our industry;
- the impact of the COVID-19 pandemic;
- the timing, effects, costs, and benefits, including the tax treatment of the planned separation of our portfolio of products and programs into two independent, publicly-traded companies; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. 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.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Summary of the Material and Other Risks Associated with Our Business

Below is a summary of the material risks to our business, operations and the investment in our common stock. This summary does not address all of the risks that we face. Risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q in its entirety before making investment decisions regarding our common stock.

- We have limited experience as a commercial company and the marketing and sale of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, may be unsuccessful or less successful than anticipated.
- The commercial success of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates, will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community. Following marketing approval of beti-cel in the European Union, we did not reach agreement with payers on an acceptable price for reimbursement in our priority markets in Europe, and as a consequence, we are focusing on our severe genetic disease business on the U.S. market. If we fail to obtain sufficient pricing or reimbursement approval in the United States for beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, our revenues may be adversely affected and our business may suffer.
- If the market opportunities for our product or any future products are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.
- We rely on a complex supply chain for beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates. The manufacture and delivery of our lentiviral vectors and drug products present significant challenges for us, and we may not be able to produce our lentiviral vectors and drug products at the quality, quantities, locations or timing needed to support our clinical programs or commercialization following marketing approval, if and when obtained. In addition, we may encounter challenges with engaging or coordinating with qualified treatment centers needed to support commercialization.
- We cannot predict when or if we will obtain marketing approval to commercialize our product candidates, and any marketing approvals that we receive may ultimately be for more narrow indications than we expect.
- Insertional oncogenesis is a risk of gene therapies using viral vectors that can integrate into the genome, and a patient with CALD treated with eli-cel in one of our clinical studies has been diagnosed with myelodysplastic syndrome likely mediated by Lenti-D lentiviral vector insertion. As a result, the FDA has placed our clinical studies of eli-cel on clinical hold, and we can make no assurances as to when the clinical hold will be lifted, if ever. These events may require us to halt or delay further clinical development of our product candidates, such as eli-cel, or to suspend or cease commercialization following marketing approval, and the commercial potential of our product candidates may be materially and negatively impacted.
- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced, safer or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates following marketing approval, if and when obtained. If our competitors obtain orphan drug exclusivity for products that regulatory authorities determine constitute the same drug and treat the same indications as our product or any future products, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.
- We may not be successful in our efforts to identify or discover additional product candidates.
- We are dependent on BMS for the successful development and commercialization of idecabtagene vicleucel (ide-cel, marketed as ABECMA®) and bb21217. If BMS does not devote sufficient resources to the commercialization of ide-cel and the development of bb21217, is unsuccessful in its efforts, or chooses to terminate its agreements with us, our business will be materially harmed.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- From time to time, we will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

- Our business may be materially and adversely affected by the ongoing COVID-19 pandemic. The COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our business and that of third parties on which we rely. The extent to which the COVID-19 pandemic impacts our business will depend in part on future developments, which are uncertain and unpredictable in nature.
- The proposed separation of our business into two independent, publicly traded companies is subject to various risks and uncertainties and may not be completed on the terms or timeline currently contemplated, if at all, and will involve significant time, effort and expense, which could harm our business, results of operations and financial condition.

bluebird bio, Inc.

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

bluebird bio, Inc.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except par value amounts)

	As of June 30, 2021	As of December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 353,468	$ 317,705
Marketable securities	486,233	833,546
Prepaid expenses	33,726	37,472
Receivables and other current assets	16,597	16,116
Inventory	13,502	10,698
Total current assets	903,526	1,215,537
Marketable securities	101,927	122,891
Property, plant and equipment, net	158,820	162,831
Intangible assets, net	16,263	10,041
Goodwill	13,128	13,128
Operating lease right-of-use assets	190,993	184,019
Restricted cash and other non-current assets	69,802	72,805
Total assets	$ 1,454,459	$ 1,781,252
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 39,294	$ 21,602
Accrued expenses and other current liabilities	168,035	145,406
Operating lease liability, current portion	28,669	25,024
Deferred revenue, current portion	2,687	2,320
Collaboration research advancement, current portion	9,080	9,236
Total current liabilities	247,765	203,588
Deferred revenue, net of current portion	25,762	25,762
Collaboration research advancement, net of current portion	18,547	21,581
Operating lease liability, net of current portion	169,933	167,997
Other non-current liabilities	7,891	7,268
Total liabilities	469,898	426,196
Commitments and contingencies *(Note 9)*		
Stockholders' equity:		
Preferred stock, $0.01 par value, 5,000 shares authorized; 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value, 125,000 shares authorized; 67,551 and 66,432 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	676	665
Additional paid-in capital	4,337,719	4,260,443
Accumulated other comprehensive loss	(5,777)	(5,505)
Accumulated deficit	(3,348,057)	(2,900,547)
Total stockholders' equity	984,561	1,355,056
Total liabilities and stockholders' equity	$ 1,454,459	$ 1,781,252

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share data)

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Revenue:				
Service revenue	$ 5,314	$ 78,357	$ 11,232	$ 95,190
Collaborative arrangement revenue	1,670	109,674	3,190	111,976
Royalty and other revenue	488	10,859	5,845	13,587
Total revenues	7,472	198,890	20,267	220,753
Operating expenses:				
Research and development	144,315	156,308	298,793	310,431
Selling, general and administrative	78,576	68,628	165,451	141,876
Share of collaboration loss	10,071	—	10,071	—
Cost of royalty and other revenue	15,301	1,554	17,582	2,579
Change in fair value of contingent consideration	47	(1,655)	416	(4,763)
Total operating expenses	248,310	224,835	492,313	450,123
Loss from operations	(240,838)	(25,945)	(472,046)	(229,370)
Interest income, net	439	2,939	1,149	8,294
Other (expense) income, net	(1,087)	1,551	23,669	(2,896)
Loss before income taxes	(241,486)	(21,455)	(447,228)	(223,972)
Income tax expense	(216)	(10)	(282)	(104)
Net loss	$ (241,702)	$ (21,465)	$ (447,510)	$ (224,076)
Net loss per share - basic and diluted:	$ (3.58)	$ (0.36)	$ (6.66)	$ (3.86)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	67,487	60,384	67,233	57,987
Other comprehensive (loss) income:				
Other comprehensive (loss) income, net of tax benefit (expense) of $0.0 million and $(0.1) million for the three and six months ended June 30, 2021 and 2020, respectively.	(328)	399	(272)	(507)
Total other comprehensive (loss) income	(328)	399	(272)	(507)
Comprehensive loss	$ (242,030)	$ (21,066)	$ (447,782)	$ (224,583)

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(in thousands)

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2020	66,432	$ 665	$ 4,260,443	$ (5,505)	$ (2,900,547)	$ 1,355,056
Vesting of restricted stock units	294	3	(3)	—	—	—
Exercise of stock options	207	2	1,217	—	—	1,219
Purchase of common stock under ESPP	67	1	1,706	—	—	1,707
Stock-based compensation	—	—	36,090	—	—	36,090
Issuance of unrestricted stock awards to settle accrued employee compensation	422	4	12,009	—	—	12,013
Other comprehensive income	—	—	—	56	—	56
Net loss	—	—	—	—	(205,808)	(205,808)
Balances at March 31, 2021	67,422	$ 675	$ 4,311,462	$ (5,449)	$ (3,106,355)	$ 1,200,333
Vesting of restricted stock units	127	1	(1)	—	—	—
Exercise of stock options	2	—	36	—	—	36
Stock-based compensation	—	—	26,222	—	—	26,222
Other comprehensive loss	—	—	—	(328)	—	(328)
Net loss	—	—	—	—	(241,702)	(241,702)
Balances at June 30, 2021	67,551	$ 676	$ 4,337,719	$ (5,777)	$ (3,348,057)	$ 984,561

	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balances at December 31, 2019	55,368	$ 554	$ 3,568,184	$ (1,893)	$ (2,281,852)	$ 1,284,993
Vesting of restricted stock units	204	2	(2)	—	—	—
Exercise of stock options	20	—	750	—	—	750
Purchase of common stock under ESPP	28	—	1,872	—	—	1,872
Stock-based compensation	—	—	36,335	—	—	36,335
Other comprehensive loss	—	—	—	(906)	—	(906)
Net loss	—	—	—	—	(202,611)	(202,611)
Balances at March 31, 2020	55,620	$ 556	$ 3,607,139	$ (2,799)	$ (2,484,463)	$ 1,120,433
Issuance of common stock upon public offering, net of issuance costs of $33,465	10,455	105	541,431	—	—	541,536
Vesting of restricted stock units	114	1	(1)	—	—	—
Exercise of stock options	7	—	347	—	—	347
Stock-based compensation	—	—	40,781	—	—	40,781
Other comprehensive income	—	—	—	399	—	399
Net loss	—	—	—	—	(21,465)	(21,465)
Balances at June 30, 2020	66,196	$ 662	$ 4,189,697	$ (2,400)	$ (2,505,928)	$ 1,682,031

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	For the six months ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (447,510)	$ (224,076)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of contingent consideration	416	(4,763)
Depreciation and amortization	11,353	9,430
Stock-based compensation expense	73,687	84,822
(Gain) loss on equity securities	(28,286)	3,343
Excess inventory reserve	15,084	—
Other non-cash items	6,228	(1,841)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	13,923	(9,347)
Inventory	(17,404)	(4,466)
Operating lease right-of-use assets	15,074	11,085
Accounts payable	7,475	(14,042)
Accrued expenses and other liabilities	20,276	(14,025)
Operating lease liabilities	(16,468)	(10,131)
Deferred revenue	367	11,412
Collaboration research advancement	(3,190)	(3,779)
Net cash used in operating activities	(348,975)	(166,378)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(9,204)	(15,478)
Purchases of marketable securities	(196,145)	(101,421)
Proceeds from maturities of marketable securities	557,751	580,875
Proceeds from sales of marketable securities	31,318	29,878
Purchase of intangible assets	(2,000)	—
Net cash provided by investing activities	381,720	493,854
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of issuance costs	—	541,536
Proceeds from exercise of stock options and ESPP contributions	4,192	2,549
Net cash provided by financing activities	4,192	544,085
Increase in cash, cash equivalents and restricted cash	36,937	871,561
Cash, cash equivalents and restricted cash at beginning of period	373,728	381,709
Cash, cash equivalents and restricted cash at end of period	$ 410,665	$ 1,253,270
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 353,468	$ 1,198,768
Restricted cash included in receivables and other current assets	$ 2,687	$ —
Restricted cash included in restricted cash and other non-current assets	$ 54,510	$ 54,502
Total cash, cash equivalents and restricted cash	$ 410,665	$ 1,253,270
Supplemental cash flow disclosures from investing and financing activities:		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 1,508	$ 1,257
Right-of-use assets obtained in exchange for operating lease liabilities	$ 22,049	$ 14,663
Issuance of unrestricted stock awards to settle accrued employee compensation	$ 12,013	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of the business

bluebird bio, Inc. (the “Company” or “bluebird”) was incorporated in Delaware on April 16, 1992, and is headquartered in Cambridge, Massachusetts. The Company is a biotechnology company committed to researching, developing and commercializing, following marketing approval, potentially transformative gene therapies for severe genetic diseases and cancer. Since its inception, the Company has devoted substantially all of its resources to its research and development efforts relating to its product candidates, including activities to manufacture product candidates, conduct clinical studies of its product candidates, perform preclinical research to identify new product candidates and provide selling, general and administrative support for these operations, including commercial activities in Europe as well as commercial-readiness activities in the United States.

The Company’s programs in severe genetic diseases include programs for transfusion-dependent β-thalassemia, or TDT, sickle cell disease, or SCD, and cerebral adrenoleukodystrophy, or CALD. The Company’s programs in oncology are focused on developing novel engineered cell and gene therapies for cancer, including the anti-BCMA CAR T programs for multiple myeloma under the Company’s collaboration arrangement with Bristol-Myers Squibb ("BMS"). Please refer to Note 10, *Collaborative arrangements*, for further discussion of the Company’s collaboration with BMS.

In March 2021, BMS received marketing approval from the U.S. Food and Drug Administration for idecabtagene vicleucel (ide-cel, marketed as ABECMA®) as a treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. In July 2021, the Company received marketing approval from the European Commission for elivaldogene autotemcel (eli-cel; formerly Lenti-D gene therapy) as a treatment for patients less than 18 years of age with early cerebral adrenoleukodystrophy and without a matched sibling donor. In June 2019, the Company received conditional marketing authorization from the European Commission for betibeglogene autotemcel (beti-cel; formerly LentiGlobin for β-thalassemia gene therapy) as a treatment of patients 12 years and older with TDT who do not have a β^0/β^0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte-matched related HSC donor is not available.

In January 2021, the Company announced its intent to separate its severe genetic disease and oncology programs into two separate, independent publicly traded companies, bluebird bio, Inc. and 2seventy bio, Inc., a newly-formed Delaware corporation and wholly-owned subsidiary of the Company prior to the separation. bluebird bio, Inc. intends to retain focus on its severe genetic disease programs, with a focus on the U.S. market. As part of this strategy, bluebird bio, Inc. plans to execute an orderly wind down of its European operations. 2seventy bio, Inc. is expected to focus on the Company's oncology programs. The spin-off transaction is expected to be completed in late 2021 and is anticipated to be tax-free, subject to receipt of a favorable Internal Revenue Service (“IRS”) ruling.

In accordance with Accounting Standards Codification (“ASC”) 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. The Company has incurred losses since inception and to date has financed its operations primarily through the sale of equity securities and, to a lesser extent, through collaboration agreements and grants from governmental agencies and charitable foundations. As of June 30, 2021, the Company had an accumulated deficit of $3.35 billion. During the six months ended June 30, 2021, the Company incurred a loss of $447.5 million and used $349.0 million of cash in operations. The Company expects to continue to generate operating losses and negative operating cash flows for the next few years and will need additional funding to support its planned operating activities through profitability. The transition to profitability is dependent upon the successful development, approval, and commercialization of beti-cel, eli-cel, LentiGlobin for SCD, and its oncology product candidates, and the achievement of a level of revenues adequate to support its cost structure.

As of June 30, 2021, the Company had cash, cash equivalents and marketable securities of $941.6 million. The Company expects its cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months from the date of issuance of these financial statements, although it intends to pursue additional cash resources through public or private equity or debt financings or by establishing additional collaborations with other companies. Management's expectations with respect to its ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional

strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand its operations or commercialize products following marketing approval.

2. Basis of presentation, principles of consolidation and significant accounting policies

Basis of presentation

The accompanying condensed consolidated financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States (“GAAP”) as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. These condensed consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company’s financial position and results of operations for the interim periods ended June 30, 2021 and 2020.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on February 23, 2021.

Inventory in the prior year’s condensed consolidated financial statements has been reclassified to conform to the current presentation on the condensed consolidated balance sheets and condensed consolidated statements of cash flows. However, no subtotals in the prior year condensed consolidated financial statements were impacted as a result.

Amounts reported are computed based on thousands. As a result, certain totals may not sum due to rounding.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to GAAP. The Company views its operations and manages its business in one operating segment.

Significant accounting policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2021 are consistent with those discussed in Note 2 to the consolidated financial statements included in the Company’s 2020 Annual Report on Form 10-K, except as noted immediately below and as noted within the *"Recent accounting pronouncements - Recently adopted"* section.

Collaborative arrangement revenue

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808"), which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* ("Topic 606" or "ASC 606"). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606.

In arrangements where the Company does not deem its collaborator to be its customer, payments to and from its collaborator are presented in the condensed consolidated statements of operations based on the nature of the payments, as summarized in the table and further described below.

Nature of Payment	Statement of Operations Presentation
The Company's share of profits in connection with commercialization of products	Collaborative arrangement revenue
The Company's share of losses in connection with commercialization of products	Share of collaboration loss
Net reimbursement of the Company's research and development expenses	Collaborative arrangement revenue
Net reimbursement of the collaborator's research and development expenses	Research and development expense

Where the collaborator is the principal in the product sales, the Company recognizes its share of any profits or losses, representing net product sales less cost of goods sold and shared commercial and other expenses, in the period in which such underlying sales occur and costs are incurred by the collaborator. The Company also recognizes its share of costs arising from research and development activities performed by collaborators in the period its collaborators incur such expenses.

Royalty and other revenue

During the first half of 2021, the Company recognized an immaterial amount of product revenue related to the sale of beti-cel (marketed as ZYNTEGLO) in the European Union and the related cost of goods sold, which is included within royalty and other revenue and cost of royalty and other revenue, respectively.

Inventory

Inventories are stated at the lower of cost or net realizable value under the first-expired, first-out (FEFO) methodology. Given human gene therapy products are a new and novel category of therapeutics and future economic benefit is not probable until regulatory approval for the product has been obtained, the Company has only considered inventory for capitalization upon regulatory approval. Manufacturing costs incurred prior to regulatory approval for pre-launch inventory that did not qualify for capitalization and clinical manufacturing costs are charged to research and development expense in the Company’s condensed consolidated statements of operations and comprehensive loss as costs are incurred. Additionally, inventory that initially qualifies for capitalization but that may ultimately be used for the production of clinical drug product is expensed as research and development expense when it has been designated for the manufacture of clinical drug product.

Inventory consists of cell banks, plasmids, lentiviral vectors, other materials and compounds sourced from third party suppliers and utilized in the manufacturing process, and drug product, which has been produced for the treatment of specific patients, that are owned by the Company.

Management periodically reviews inventories for excess or obsolescence, considering factors such as sales forecasts compared to quantities on hand and firm purchase commitments as well as remaining shelf life of on hand inventories. The Company writes-down its inventory that is obsolete or otherwise unmarketable to its estimated net realizable value in the period in which the impairment is first identified. Any such adjustments are included as a component of cost of goods sold within cost of royalty and other revenue on the Company’s condensed consolidated statements of operations.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements. Estimates are used in the following areas, among others: future undiscounted cash flows and subsequent fair value estimates used to assess potential and measure any impairment of long-lived assets, including goodwill and intangible assets, and the measurement of right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, revenue recognition, income taxes, inventory capitalization, excess inventory analyses, and the assessment of the Company's ability to fund its operations for at least the next twelve months from the date of issuance of these financial statements.

Recent accounting pronouncements

Recently adopted

ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (“ASU 2019-12”), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard was effective beginning January 1, 2021. The adoption of ASU 2019-12 did not have a material impact on the Company's financial position or results of operations upon adoption.

ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity* (“ASU 2020-06”). ASU 2020-06 simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exception for contracts in an entity's own equity. The Company early adopted the new standard, effective January 1, 2021. The adoption of ASU 2020-06 did not have an impact on the Company's financial position or results of operations upon adoption.

ASU No. 2020-08, Codification Improvements to Subtopic 310-20, Receivables - Nonrefundable Fees and Other Costs

In October 2020, the FASB issued ASU 2020-08, *Codification Improvements to Subtopic 310-20, Receivables - Nonrefundable Fees and Other Costs* (“ASU 2020-08”) to provide further clarification and update the previously issued guidance in ASU 2017-08, *Receivables - Nonrefundable Fees and Other Costs (Subtopic 310-20: Premium Amortization on Purchased Callable Debt Securities)* (“ASU 2017-08”). ASU 2017-08 shortened the amortization period for certain callable debt securities purchased at a premium by requiring that the premium be amortized to the earliest call date. ASU 2020-08 requires that at each reporting period, to the extent that the amortized cost of an individual callable debt security exceeds the amount repayable by the issuer at the next call date, the excess premium shall be amortized to the next call date. The new standard was effective beginning January 1, 2021. The adoption of ASU 2020-08 did not have a material impact on the Company's financial position or results of operations upon adoption.

ASU No. 2020-10, Codification Improvements

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements* ("ASU 2020-10"). The amendments in this ASU represent changes to clarify the ASC, correct unintended application of the guidance, or make minor improvements to the ASC that are not expected to have a significant effect on current accounting practice or create a significant administrative cost to most entities. This new standard was effective beginning January 1, 2021. The adoption of ASU 2020-10 did not have a material impact on the Company's financial position or results of operations upon adoption.

3. Marketable securities

The following table summarizes the marketable securities held at June 30, 2021 and December 31, 2020 (in thousands):

Description	Amortized cost / Cost	Unrealized gains	Unrealized losses	Fair value
June 30, 2021				
U.S. government agency securities and treasuries	$ 346,331	$ 138	$ (13)	$ 346,456
Corporate bonds	136,133	41	(27)	136,147
Commercial paper	102,937	—	—	102,937
Equity securities	4,305	—	(1,685)	2,620
Total	$ 589,706	$ 179	$ (1,725)	$ 588,160
December 31, 2020				
U.S. government agency securities and treasuries	$ 675,043	$ 302	$ (74)	$ 675,271
Corporate bonds	197,171	432	(40)	197,563
Commercial paper	77,949	1	—	77,950
Equity securities	20,017	—	(14,364)	5,653
Total	$ 970,180	$ 735	$ (14,478)	$ 956,437

No available-for-sale debt securities held as of June 30, 2021 or December 31, 2020 had remaining maturities greater than five years.

4. Fair value measurements

The following table sets forth the Company's assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2021 and December 31, 2020 (in thousands):

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
June 30, 2021				
Assets:				
Cash and cash equivalents	$ 353,468	$ 310,833	$ 42,635	$ —
Marketable securities:				
U.S. government agency securities and treasuries	346,456	—	346,456	—
Corporate bonds	136,147	—	136,147	—
Commercial paper	102,937	—	102,937	—
Equity securities	2,620	2,620	—	—
Total	$ 941,628	$ 313,453	$ 628,175	$ —
Liabilities:				
Contingent consideration	$ 1,925	$ —	$ —	$ 1,925
Total	$ 1,925	$ —	$ —	$ 1,925
December 31, 2020				
Assets:				
Cash and cash equivalents	$ 317,705	$ 317,705	$ —	$ —
Marketable securities:				
U.S. government agency securities and treasuries	675,271	—	675,271	—
Corporate bonds	197,563	—	197,563	—
Commercial paper	77,950	—	77,950	—
Equity securities	5,653	5,653	—	—
Total	$ 1,274,142	$ 323,358	$ 950,784	$ —
Liabilities:				
Contingent consideration	$ 1,509	$ —	$ —	$ 1,509
Total	$ 1,509	$ —	$ —	$ 1,509

Cash and cash equivalents

The Company considers all highly liquid securities with original final maturities of 90 days or less from the date of purchase to be cash equivalents. As of June 30, 2021, cash and cash equivalents comprise funds in cash, money market accounts, U.S. government agency securities and treasuries, corporate bonds, and commercial paper. As of December 31, 2020, cash and cash equivalents comprise funds in cash and money market accounts.

Marketable securities

Marketable securities classified as Level 2 within the valuation hierarchy generally consist of U.S. government agency securities and treasuries, corporate bonds, and commercial paper. The Company estimates the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Company validates the prices provided by its third-party pricing sources by understanding the models used, obtaining market values from other pricing sources and analyzing pricing data in certain instances.

The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to the next call date for premiums or to maturity for discounts. At June 30, 2021 and December 31, 2020, the balance in the Company's accumulated other comprehensive loss includes activity related to the Company's available-for-sale debt securities.

There were no material realized gains or losses recognized on the sale or maturity of available-for-sale debt securities during the three and six months ended June 30, 2021 or 2020.

Accrued interest receivable on the Company's available-for-sale debt securities totaled $1.9 million and $3.1 million as of June 30, 2021 and December 31, 2020, respectively. No accrued interest receivable was written off during the three and six months ended June 30, 2021 or 2020.

The following table summarizes available-for-sale debt securities in a continuous unrealized loss position for less than and greater than twelve months, and for which an allowance for credit losses has not been recorded at June 30, 2021 and December 31, 2020 (in thousands):

	Less than 12 months		12 months or greater		Total	
Description	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
June 30, 2021						
U.S. government agency securities and treasuries	$ 25,988	$ (13)	$ —	$ —	$ 25,988	$ (13)
Corporate bonds	85,129	(27)	—	—	85,129	(27)
Total	$ 111,117	$ (40)	$ —	$ —	$ 111,117	$ (40)
December 31, 2020						
U.S. government agency securities and treasuries	$ 211,384	$ (74)	$ —	$ —	$ 211,384	$ (74)
Corporate bonds	76,598	(40)	1,205	—	77,803	(40)
Total	$ 287,982	$ (114)	$ 1,205	$ —	$ 289,187	$ (114)

The Company determined that there was no material change in the credit risk of the above investments during the six months ended June 30, 2021. As such, an allowance for credit losses was not recognized. As of June 30, 2021, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of their amortized cost bases.

The Company held equity securities with an aggregate fair value of $2.6 million and $5.7 million as of June 30, 2021 and December 31, 2020, respectively, within short-term marketable securities on its condensed consolidated balance sheets. In January 2021, the Company sold a portion of its equity securities for proceeds of $31.3 million. During the three months ended June 30, 2021 and 2020, the Company recorded losses of $0.1 million and gains of $1.2 million, respectively, related to its equity securities. During the six months ended June 30, 2021 and 2020, the Company recorded gains of $28.3 million and losses of $3.3 million, respectively, related to its equity securities. Gains and losses related to equity securities are included in other (expense) income, net on the condensed consolidated statements of operations and comprehensive loss.

Contingent consideration

In connection with its prior acquisition of Precision Genome Engineering, Inc. (“Pregenen”), the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. Contingent consideration is measured at fair value and is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The valuation of contingent consideration uses assumptions the Company believes would be made by a market participant. The Company assesses these estimates on an on-going basis as additional data impacting the assumptions is obtained. Future changes in the fair value of contingent consideration related to updated assumptions and estimates are recognized within the condensed consolidated statements of operations and comprehensive loss. In the absence of new information, changes in fair value will reflect changing discount rates and the passage of time. Contingent consideration is included in accrued expenses and other current liabilities and other non-current liabilities on the condensed consolidated balance sheets.

Please refer to Note 9, *Commitments and contingencies*, for further information.

5. Inventory

Inventory consists of the following (in thousands):

	As of June 30, 2021	As of December 31, 2020
Raw materials	$ 12,290	$ 8,967
Finished goods	1,212	1,731
Inventory	$ 13,502	$ 10,698

During the six months ended June 30, 2021, the Company recorded a reserve for excess inventories of $15.1 million, which is included within cost of royalty and other revenue within the condensed consolidated statements of operations.

6. Property, plant and equipment, net

Property, plant and equipment, net, consists of the following (in thousands):

	As of June 30, 2021	As of December 31, 2020
Land	$ 1,210	$ 1,210
Building	88,942	15,745
Computer equipment and software	6,919	6,950
Office equipment	7,335	7,665
Laboratory equipment	67,313	55,521
Leasehold improvements	31,259	34,286
Construction-in-progress	14,803	92,514
Total property, plant and equipment	217,781	213,891
Less accumulated depreciation and amortization	(58,961)	(51,060)
Property, plant and equipment, net	$ 158,820	$ 162,831

North Carolina manufacturing facility

In November 2017, the Company acquired a manufacturing facility in Durham, North Carolina for the future manufacture of lentiviral vector for the Company's gene therapies. As of June 30, 2021, the majority of the facility has been placed into service. The remainder of the facility is still in process of qualification, which is required for the facility to be ready for its intended use. Construction-in-progress as of June 30, 2021 and December 31, 2020 includes $14.1 million and $91.1 million, respectively, related to the North Carolina manufacturing facility.

7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	As of June 30, 2021	As of December 31, 2020
Employee compensation	$ 71,749	$ 55,802
Manufacturing costs	24,186	22,571
Clinical and contract research organization costs	19,865	23,766
Collaboration costs	20,974	20,004
Property, plant and equipment	1,201	789
License and milestone fees	183	278
Professional fees	1,982	1,541
Other	27,895	20,655
Accrued expenses and other current liabilities	$ 168,035	$ 145,406

8. Leases

The Company leases certain office and laboratory space, primarily located in Cambridge, Massachusetts and Seattle, Washington. Additionally, the Company has embedded leases at various contract manufacturing organizations in both the United States and internationally. Except as described below, there have been no material changes in lease obligations from those disclosed in Note 8 to the consolidated financial statements included in the Company's 2020 Annual Report on Form 10-K.

Embedded operating leases

In July 2020, the Company entered into an agreement reserving manufacturing capacity with a contract manufacturing organization. The Company concluded that this agreement contains an embedded operating lease as a controlled environment room at the facility is designated for the Company's exclusive use during the term of the agreement, with the option to sublease the space if the Company provides notice that it will not utilize it for a specified duration of time. Under the terms of the agreement, the Company will be required to pay up to $5.4 million per year in maintenance fees in addition to the cost of any services provided and may terminate this agreement with eighteen months' notice. The term of the agreement is five years, with the option to extend. The Company recorded a right-of-use asset and lease liability for this operating lease upon lease commencement in March 2021 and is recognizing rent expense on a straight-line basis throughout the remaining term of the embedded lease.

9. Commitments and contingencies

Contingent consideration related to business combinations

In June 2014, the Company acquired Pregenen. The Company may be required to make up to $99.9 million in remaining future contingent cash payments to the former equity holders of Pregenen upon the achievement of certain commercial milestones related to the Pregenen technology. In accordance with accounting guidance for business combinations, contingent consideration liabilities are required to be recognized on the condensed consolidated balance sheets at fair value. Estimating the fair value of contingent consideration requires the use of significant assumptions primarily relating to probabilities of successful achievement of certain clinical and commercial milestones, the expected timing in which these milestones will be achieved, and discount rates. The use of different assumptions could result in materially different estimates of fair value.

Other funding commitments

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 and license agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in the Company’s financial statements. Please refer to Note 10, *Collaborative arrangements*, for further information on the Company's collaboration agreements and to Note 11, *Royalty and other revenue*, for further information on the Company's license agreements.

Additionally, the Company is party to various contracts with contract research organizations and contract manufacturers that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement. There have been no material changes in future minimum purchase commitments from those disclosed in Note 9 to the consolidated financial statements included in the Company's 2020 Annual Report on Form 10-K.

While there are no material legal proceedings the Company is aware of, the Company may become party to various claims and complaints arising in the ordinary course of business. The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company’s business partners. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Management does not believe that any ultimate liability resulting from any of these claims will have a material adverse effect on its results of operations, financial position, or liquidity. However, management cannot give any assurance regarding the ultimate outcome of any claims, and their resolution could be material to operating results for any particular period.

The Company also indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity, as permitted under Delaware law and

in accordance with its certificate of incorporation and by-laws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director or officer in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director and officer liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations.

10. Collaborative arrangements

To date, the Company's revenue has been primarily generated from its collaboration arrangements with BMS and Regeneron Pharmaceuticals, Inc. ("Regeneron"), each as further described below.

Bristol-Myers Squibb

In March 2013, the Company entered into a collaboration agreement with BMS. The details of the collaboration agreements and the payments the Company has received, and is entitled to receive, are further described in Note 11, *Collaborative arrangements*, to the Company's consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2020. During the second quarter of 2021, there have been no changes to the terms of the Company's collaboration agreement with BMS.

Ide-cel

Under the Company's collaboration agreement with BMS, the Company shares equally in the profit and loss related to the development and commercialization of ide-cel in the United States. The Company has no remaining financial rights with respect to the development or commercialization of ide-cel outside of the United States. The Company accounts for its collaborative arrangement efforts with BMS in the United States within the scope of ASC 808 given that both parties are active participants in the activities and both parties are exposed to significant risks and rewards dependent on the commercial success of the activities. The Company recognizes revenue related to the combined unit of accounting for the ex-U.S. license and lentiviral vector manufacturing services under Topic 606.

Ide-cel U.S. Share of Collaboration Profit or Loss

In March 2021, BMS received marketing approval from the U.S. Food and Drug Administration for ide-cel as a treatment for adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. BMS is primarily responsible for the commercialization of ide-cel and they are the principal for commercial activity. On a quarterly basis, the Company determines its share of collaboration profit or loss for commercial activities. The Company's share of any collaboration profit for commercial activities is recognized as collaborative arrangement revenue and its share of any collaboration loss for commercial activity is recognized as an operating expense and classified as share of collaboration loss on the Company's condensed consolidated statement of operations. The Company also is responsible for equally sharing in the ongoing ide-cel research and development activities being conducted by BMS in the United States. The net amount owed to BMS for research and development activities is classified as research and development expense on the condensed consolidated statement of operations. If BMS is obligated to reimburse the Company because the Company's research and development costs exceeds BMS' research and development costs, the net amount is recorded as collaborative arrangement revenue.

During the three and six months ended June 30, 2021, the Company recognized $10.1 million, included as a component of share of collaboration loss on the condensed consolidated statement of operations, related to its share of collaboration loss associated with ide-cel commercial activities. This amount includes the Company's share of BMS' ide-cel product revenue, cost of goods sold, and selling costs, offset by any reimbursement of commercial costs incurred by the Company during the three and six month periods.

The following table summarizes the amounts associated with the research activities under the collaboration included in research and development expense or recognized as collaborative arrangement revenue for the three and six months ended June 30, 2021, and 2020 (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
ASC 808 ide-cel research and development revenue - U.S. (1) (2)	$ —	$ 108,196	$ —	$ 108,19
ASC 808 ide-cel research and development expense - U.S. (1)	$ (9,193)	$ —	$ (26,018)	$ (5,08

(1) As noted above, the calculation of collaborative arrangement activity to be recognized for joint ide-cel efforts in the United States is performed on a quarterly basis. The calculation is independent of previous activity, which may result in fluctuations between revenue and expense recognition period over period, depending on the varying extent of effort performed by each party during the period.

(2) In the second quarter of 2020, the Company recognized $169.2 million as a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement ("Amended Ide-cel CCPS"), a portion of which was recognized as ASC 808 research and development collaboration revenue. Refer to Note 11, *Collaborative arrangements*, of the Company's Annual Report on Form 10-K for further discussion on the Amended Ide-cel CCPS.

Ide-cel ex-U.S. Service Revenue

The following table summarizes the revenue recognized related to ide-cel ex-U.S. activities for the three and six months ended June 30, 2021, and 2020 (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
ASC 606 ide-cel license and manufacturing revenue - ex-U.S. (1)	$ 4,280	$ 73,850	$ 9,384	$ 87,820

(1) In the second quarter of 2020, the Company recognized $169.2 million as a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 First Amendment to the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement ("Amended Ide-cel CCPS"), a portion of which was recognized as ASC 606 license and manufacturing revenue. Refer to Note 11, *Collaborative arrangements*, of the Company's Annual Report on Form 10-K for further discussion on the Amended Ide-cel CCPS.

bb21217

In addition to the activities related to ide-cel, BMS previously exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, the second product candidate under the collaboration arrangement with BMS which is further described in Note 11, *Collaborative arrangements*, to the Company's consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2020.

Under the collaboration arrangement with BMS, the Company has an option to co-develop and co-promote bb21217 within the United States. The Company currently expects it will exercise its option to co-develop and co-promote bb21217 within the United States. The Company's election to co-develop and co-promote bb21217 within the United States must be made by the substantial completion of CRB-402, the on-going phase 1 clinical trial of bb21217. If elected, the Company expects the responsibilities of the parties to remain largely unchanged, however, the Company expects it will share equally in all profits and losses relating to developing, commercializing and manufacturing bb21217 within the United States and to have the right to participate in the development and promotion of bb21217 within the United States. Under this scenario, the U.S. milestones and royalties payable would be adjusted and the Company would be eligible to receive a $10.0 million development milestone payment related to the development of bb21217 within the United States. The Company would not be eligible for royalties on U.S. sales of bb21217 under this scenario.

In the event the Company does not exercise its option to co-develop and co-promote bb21217, the Company will receive an additional fee in the amount of $10.0 million. Under this scenario, the Company is eligible to receive U.S. milestones of up to $85.0 million for the first indication to be addressed by bb21217 and royalties for U.S. sales of bb21217.

All of the remaining development, regulatory, and commercial milestones related to U.S. development, regulatory and commercialization activities are fully constrained and are therefore excluded from the transaction price. As part of its evaluation of the constraint, the Company considered numerous factors, including the fact that achievement of the milestones is outside the

control of the Company and contingent upon the future success of its clinical trials, the licensee's efforts, or the receipt of regulatory approval. Any consideration related to U.S. sales-based milestones (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to BMS and therefore are recognized at the later of when the performance obligation is satisfied or the related sales occur.

The transaction price associated with the collaboration arrangement consists of $31.0 million of upfront payments and option payments received from BMS and $1.8 million in variable consideration which represents reimbursement to be received from BMS for manufacturing vector and associated payloads through development. The Company has identified two performance obligations with respect to the arrangement with BMS. The initial performance obligation was for research and development services substantially completed in September 2019, associated with the initial phase 1 clinical trial. The Company allocated $5.4 million of consideration to the research and development services performance obligation and fully recognized the consideration through September 2019. The other performance obligation relates to a combined performance obligation for the bb21217 license and vector manufacturing services through development, and the remaining $27.3 million in consideration was allocated to this combined performance obligation. The Company will satisfy this combined performance obligation as the bb21217 manufacturing services are performed. As of June 30, 2021, the Company has not commenced manufacturing and the full amount of the allocated transaction price remains unsatisfied.

The Company re-evaluates the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Contract assets and liabilities – ide-cel and bb21217

The Company receives payments from its collaborative partners based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under these arrangements. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

The following table presents changes in the balances of the Company's BMS receivables and contract liabilities during the six months ended June 30, 2021 (in thousands):

	Balance at December 31, 2020	Additions	Deductions	Balance at June 30, 2021
Receivables	$ 400	$ —	$ (400)	$ —
Contract liabilities:				
Deferred revenue	$ 26,582	$ —	$ (820)	$ 25,762

The decrease in the receivables balance for the six months ended June 30, 2021 is driven by amounts collected from BMS in the period.

The decrease in deferred revenue during the six months ended June 30, 2021 is driven by the release of the remaining $0.8 million of deferred revenue associated with the combined performance obligation consisting of the ide-cel license and manufacturing services.

Regeneron

Regeneron Collaboration Agreement

In August 2018, the Company entered into a Collaboration Agreement (the "Regeneron Collaboration Agreement") with Regeneron pursuant to which the parties will apply their respective technology platforms to the discovery, development, and commercialization of novel immune cell therapies for cancer. In August 2018, following the completion of required regulatory reviews, the Regeneron Collaboration Agreement became effective. Under the terms of the agreement, the parties will leverage Regeneron's proprietary platform technologies for the discovery and characterization of fully human antibodies, as well as T cell receptors directed against tumor-specific proteins and peptides and the Company will contribute its field-leading expertise in gene therapy.

In accordance with the Regeneron Collaboration Agreement, the parties jointly selected six initial targets and intend to equally share the costs of research up to the point of submitting an IND application for a potential gene therapy product directed to a particular target. Additional targets may be selected to add to or replace any of the initial targets during the five-year research collaboration term as agreed to by the parties.

Regeneron will accrue a certain number of option rights exercisable against targets as the parties reach certain milestones under the terms of the agreement. Upon the acceptance of an IND for the first product candidate directed to a target, Regeneron will have the right to exercise an option for co-development/co-commercialization of product candidates directed to such target on a worldwide or applicable opt-in territory basis, with certain exceptions. Where Regeneron chooses to opt-in, the parties will share equally in the costs of development and commercialization and will share equally in any profits or losses therefrom in applicable opt-in territories. Outside of the applicable opt-in territories, the target becomes a licensed target and Regeneron would be eligible to receive, with respect to any resulting product, milestone payments of up to $130.0 million per product and royalties on net sales outside of the applicable opt-in territories at a rate ranging from the mid-single digits to low-double digits. A target would also become a licensed target in the event Regeneron does not have an option to such target, or Regeneron does not exercise its option with respect to such target.

Either party may terminate a given research program directed to a particular target for convenience, and the other party may elect to continue such research program at its expense, receiving applicable cross-licenses. The terminating party will receive licensed product royalties and milestone payments on the potential applicable gene therapy products. Where the Company terminates a given research program for convenience, and Regeneron elects to continue such research program, the parties will enter into a transitional services agreement. Under certain conditions, following its opt-in, Regeneron may terminate a given collaboration program and the Company may elect to continue the development and commercialization of the applicable potential gene therapy products as licensed products.

Regeneron Share Purchase Agreement

A Share Purchase Agreement (“SPA”) was entered into by the parties in August 2018. In August 2018, the closing date of the transaction, the Company issued Regeneron 0.4 million shares of the Company’s common stock, subject to certain restrictions, for $238.10 per share, or $100.0 million in the aggregate. The purchase price represents $63.0 million worth of common stock plus a $37.0 million premium, which represents a collaboration research advancement, or credit to be applied to Regeneron’s initial 50 percent funding obligation for collaboration research, after which the collaborators will continue to fund ongoing research equally. The collaboration research advancement only applies to pre-IND research activities and is not refundable or creditable against post-IND research activities for any programs where Regeneron exercises their opt-in rights.

Accounting analysis – Regeneron

At the commencement of the arrangement, two units of accounting were identified, which are the issuance of 0.4 million shares of the Company’s common stock and joint research activities during the five-year research collaboration term. The Company determined the total transaction price to be $100.0 million, which comprises $54.5 million attributed to the equity sold to Regeneron and $45.5 million attributed to the joint research activities. 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 Regeneron received shares subject to certain restrictions.

The Company analyzed the joint research activities to assess whether they fall within the scope of ASC 808, and will reassess this throughout the life of the arrangement based on changes in the roles and responsibilities of the parties. Based on the terms of the arrangement as outlined above, for the collaboration research performed prior to submission of an IND application for a potential gene therapy product, both parties are deemed to be active participants in the collaboration. Both parties are performing research and development activities and will share equally in these costs through IND. Additionally, Regeneron and the Company are exposed to significant risks and rewards dependent on the commercial success of any product candidates that may result from the collaboration. As such, the collaboration arrangement is deemed to be within the scope of ASC 808.

The $45.5 million attributed to the joint research activities includes the $37.0 million creditable against amounts owed to the Company by Regeneron. The collaboration research advancement will be reduced over time for amounts due to the Company by Regeneron as a result of the parties agreeing to share in the costs of collaboration research equally. The remainder of the amount attributed to the joint research activities will be recognized over the five-year research collaboration term.

Consistent with its collaboration accounting policy, the Company will recognize collaborative arrangement revenue or research and development expense related to the joint research activities in future periods depending on the amounts incurred

by each party in a given reporting period. That is, if the Company's research costs incurred exceed those research costs incurred by Regeneron in a given quarter, the Company will record collaborative arrangement revenue and reduce the original $37.0 million advance by the amount due from Regeneron until such advancement is fully utilized, after which the Company would record an amount due from Regeneron. If Regeneron's research costs incurred exceed those research costs incurred by the Company in a given quarter, the Company will record research and development expense and record a liability for the amount due to Regeneron. As of June 30, 2021 and December 31, 2020, the Company has $27.6 million and $30.8 million, respectively, of the amount attributed to the joint research activities remaining to be recognized, which is classified as collaboration research advancement, current portion and collaboration research advancement, net of current portion on the condensed consolidated balance sheets.

The Company recognized $1.7 million and $3.2 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three and six months ended June 30, 2021, respectively. The Company recognized $1.5 million and $3.8 million of collaborative arrangement revenue from the Regeneron Collaboration Agreement during the three and six months ended June 30, 2020, respectively.

11. Royalty and other revenue

The Company has out-licensed intellectual property to various third parties. Under the terms of these agreements, the Company may be entitled to royalties and milestone payments.

In April 2017, the Company entered into a worldwide license agreement with Novartis, which is further described in Note 12, *Royalty and other revenue*, to the consolidated financial statements included in the Company's 2020 Annual Report on Form 10-K. Beginning in the fourth quarter of 2017, the Company began recognizing royalty revenue from sales of tisagenlecleucel under the agreement. This license agreement was terminated effective March 2021, at which point in time Novartis was no longer required to pay the Company royalty or other payments on net sales of tisagenlecleucel or any future products. Royalty revenue recognized from sales of tisagenlecleucel is included within royalty and other revenue on the condensed consolidated statement of operations and comprehensive loss.

In April 2017, the Company entered into a worldwide license agreement with GlaxoSmithKline Intellectual Property Development Limited ("GSK"), which was assigned by GSK to Orchard Therapeutics Limited ("Orchard"), effective April 2018. The terms of this license agreement are further described in Note 12, *Royalty and other revenue*, to the consolidated financial statements included in the Company's 2020 Annual Report on Form 10-K. During the second quarter of 2021, the Company and Orchard amended this license agreement to remove the potential milestone payments related to marketing authorization of covered products. In addition, the Company and Orchard entered into a new license agreement, under which the Company licensed to Orchard certain lentiviral vector-based technologies. Financial terms of the agreement include a potential milestone payment upon the first commercial sale of a licensed product in a territory, as well as low single-digit royalties on net sales of covered products.

In May 2020, the Company entered into a non-exclusive license agreement with Juno Therapeutics, Inc. ("Juno"), a wholly-owned subsidiary of BMS, related to lentiviral vector technology to develop and commercialize CD-19-directed CAR T cell therapies. Upon regulatory approval of lisocabtagene maraleucel during the first quarter of 2021, the Company received a $2.5 million milestone payment from Juno, which is included within royalty and other revenue. Royalty revenue recognized from sales of lisocabtagene maraleucel is also included within royalty and other revenue on the condensed consolidated statement of operations and comprehensive loss.

The Company may also be obligated to pay third-party licensors as a result of revenue recognized under out-license agreements, which is included within cost of royalty and other revenue on the condensed consolidated statement of operations and comprehensive loss.

During the first half of 2021, the Company recognized an immaterial amount of product revenue related to the sale of beti-cel in the European Union and the related cost of goods sold, which is included within royalty and other revenue and cost of royalty and other revenue, respectively.

12. Stock-based compensation

In January 2021 and 2020, the number of shares of common stock available for issuance under the 2013 Stock Option and Incentive Plan ("2013 Plan") was increased by approximately 2.7 million and 2.2 million shares, respectively, as a result of the automatic increase provision of the 2013 Plan. As of June 30, 2021, the total number of shares of common stock available for issuance under the 2013 Plan was approximately 3.9 million.

Stock-based compensation expense

The Company recognized stock-based compensation expense totaling $31.1 million and $73.5 million for the three and six months ended June 30, 2021, respectively. The Company recognized stock-based compensation expense totaling $48.5 million and $84.8 million for the three and six months ended June 30, 2020, respectively. Stock-based compensation expense by award type included within the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Stock options	$ 17,324	$ 26,073	$ 37,983	$ 50,513
Restricted stock units	8,534	14,143	23,267	25,996
Employee stock purchase plan and other	5,193	8,313	12,275	8,313
	$ 31,051	$ 48,529	$ 73,525	$ 84,822

Stock-based compensation expense by classification included within the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Research and development	$ 15,768	$ 23,098	$ 35,636	$ 39,367
Selling, general and administrative	15,283	25,431	37,889	45,455
	$ 31,051	$ 48,529	$ 73,525	$ 84,822

Stock-based compensation of $0.4 million and $0.7 million was capitalized into inventory for the three and six months ended June 30, 2021, respectively. Stock-based compensation of less than $0.1 million and $0.1 million was capitalized into inventory for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, the Company had approximately $193.9 million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of approximately 2.1 years.

Unrestricted stock awards

During the first quarter of 2021, the Company granted 0.4 million unrestricted stock awards to employees as part of its 2020 annual incentive program. In addition, the Company implemented a retention program designed to incentivize and retain employees through the separation of its severe genetic disease and oncology programs, which is intended to occur by the end of 2021. Under the retention program, employees are entitled to a one-time bonus payment, consisting of both a cash payment and unrestricted stock awards, with the condition that the employee remains employed at the end of 2021. For the three and six months ended June 30, 2021, respectively, the Company recognized $10.7 million and $24.0 million in expense related to this program, which includes $5.2 million and $11.9 million in stock compensation expense related to the anticipated grants of stock.

Stock option activity

The following table summarizes the stock option activity under the Company's equity award plans:

	Shares (in thousands)	Weighted-average exercise price per share
Outstanding at December 31, 2020	6,262	$ 105.02
Granted	811	$ 29.52
Exercised	(209)	$ 6.02
Canceled, forfeited, or expired	(765)	$ 108.51
Outstanding at June 30, 2021	6,099	$ 97.93
Exercisable at June 30, 2021	3,854	$ 110.83
Vested and expected to vest at June 30, 2021	6,099	$ 97.93

During the six months ended June 30, 2021, 0.2 million stock options were exercised, resulting in total proceeds to the Company of $1.3 million.

Restricted stock unit activity

The following table summarizes the restricted stock unit activity under the Company's equity award plans:

	Shares (in thousands)	Weighted-average grant date fair value
Unvested balance at December 31, 2020	1,495	$ 102.34
Granted	1,128	$ 21.38
Vested	(421)	$ 59.35
Forfeited	(337)	$ 77.19
Unvested balance at June 30, 2021	1,865	$ 59.02

Employee stock purchase plan

In June 2013, the Company adopted its 2013 Employee Stock Purchase Plan ("2013 ESPP"), which authorized the initial issuance of up to a total of 0.2 million shares of the Company's common stock to participating employees. In June 2021, the Company amended the 2013 ESPP to include an additional 1.4 million shares of the Company's common stock available to participating employees. During each of the six months ended June 30, 2021 and 2020, less than 0.1 million shares of common stock were issued under the 2013 ESPP.

13. Income taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets. The tax expense recognized during the three and six months ended June 30, 2021 is due to income taxes on foreign earnings.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was enacted. This law temporarily suspends and adjusts certain law changes enacted in the Tax Cuts and Jobs Act in 2017. In December 2020, the Consolidated Appropriations Act was enacted. This law modified the employee retention credit under the CARES Act and created credit extenders for certain credits. In March 2021, the American Rescue Plan Act ("ARPA") was enacted and contained extenders to the refundable employee retention credit and provided further limitations to executive compensation effective for tax years beginning after 2026. The Company has concluded that the provisions in the CARES Act, Consolidated Appropriations Act, and ARPA have an immaterial impact on the Company's income tax expense due to its cumulative losses and full valuation allowance position.

14. Net loss per share

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	For the three and six months ended June 30,	
	2021	2020
Outstanding stock options	6,099	6,466
Restricted stock units	1,865	1,593
ESPP shares and other	746	323
	8,710	8,382

15. Subsequent events

In July 2021, the Company and National Resilience, Inc. ("Resilience") announced a strategic manufacturing collaboration aimed to accelerate the early research, development, and delivery of cell therapies. As part of the agreement, Resilience will acquire the Company's manufacturing facility located in Durham, North Carolina upon closing, and is expected to retain all staff currently employed at the site. Following closing, Resilience is expected to continue to support vector supply for both bluebird bio, Inc. and 2seventy bio, Inc. upon the closing of the spin-off transaction, which is expected by the end of 2021.

In late July 2021, the Company made the decision to focus its efforts on the U.S. market for beti-cel, eli-cel, and LentiGlobin for SCD and plans to execute an orderly wind down of its European operations. It has commenced its assessment of the financial impact of this decision and anticipates disclosing the impact within its Quarterly Report on Form 10-Q for the third quarter of 2021.

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC, on February 23, 2021.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "may," "expect," "anticipate," "estimate," "intend," "plan," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biotechnology company committed to researching, developing, and commercializing, following marketing approval, potentially transformative gene therapies for severe genetic diseases and cancer. We have built an integrated product platform with broad therapeutic potential in a variety of indications based on our lentiviral gene addition platform, gene editing and cancer immunotherapy capabilities. We believe that gene therapy for severe genetic diseases has the potential to change the way patients living with these diseases are treated by addressing the underlying genetic defect that is the cause of their disease, rather than offering treatments that only address their symptoms. Our gene therapy programs in severe genetic diseases include programs for transfusion-dependent β-thalassemia (TDT), sickle cell disease (SCD), and cerebral adrenoleukodystrophy (CALD). The Company's programs in oncology are focused on developing novel engineered cell and gene therapies for cancer, including the anti-BCMA CAR T programs for multiple myeloma under the Company's collaboration arrangement with Bristol-Myers Squibb (BMS).

Based on our discussions with the FDA, we believe that we may be able to seek approval for eli-cel for the treatment of patients with CALD on the basis of our clinical data from our ongoing Starbeam study, safety data from our ongoing ALD-104 study, and the completed ALD-103 observational study. However, in August 2021, we reported that a patient in our ALD-104 study has been diagnosed with myelodysplastic syndrome likely mediated by Lenti-D lentiviral vector insertion and the FDA has placed our clinical studies of eli-cel on clinical hold. We are investigating this safety event and two other instances of clonal predominance in patients treated with eli-cel. We plan to continue working closely with the FDA in their review. We believe that eli-cel continues to present a favorable benefit-risk profile for patients with CALD and, subject to reaching an agreement with the FDA on the resolution of the clinical hold, we believe we can submit the BLA for eli-cel for the treatment of patients with CALD in 2021.

Based on our discussions with the FDA, we believe that we may be able to seek approval for beti-cel for the treatment of patients with TDT on the basis of our clinical data from our HGB-207 and HGB-212 studies supported by data from the long-term follow up protocol, as well as the earlier HGB-205 and HGB-204 studies. We currently expect to complete our BLA submission for beti-cel in the third quarter of 2021 for the treatment of all patients with TDT across all ages and genotypes, including non-β0/β0 and β0/β0 genotypes. Based on our discussions with the FDA, we believe that we may be able to seek accelerated approval for LentiGlobin for SCD in the United States on the basis of clinical data from Group C of our ongoing HGB-206 clinical study, and with our ongoing HGB-210 clinical study providing confirmatory data for full approval. In light of

safety events reported in our HGB-206 clinical study, the clinical studies of LentiGlobin for SCD were subject to a clinical hold from February 2021 to June 2021. We are working closely with study investigators and clinical trial sites to resume enrolling patients as soon as possible.

We received conditional marketing authorization from the European Commission for beti-cel in June 2019, and marketing authorization from the European Commission for eli-cel in July 2021. However, in August 2021 we announced that we intend to focus our severe genetic disease business on the U.S. market and further invest in research and development for our core programs in TDT, SCD, and CALD in that market. As part of our strategy to focus on the U.S. market, we plan to execute an orderly wind down of our European operations, which we anticipate will result in a reduction of selling, general and administrative costs and will have an impact on our excess inventory analysis, which is based on forecasted consumption levels driven by sales forecasts.

In collaboration with BMS, we are commercializing ide-cel and developing bb21217 as treatments for multiple myeloma, a hematologic malignancy that develops in the bone marrow and is fatal if untreated. We are co-developing and co-promoting ide-cel as ABECMA in the United States with BMS and we have exclusively licensed to BMS the development and commercialization rights for ide-cel outside of the United States. We have exclusively licensed the development and commercialization rights for the bb21217 product candidate to BMS, with an option for us to elect to co-develop and co-promote bb21217 within the United States. In May 2020, we and BMS entered into an amendment and restatement of the ide-cel co-promotion/co-development agreement, an amendment and restatement of the bb21217 license agreement, and a non-exclusive license agreement to certain patent rights controlled by us and related to lentiviral vector technology for BMS to develop and commercialize CD19-directed CAR T cell therapies. Under the amended agreements, BMS was relieved of its obligations to pay us for future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217 in exchange for an up-front, non-refundable, non-creditable payment of $200.0 million, which represents the aggregate of the probability-weighted, net present value of the future ex-U.S. milestones and royalties on ex-U.S. sales for each of ide-cel and bb21217. BMS also assumed the contract manufacturing agreements relating to ide-cel adherent lentiviral vector and over time, BMS is assuming responsibility for manufacturing ide-cel suspension lentiviral vector outside of the U.S., with bluebird responsible for manufacturing ide-cel suspension lentiviral vector in the U.S. In addition, the parties are released from future exclusivity related to BCMA-directed T cell therapies. In March 2021, BMS received marketing approval from the FDA for ide-cel, marketed as ABECMA, as a treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Sales of ABECMA by BMS began in the second quarter of 2021.

Since our inception in 1992, we have devoted substantially all of our resources to our development efforts relating to our product candidates, including activities to manufacture product candidates in compliance with good manufacturing practices, or GMP, to conduct clinical studies of our product candidates, to provide selling, general and administrative support for these operations and to protect our intellectual property. We have generated immaterial revenues from product sales. We have funded our operations primarily through the sale of common stock in our public offerings, private placements of preferred stock and warrants, and through collaborations.

As of June 30, 2021, we had cash, cash equivalents and marketable securities of approximately $941.6 million. We have never been profitable and have incurred net losses in each year since inception. Our net loss was $241.7 million and $447.5 million for the three and six months ended June 30, 2021, respectively, and our accumulated deficit was $3.35 billion as of June 30, 2021. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- conduct clinical studies for our clinical programs in β-thalassemia, SCD, and ALD, fund our share of the costs of clinical studies for our program in multiple myeloma in collaboration with BMS, and advance our preclinical programs into clinical development;
- increase research and development-related activities for the discovery and development of product candidates in severe genetic diseases and oncology;
- manufacture clinical study materials and establish the infrastructure necessary to support and develop large-scale manufacturing capabilities;
- seek regulatory approval for our product candidates;
- add personnel to support our product development and commercialization efforts;
- fund activities related to the potential commercial launches of our late-stage product candidates in the United States;

- fund our share of the costs of commercialization of ide-cel in collaboration with BMS; and
- incur costs related to the separation of our portfolio of programs and product in severe genetic disease and oncology into two separate, independent publicly traded companies.

In March 2021, we placed a portion our internal lentiviral vector manufacturing facility into service, while still completing qualification of the remaining portion. In July 2021, we entered into a definitive agreement for a strategic manufacturing collaboration, which includes the sale of this lentiviral vector manufacturing facility to National Resilience, Inc. The closing of this transaction will be subject to the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, and other customary conditions. Currently all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities. As we seek to obtain regulatory approval for our product candidates and begin commercialization following marketing approval, we expect to incur significant commercialization expenses as we prepare for and begin product sales, marketing, commercial manufacturing, and distribution. Accordingly, until we generate significant revenues from product sales, we will seek to fund our operations through public or private equity or debt financings, strategic collaborations, or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our products.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our product, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Business update

Beginning in late 2019, the outbreak of a novel strain of coronavirus (COVID-19) has evolved into a global pandemic. As a result, we continue to experience disruptions and increased risk in our operations and those of third parties upon whom we rely, which may materially and adversely affect our business. These include disruptions and risks related to the conduct of our clinical trials, manufacturing, and commercialization efforts, as policies at various clinical sites and federal, state, local and foreign laws, rules and regulations continue to evolve, including quarantines, travel restrictions, and direction of healthcare resources toward pandemic response efforts. The COVID-19 pandemic has impacted the timing of our ongoing clinical studies, with the result of slower patient enrollment and treatment in our clinical studies and delays in post-treatment follow up visits, the impact of which has varied by clinical study and by program. It has also affected our activities with and operations at our third party manufacturers. It is unknown how long these disruptions could continue. The COVID-19 pandemic has also impacted the timing of our regulatory interactions for marketing approval across our programs, as well as our discussions with payers for market access and reimbursement for our products in Europe, due to shifting priorities of the local authorities and healthcare systems. As a result of the demands upon healthcare regulatory authorities, review, inspection, and other activities related to review of regulatory submissions in drug development may be impacted, and may result in delays for an unknown period of time.

We continue to evaluate the impact of the COVID-19 global pandemic on patients, healthcare providers and our employees, as well as our operations and the operations of our business partners and healthcare communities. However, the ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments which are difficult to predict.

We expect our cash, cash equivalents and marketable securities of $941.6 million as of June 30, 2021 will be sufficient to fund planned operations for at least the next twelve months from the date of issuance of these financial statements, though we intend to pursue additional cash resources through public or private equity or debt financings or by establishing additional collaborations with other companies.

In January 2021, we announced our intent to separate our severe genetic disease and oncology programs into two separate, independent publicly traded companies, bluebird bio, Inc. and 2seventy bio, Inc., a newly-formed Delaware corporation and wholly-owned subsidiary prior to the separation. bluebird bio, Inc. intends to retain focus on our severe genetic disease programs and 2seventy bio, Inc. is expected to focus on our oncology programs. The transaction is expected to be completed in late 2021 and is anticipated to be tax-free, subject to receipt of a favorable IRS ruling.

Financial operations overview

Revenues

To date, we have generated immaterial revenues from the sale of products. Our revenues have primarily been derived from collaboration arrangements, out-licensing arrangements, research fees, and grant revenues.

To date, revenue recognized under our collaborative arrangements has been primarily generated from our collaboration arrangement with BMS. The terms of the arrangement with respect to ide-cel contain multiple promised goods or services, which include at inception: (i) research and development services, (ii) a license to ide-cel, and (iii) manufacture of vectors and associated payload for incorporation into ide-cel under the license. These performance obligations were fully satisfied during the first quarter of 2021. As of September 2017, the collaboration also included the following promised goods or services with respect to bb21217: (i) research and development services, (ii) a license to bb21217, and (iii) manufacture of vectors and associated payload for incorporation into bb21217 under the license. We entered into an agreement with BMS to co-develop and co-promote ide-cel in March 2018, which was subsequently amended in May 2020, in which both parties will share equally in U.S. costs and profits. Revenue from our collaborative arrangements is recognized as the underlying performance obligations are satisfied.

We analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* (“ASC 808”) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* (“Topic 606” or "ASC 606"). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606.

In arrangements where we do not deem our collaborator to be our customer, payments to and from our collaborator are presented in our condensed consolidated statements of operations based on the nature of the payments, as summarized in the table and further described below.

Nature of Payment	Statement of Operations Presentation
Our share of profits in connection with commercialization of products	Collaborative arrangement revenue
Our share of losses in connection with commercialization of products	Share of collaboration loss
Net reimbursement of our research and development expenses	Collaborative arrangement revenue
Net reimbursement of our research and development expenses	Research and development expense

Where our collaborator is the principal in the product sales, we recognize our share of any profits or losses, representing net product sales less cost of goods sold and share commercialization and other expenses, in the period in which such underlying sales occur and costs are incurred by our collaborator. We also recognize our share of costs arising from research and development activities performed by our collaborators in the period our collaborators incur such expenses.

Non-refundable license fees paid to us are recognized as revenue upon delivery of the license provided there are no unsatisfied performance obligations in the arrangement. License revenue has historically been generated from out-license agreements, under which we may also recognize revenue from potential future milestone payments and royalties.

For arrangements with licenses of intellectual property that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which the royalty has been allocated has been satisfied.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;

- expenses incurred under agreements with CROs and clinical sites that conduct our clinical studies;
- costs of acquiring, developing, and manufacturing inventory;
- reimbursable costs to our partners for collaborative activities;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, information technology, insurance, and other supplies in support of research and development activities;
- costs associated with our research platform and preclinical activities;
- milestones and up-front license payments;
- costs associated with our regulatory, quality assurance and quality control operations; and
- amortization of intangible assets.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites. We cannot determine with certainty the duration and completion costs of the current or future clinical studies of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may not succeed in achieving regulatory approval for all of our product candidates. The duration, costs, and timing of clinical studies and development of our product candidates will depend on a variety of factors, any of which could mean a significant change in the costs and timing associated with the development of our product candidates including:

- the scope, rate of progress, and expense of our ongoing as well as any additional clinical studies and other research and development activities we undertake;
- future clinical study results;
- uncertainties in clinical study enrollment rates;
- new manufacturing processes or protocols that we may choose to or be required to implement in the manufacture of our lentiviral vector or drug product;
- regulatory feedback on requirements for regulatory approval, as well as changing standards for regulatory approval; and
- the timing and receipt of any regulatory approvals.

We plan to continue to invest in research and development for the foreseeable future as we continue to advance the development of beti-cel, eli-cel, LentiGlobin for SCD, and oncology product candidates, conduct research and development activities in severe genetic diseases and oncology, fund our share of the costs of development of ide-cel in collaboration with BMS, and continue the research and development of product candidates using our gene editing technology platform. Our research and development expenses include expenses associated with the following activities:

- for the clinical studies of beti-cel, including our Northstar-2 Study (HGB-207), our Northstar-3 Study (HGB-212), and the associated long-term follow-up protocol;
- for the clinical studies of LentiGlobin for SCD, including our HGB-206 study, our HGB-210 study, and the associated long-term follow-up protocol;
- for the clinical studies of eli-cel, including our ALD-102 study, our ALD-104 study, and the associated long-term follow-up protocol;
- for the clinical studies of ide-cel that are sponsored by BMS as part of our collaboration arrangement;
- for the clinical study of bb21217; and
- for initiation of clinical studies of our other oncology product candidates in our pipeline.

The costs of conducting these studies include the costs related to the manufacture of clinical study materials.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate salary and benefit costs directly related to specific programs. We do not allocate personnel-related discretionary bonus or stock-based compensation costs, costs associated with our general discovery

platform improvements, depreciation or other indirect costs that are deployed across multiple projects under development and, as such, the costs are separately classified as other research and development expenses in the table below:

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
beti-cel	$ 14,654	$ 16,406	$ 28,360	$ 36,994
LentiGlobin for SCD	16,030	14,467	29,192	30,760
eli-cel	16,792	15,219	30,103	23,032
ide-cel	16,203	21,079	45,572	52,241
bb21217	1,906	6,955	4,612	13,026
Preclinical programs	14,528	10,696	28,218	28,146
Total direct research and development expense	80,113	84,822	166,057	184,199
Employee-and contractor-related expenses	23,701	17,906	46,284	33,810
Stock-based compensation expense	15,768	23,098	35,636	39,367
Laboratory and related expenses[(1)]	3,216	1,787	6,605	5,582
License and other collaboration expenses[(1)]	1,163	9,705	2,205	10,927
Facility expenses	20,198	17,801	40,985	34,553
Other expenses	156	1,189	1,021	1,993
Total other research and development expenses	64,202	71,486	132,736	126,232
Total research and development expense	$ 144,315	$ 156,308	$ 298,793	$ 310,431

(1) Prior to the fourth quarter of 2020, costs within these categories were disclosed in the aggregate as "platform-related expenses."

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, legal, business development, commercial, information technology, and human resource functions. Other selling, general and administrative expenses include facility-related costs, professional fees for accounting, tax, legal and consulting services, directors' fees and expenses associated with obtaining and maintaining patents.

Share of collaboration loss

Share of collaboration loss represents our share of net loss arising from product sales less cost of goods sold and shared commercial costs and other expenses related to the commercialization of a product where the collaborator is the principal in the product sales.

Cost of royalty and other revenue

Cost of royalty and other revenue consists of expense associated with amounts owed to third party licensors as a result of revenue recognized under our out-license arrangements, reserves for excess inventory, and an immaterial amount of cost of goods sold related to product revenue.

Change in fair value of contingent consideration

In June 2014, we acquired Precision Genome Engineering, Inc., or Pregenen. The agreement provided for up to $135.0 million in future contingent cash payments by us upon the achievement of certain preclinical, clinical and commercial milestones related to the Pregenen technology.

As of June 30, 2021, there are $99.9 million in future contingent cash payments related to commercial milestones. We estimate future contingent cash payments have a fair value of $1.9 million as of June 30, 2021, which are classified within accrued expenses and other current liabilities and other non-current liabilities on our condensed consolidated balance sheets.

Interest income, net

Interest income, net consists primarily of interest income earned on investments.

Other (expense) income, net

Other (expense) income, net consists primarily of gains and losses on equity securities held by us, gains and losses on disposal of assets, and gains and losses on foreign currency.

Critical accounting policies and estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. We base our estimates on historical experience, known trends and events and various other 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. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies. During the six months ended June 30, 2021, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on February 23, 2021, except as otherwise described in Note 2, *Basis of presentation, principles of consolidation and significant accounting policies*, in the Notes to Condensed Consolidated Financial Statements.

Results of Operations

Comparison of the three months ended June 30, 2021 and 2020:

	For the three months ended June 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Service revenue	$ 5,314	$ 78,357	$ (73,043)
Collaborative arrangement revenue	1,670	109,674	(108,004)
Royalty and other revenue	488	10,859	(10,371)
Total revenues	7,472	198,890	(191,418)
Operating expenses:			
Research and development	144,315	156,308	(11,993)
Selling, general and administrative	78,576	68,628	9,948
Share of collaboration loss	10,071	—	10,071
Cost of royalty and other revenue	15,301	1,554	13,747
Change in fair value of contingent consideration	47	(1,655)	1,702
Total operating expenses	248,310	224,835	23,475
Loss from operations	(240,838)	(25,945)	(214,893)
Interest income, net	439	2,939	(2,500)
Other (expense) income, net	(1,087)	1,551	(2,638)
Loss before income taxes	(241,486)	(21,455)	(220,031)
Income tax expense	(216)	(10)	(206)
Net loss	$ (241,702)	$ (21,465)	$ (220,237)

`

Revenues. Total revenue was $7.5 million for the three months ended June 30, 2021, compared to $198.9 million for the three months ended June 30, 2020. The decrease of $191.4 million was primarily attributable to a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 BMS contract modification in the second quarter of 2020.

Research and development expenses. Research and development expenses were $144.3 million for the three months ended June 30, 2021, compared to $156.3 million for the three months ended June 30, 2020. The overall decrease of $12.0 million was primarily attributable to the following:

- $14.3 million of decreased manufacturing expenditures, primarily driven by the capitalization of commercial inventory in the second quarter of 2021 and partially offset by increased manufacturing capacity and maintenance fees incurred under an agreement with one of our contract manufacturing organizations;
- $9.0 million of decreased license and milestone fees due to sublicense payments made to a third party licensor in the second quarter of 2020. In the current period, the milestone payment associated with the commercial launch of ide-cel was capitalized as intangible assets; and
- $3.5 million of decreased clinical trial costs, primarily driven by the clinical hold from February 2021 to June 2021 on our studies of LentiGlobin for SCD.

These decreased costs were partially offset by:

- $10.0 million increase in collaboration research funding costs, which represents our share of research and development costs under our collaboration with BMS. In the second quarter of 2020, the May 2020 contract modification resulted in recognition of collaborative arrangement revenue rather than collaboration expense; and
- an overall increase in operating expenses incurred in the normal course of business, such as compensation and benefits, which we expect to be variable depending on the timing of recognition based on ongoing business operations.

Selling, general and administrative expenses. Selling, general and administrative expenses were $78.6 million for the three months ended June 30, 2021, compared to $68.6 million for the three months ended June 30, 2020. The overall increase of $9.9 million was primarily attributable to the following:

- $6.5 million of increased consulting and professional fees associated with the on-going project to separate our severe genetic disease and oncology programs into two separate, independent publicly traded companies; and
- an overall increase in operating expenses incurred in the normal course of business, such as compensation and benefits, which we expect to be variable depending on the timing of recognition based on ongoing business operations.

Share of collaboration loss. Share of collaboration loss represents our share of net loss arising from the commercialization of ide-cel, under the BMS collaboration. BMS is the principal seller in the sales of ide-cel. BMS received marketing approval in the United States for ide-cel in March 2021 and recognized gross product revenue from sales of ide-cel of $24.3 million in the second quarter of 2021. Net loss from commercialization represents our share of gross product revenue from product sales less cost of goods sold and selling costs offset by the reimbursement of a portion of commercial related costs incurred by us during the quarter.

Cost of royalty and other revenue. Cost of royalty and other revenue was $15.3 million for the three months ended June 30, 2021, compared to $1.6 million for the three months ended June 30, 2020. The increase is primarily attributable to reserves for excess inventory recognized during the second quarter of 2021 based on forecasted consumption levels as of June 30, 2021.

Change in fair value of contingent consideration. The change in fair value of contingent consideration was primarily due to the change in significant unobservable inputs used in the fair value measurement of contingent consideration, including the probabilities of successful achievement of clinical and commercial milestones and discount rates.

Interest income, net. The decrease in interest income, net was primarily related to decreased interest income earned on investments due to an overall decrease in investments.

Other (expense) income, net. The decrease in other income, net was primarily related to changes in fair value of equity securities.

Comparison of the six months ended June 30, 2021 and 2020:

	For the six months ended June 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Service revenue	$ 11,232	$ 95,190	$ (83,958)
Collaborative arrangement revenue	3,190	111,976	(108,786)
Royalty and other revenue	5,845	13,587	(7,742)
Total revenues	20,267	220,753	(200,486)
Operating expenses:			
Research and development	298,793	310,431	(11,638)
Selling, general and administrative	165,451	141,876	23,575
Share of collaboration loss	10,071	—	10,071
Cost of royalty and other revenue	17,582	2,579	15,003
Change in fair value of contingent consideration	416	(4,763)	5,179
Total operating expenses	492,313	450,123	42,190
Loss from operations	(472,046)	(229,370)	(242,676)
Interest income, net	1,149	8,294	(7,145)
Other income (expense), net	23,669	(2,896)	26,565
Loss before income taxes	(447,228)	(223,972)	(223,256)
Income tax expense	(282)	(104)	(178)
Net loss	$ (447,510)	$ (224,076)	$ (223,434)

Revenues. Total revenue was $20.3 million for the six months ended June 30, 2021, compared to $220.8 million for the six months ended June 30, 2020. The decrease of $200.5 million was primarily attributable to a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 BMS contract modification in the second quarter of 2020.

Research and development expenses. Research and development expenses were $298.8 million for the six months ended June 30, 2021, compared to $310.4 million for the six months ended June 30, 2020. The overall decrease of $11.6 million was primarily attributable to the following:

- $34.5 million of decreased manufacturing-related expenditures, primarily driven by the capitalization of commercial inventory in the first half of 2021 and partially offset by increased manufacturing capacity and maintenance fees incurred under an agreement with one of our contract manufacturing organizations;
- $9.0 million of decreased license and milestone fees due to sublicense payments made to a third party licensor in the second quarter of 2020. In current period, the milestone payments associated with the commercial launch of ide-cel were capitalized as intangible assets; and
- $4.4 million of decreased clinical trial costs, primarily driven by the clinical hold from February 2021 to June 2021 in our studies of LentiGlobin for SCD.

These decreased costs were partially offset by:

- $25.3 million of increased collaboration research funding costs, which represents our share of research and development costs under our collaboration with BMS. The increase is also attributable to our recognition of collaborative arrangement revenue rather than collaboration expense in the second quarter of 2020 as a result of the May 2020 contract modification with BMS; and
- $9.6 million of increased employee compensation, benefit, and other headcount related expenses, primarily driven by our employee retention program which commenced during the first quarter of 2021.

Selling, general and administrative expenses. Selling, general and administrative expenses were $165.5 million for the six months ended June 30, 2021, compared to $141.9 million for the six months ended June 30, 2020. The overall increase of $23.6 million was primarily attributable to the following:

- $13.7 million of increased consulting and professional fees associated with the on-going project to separate our severe genetic disease and oncology programs into two separate, independent publicly traded companies; and
- $13.0 million of increased employee compensation, benefit, and other headcount related expenses, primarily driven by our employee retention program which commenced during the first quarter of 2021.

These increased costs were partially offset by $1.9 million of decreased commercial readiness costs, driven by the temporary suspension of the marketing of beti-cel in light of safety events reported in February 2021 in the HGB-206 study of LentiGlobin for SCD.

Share of collaboration loss. Share of collaboration loss represents our share of net loss arising from the commercialization of ide-cel, under the BMS collaboration. BMS is the principal seller in the sales of ide-cel. BMS received marketing approval for ide-cel in March 2021 and recognized gross product revenue from sales of ide-cel of $24.3 million in the second quarter of 2021. Net loss from commercialization represents our share of gross product revenue from product sales less cost of goods sold and selling costs offset by the reimbursement of a portion of commercial related costs incurred by us during the quarter.

Cost of royalty and other revenue. Cost of royalty and other revenue was $17.6 million for the six months ended June 30, 2021, compared to $2.6 million for the six months ended June 30, 2021. The increase is primarily attributable to reserves for excess inventory recognized during the second quarter of 2021 based on forecasted consumption levels as of June 30, 2021.

Change in fair value of contingent consideration. The change in fair value of contingent consideration was primarily due to the change in significant unobservable inputs used in the fair value measurement of contingent consideration, including the probabilities of successful achievement of clinical and commercial milestones and discount rates.

Interest income, net. The decrease in interest income, net was primarily related to decreased interest income earned on investments due to an overall decrease in investments.

Other income (expense), net. The increase in other income (expense), net was primarily related to the gain recognized on equity securities.

Liquidity and Capital Resources

As of June 30, 2021, we had cash, cash equivalents and marketable securities of approximately $941.6 million. We expect our cash, cash equivalents, and marketable securities will be sufficient to fund planned operations for at least the next twelve months from the date of issuance of these financial statements, though we may pursue additional cash resources through public or private equity or debt financings or by establishing additional collaborations with other companies. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. As of June 30, 2021, our funds are primarily held in U.S. Treasury securities, U.S. government agency securities, equity securities, corporate bonds, commercial paper, and money market accounts.

We have incurred losses and cumulative negative cash flows from operations since our inception in April 1992, and as of June 30, 2021 we had an accumulated deficit of $3.35 billion. We expect that our research and development and selling, general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through public or private equity or debt financings, strategic collaborations, or other sources. The likelihood of our long-term success must be considered in light of the expenses, difficulties, and potential delays to be encountered in the development and commercialization of new pharmaceutical products, competitive factors in the marketplace and the complex regulatory environment in which we operate. We may never achieve significant revenue or profitable operations.

Sources of Liquidity

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods below:

	For the six months ended June 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (348,975)	$ (166,378)
Net cash provided by investing activities	381,720	493,854
Net cash provided by financing activities	4,192	544,085
Net increase in cash, cash equivalents and restricted cash	$ 36,937	$ 871,561

Cash Flows from Operating Activities. The $182.6 million increase in cash used in operating activities for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 was primarily due to the increase in net loss during this period of $223.4 million, which was driven by a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 BMS contract modification in the second quarter of 2020. Cash used in operating activities was also driven by changes in operating assets and liabilities.

Cash Flows from Investing Activities. The $112.1 million decrease in cash provided by investing activities for the six months ended June 30, 2021 was primarily due to an increase in cash used to purchase marketable securities of $94.7 million and a decrease in proceeds from maturities of marketable securities of $23.1 million compared to the six months ended June 30, 2020.

Cash Flows from Financing Activities. The $539.9 million decrease in cash provided by financing activities was primarily driven by a decrease of $541.5 million in proceeds from public offering of common stock, net of issuance costs, during the six months ended June 30, 2021 compared to the six months ended June 30, 2020.

Contractual Obligations and Commitments

Except as discussed in Note 8, *Leases*, and Note 9, *Commitments and contingencies*, in the Notes to Condensed Consolidated Financial Statements, there have been no material changes to our contractual obligations and commitments as included in our Annual Report on Form 10-K, which was filed with the SEC on February 23, 2021.

Off-Balance Sheet Arrangements

As of June 30, 2021, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

We are exposed to market risk related to changes in interest rates. As of June 30, 2021 and December 31, 2020, we had cash, cash equivalents and marketable securities of $941.6 million and $1.27 billion, respectively, primarily invested in U.S. government agency securities and Treasuries, equity securities, corporate bonds, commercial paper and money market accounts invested in U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at June 30, 2021, the net fair value of our interest-sensitive marketable securities would have resulted in a hypothetical decline of approximately $2.6 million.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is (1) recorded, processed, summarized, and reported

within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2021 there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, 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

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of June 30, 2021, we were not party to any legal or arbitration proceedings that may have, or have had in the recent past, significant effects on our financial position. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of executive management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

Item 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report on Form 10-K, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Those risk factors below denoted with a "" are newly added or have been materially updated from our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on February 23, 2021.*

Our business may be materially and adversely affected by the ongoing COVID-19 pandemic. The COVID-19 pandemic has had, and may continue to have, an impact on various aspects of our business and that of third parties on which we rely. The extent to which the COVID-19 pandemic impacts our business will depend in part on future developments, which are uncertain and unpredictable in nature.

In December 2019, a novel strain of coronavirus (COVID-19) was reported and in March 2020, the World Health Organization characterized COVID-19 as a pandemic. The COVID-19 pandemic, which has continued to spread, and the related adverse public health developments, including orders to shelter-in-place, travel restrictions, and the imposition of additional requirements on businesses, have adversely affected workforces, organizations, healthcare communities, economies, and financial markets globally, leading to an economic downturn and increased market volatility. It has also disrupted the normal operations of businesses across industries, including ours. As a result of the COVID-19 pandemic, we are experiencing disruptions in our operations and business, and those of third parties upon whom we rely. For instance, we have experienced disruptions in the conduct of our clinical trials, manufacturing and commercialization efforts, including the commercial launch of beti-cel in Europe and the treatment of patients in the commercial context. We cannot reasonably assess or predict at this time the full extent of the negative impact that the COVID-19 pandemic and related effects may have on our business, financial condition, results of operations and cash flows. We expect to continue experiencing these disruptions in our operations and those of our third parties for an unknown period of time, as the trajectory of the COVID-19 pandemic remains uncertain and continues to evolve in the United States and globally. These impacts, which may materially and adversely affect our business, include the following:

- We are conducting a number of clinical studies across our programs in geographies which are affected by the COVID-19 pandemic. The COVID-19 pandemic has had, and will likely continue to have, an impact on various aspects of our clinical studies. Policies at various clinical sites and federal, state, local and foreign laws, rules and regulations are continuing to evolve, including through the implementation of quarantines and travel restrictions, and direction of healthcare resources toward pandemic response efforts. For instance, the availability of intensive care unit beds and related healthcare resources available to support activities unrelated to COVID-19 response have fluctuated with the incidence of severe cases of COVID-19 in the surrounding communities, and we anticipate that the availability of healthcare resources will continue to fluctuate and may become significantly constrained, with variability across geographies. The COVID-19 pandemic has disrupted the conduct of our ongoing clinical studies, with the result of slower patient enrollment and treatment as well as delays in post-treatment patient follow-up visits. These impacts have varied by clinical study, with the most significant impacts being on our ongoing HGB-210 study for LentiGlobin for SCD. It is possible that these delays may impact the timing of our regulatory submissions. It is unknown how long these disruptions could continue.
- We currently rely on third parties to manufacture, perform quality testing, and ship our lentiviral vectors and drug products for our clinical studies and support commercialization efforts. The third parties in our supply chain have been, may continue to be, and in the future may be, subject to restrictions in operations arising from the COVID-19

pandemic, and in addition, a number of these third parties have experienced operational disruptions, which have affected activities necessary for our research, development, and commercialization efforts. These restrictions and disruptions in operations have also given rise to staffing shortages from time to time, which may result in production slowdowns and/or disruptions in delivery systems, potentially interrupting our supply chain and limiting our ability to manufacture our lentiviral vectors and drug products for our clinical studies and for commercial use. At this time, it is unknown how long these disruptions may continue, or the full extent of their impacts.

- The operations of health regulatory agencies globally have been impacted as a result of the COVID-19 pandemic. They have communicated slower response times to regulatory interactions and submissions and, in the future, may lack resources to continue to monitor our clinical studies or to engage in other activities related to review of regulatory submissions in drug development. As a result, timelines for the review of regulatory submissions for our programs have been impacted, and we may experience other delays of unknown duration in the review, inspection, and other regulatory interactions. Any de-prioritization of our clinical studies or delay in regulatory review or interaction resulting from such disruptions could materially affect the development of our product candidates. In addition, we have been engaging in reimbursement discussions with governmental health programs as part of our commercial preparation activities.
- The trading prices for our shares of common stock and other biopharmaceutical companies have been highly volatile as a result of the economic volatility and uncertainty caused by the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of shares of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of, or failure to manage or contain, the COVID-19 pandemic will materially and adversely affect our business, the value of our common stock, and our ability to operate under our operating plan and execute our strategy. Our business and operating plan have already been impacted by the COVID-19 pandemic, the associated governmental restrictions, and the resulting economic conditions, leading us to reduce and defer costs, adjust our priorities, timelines and expectations, and review and revise our operating plans in 2020 and again in 2021 with the intention that it would enable us to advance our corporate strategy and pipeline during this extended period of uncertainty.

The extent of the impacts described above will depend on numerous evolving factors that we may not be able to accurately predict, including:

- the duration, severity, and scope of the pandemic in the United States and globally;
- the effectiveness of governmental, business and individuals' protocols and actions that have been and continue to be taken in response to the pandemic;
- the impact of the pandemic on economic activity and actions taken in response;
- the effect on patients, healthcare providers and business partners;
- uncertainty as to when we will be able to resume normal clinical study enrollment and patient treatment or follow up activities, particularly at clinical study sites located in highly impacted geographies as a result of disruptions at these sites;
- the ability to obtain or deliver sufficient and timely supplies, given the disruptions to the production capabilities of our manufacturers and suppliers, particularly with respect to the priority given to the development, regulatory approval, and manufacture of COVID-19 vaccines;
- our access to the debt and equity markets on satisfactory terms, or at all;
- disruptions in regulatory oversight and actions, as a result of significant and unexpected resources expended to address the COVID-19 by regulators and industry professionals; and
- any closures of our and our partners' offices, operations and facilities.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments which are difficult to predict, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and other actions taken to contain or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies, our research programs, our commercial-readiness activities in the United States, healthcare systems or the global economy. If the ultimate impact of the COVID-19 pandemic and the resulting uncertain economic and healthcare environment is more severe than we anticipated, we may not be able to execute on our current operating plan or on our strategy. If the duration of the COVID-19 pandemic and the associated period of business and social restrictions and economic uncertainty is longer than we anticipated, our cash, cash equivalents, and marketable securities may not be sufficient to fund the activities under our operating plan for the

time period that we anticipated, and we may be required to revise our operating plan further. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Risks related to commercialization

We have limited experience as a commercial company and the marketing and sale of beti-cel, eli-cel, LentiGlobin for SCD, and any oncology product candidates following marketing approval, if and when obtained, may be unsuccessful or less successful than anticipated.

We have limited experience as a commercial company. To-date, our experience as a commercial company has been limited to commercializing beti-cel in the European Union. In August 2021, we announced that we are focusing our efforts in the near-term on the U.S. market and plan to execute an orderly wind down of our European operations. Consequently, there is limited information about our ability to overcome many of the risks and uncertainties encountered by companies commercializing products in the biopharmaceutical industry. To execute our business plan, we will need to successfully:

- gain regulatory acceptance for the development and commercialization of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates;
- obtain adequate pricing and reimbursement for beti-cel, eli-cel, LentiGlobin for SCD, as well as for our oncology product candidates;
- establish and maintain, in the geographies where we hope to treat patients, relationships with qualified treatment centers who will be treating the patients who receive beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates;
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization, including for any extension of marketing approval of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates; and
- develop and maintain successful strategic alliances.

If we are not successful in accomplishing these objectives, we may not be able to develop and commercialize beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates, raise capital, expand our business, or continue our operations.

The commercial success of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, will depend in part on the medical community, patients, and third-party or governmental payers accepting gene therapy products in general, and beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates in particular, as medically useful, cost-effective, and safe. Beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates products that we may bring to the market may not gain market acceptance by physicians, patients, payers and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from the chemotherapy and myeloablative treatments associated with the procedure by which our product and any future products are administered;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;

- the pricing of our product and of any future products;
- publicity concerning our product, any future products, or competing products and treatments; and
- sufficient insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and payers on the benefits of our products and any future products may require significant resources and may never be successful. For instance, following marketing approval of beti-cel in the European Union, we did not reach agreement with payers on an acceptable price for reimbursement in our priority markets in Europe. We can make no assurances as to when we, or any future licensee or commercialization partner, will resume marketing of beti-cel or begin marketing eli-cel in Europe, if ever. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors. Any of these factors may cause beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates, to be unsuccessful or less successful than anticipated.

If the market opportunities for our product or any future products are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

We focus our research and product development on treatments for severe genetic diseases and cancer. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product or any future products, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower or more difficult to identify than expected. Additionally, the potentially addressable patient population for our product and any future products may be limited or may not be amenable to treatment with our products. For instance, in our HGB-206 clinical study of LentiGlobin for SCD, we have received notice of safety events of acute myeloid leukemia or myelodysplastic syndrome, and additional such events may be reported in the future. If these safety events are shown to be related to the use of our lentiviral vector in the manufacture of the gene therapy or the use of myeloablative regimens prior to treatment, or if we are not able to rule out our drug product as a potential cause, the market opportunity for our gene therapies may be negatively impacted even if our gene therapies ultimately receive marketing approval.

Even if we obtain significant market share for a product within an approved indication, because the potential target populations for our product and for the product candidates in our pipeline are small, we may never achieve profitability without obtaining marketing approval for additional indications. For instance, in the field of cancer, the FDA often approves new therapies initially only for use in patients with relapsed or refractory advanced disease. We expect to initially seek approval of our T cell-based product candidates in cancer in this context. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. For example, BMS has received approval from the FDA for ide-cel as a treatment for relapsed and refractory multiple myeloma following four or more prior lines of therapy. BMS is conducting additional studies with the intention to generate data to support marketing approvals for earlier lines of therapy in multiple myeloma, but there is no assurance that such studies will be successful or be sufficient.

Any of these factors may negatively affect our ability to generate revenues from sales of our product and any future products and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

We rely on a complex supply chain for beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates. The manufacture and delivery of our lentiviral vector and drug products present significant challenges for us, and we may not be able to produce our vector and drug products at the quality, quantities, locations or timing needed to support commercialization and our clinical programs. In addition, we may encounter challenges with engaging or coordinating with qualified treatment centers needed to support commercialization.

In order to commercialize beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. We currently rely on third parties to manufacture the lentiviral vectors and the drug product for any clinical trials that we conduct. We have not secured all of the commercial-scale manufacturing capacity that we anticipate requiring for the commercialization of our product candidates, if they should receive marketing approval. If we fail to secure adequate capacity to manufacture our drug products or lentiviral vectors used in the manufacture of our drug products, we may be unable to execute on our development and commercialization plans on the timing that we expect, or at all.

The manufacture of lentiviral vectors and drug products is complex and requires significant expertise. Even with the relevant experience and expertise, manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production, managing the transition from clinical manufacturing to manufacturing in the commercial setting, and ensuring that the product meets required specifications. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot make any assurances that these problems will not occur in the future, or that we will be able to resolve or address in a timely manner or with available funds problems that occur. Because of this complexity, transitioning production of either lentiviral vectors or drug products to backup or second source manufacturing, or to internal manufacturing capacity, requires a lengthy technology transfer process and may require additional significant financial expenditures. Furthermore, our cost of goods development is at an early stage. The actual cost to manufacture our lentiviral vectors and drug products could be greater than we expect and could materially and adversely affect the commercial viability of beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates. If we or such third-party manufacturers are unable to produce the necessary quantities of lentiviral vectors and our drug products, or in compliance with GMP or other pertinent regulatory requirements, and within our planned time frame and cost parameters, the development and commercialization of our product and any future products may be materially harmed. Furthermore, if we or our third-party manufacturers are unable to produce our lentiviral vectors or our drug products in quantities, in accordance with regulatory requirements, including quality requirements, or within the time frames that we need to support our development and commercialization activities, it may result in delays in our plans or increased capital expenditures.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain key materials that are used to manufacture beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates. Such suppliers may not sell these key materials to us or to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have agreements for the commercial supply for all of these key materials.

Additionally, since the HSCs and T cells used as starting material for drug products have a limited window of stability following procurement from a patient, we must establish transduction facilities in the regions where we wish to commercialize beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained. Establishment of such facilities may be financially impractical or impeded by technical, quality, or regulatory issues related to these new sites and we may also run into technical or scientific issues related to transfer of our transduction process or other developmental issues that we may be unable to resolve in a timely manner or with available funds.

Our commercial strategy is to engage apheresis and transplant centers as qualified treatment centers for the collection of patient HSCs and infusion of the drug product once manufactured. To ensure that the qualified treatment centers are prepared to collect patient HSCs and to ship them to our transduction facilities in accordance with our specifications and regulatory requirements, we train and conduct quality assessments of each center as part of engagement. These qualified treatment centers are the first and last points on our complex supply chain to reach patients in the commercial setting. We may not be able to engage qualified treatment centers in all of the regions in our commercial launch strategy, or we may encounter other challenges or delays in engaging qualified treatment centers. We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping the drug product back to the patient. Logistical and shipment delays and problems caused by us, our third-party vendors, and other factors not in our control, such as weather, could prevent or delay the delivery of product to patients. If our qualified treatment centers fail to perform satisfactorily, we may suffer reputational, operational, and business harm. We are required to maintain a complex chain of identity and chain of custody with respect to patient material as it moves through the manufacturing process, from the qualified treatment center to the transduction facility, and back to the patient. Failure to maintain chain of identity and chain of custody could result in adverse patient outcomes, loss of product or regulatory action.

We have limited sales and distribution experience and limited capabilities for marketing and market access. We expect to invest significant financial and management resources to establish these capabilities and infrastructure to support commercial operations. If we are unable to establish these commercial capabilities and infrastructure or to enter into agreements with third parties to market and sell our product or any future products, we may be unable to generate sufficient revenue to sustain our business.

We have limited prior sales or distribution experience and limited capabilities for marketing and market access, and we have yet to generate meaningful product sales following the commercial launch of beti-cel in Europe following marketing approval. To successfully commercialize beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates following marketing approval, if and when obtained, we will need to further develop these capabilities. We may need to expand our infrastructure to support commercial operations in the United States, either on our own or with others. Commercializing an

autologous gene therapy is resource-intensive and has required, and will continue to require, substantial investment in commercial capabilities. We are competing with companies that currently have extensive and well-funded marketing and sales operations. Without significant commercial experience as a company or the support of a third-party to perform these functions, including marketing and sales functions, we may be unable to compete successfully against these more established companies. Furthermore, a significant proportion of the patient populations for beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates lies outside of the United States. We may not be able to establish our global capabilities and infrastructure in a timely manner or at all. The cost of establishing such capabilities and infrastructure may not be justifiable in light of the potential revenues generated by any particular product and/or in any specific geographic region. We currently expect to rely heavily on third parties to launch and market beti-cel, eli-cel, LentiGlobin for SCD, and our oncology product candidates in certain geographies, if approved. We may enter into collaborations with third parties to utilize their mature marketing and distribution capabilities, but we may be unable to enter into agreements on favorable terms, if at all. If our future collaborative partners do not commit sufficient resources to commercialize beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates following marketing approval, if and when obtained, if any, and we are unable to develop the necessary commercial and manufacturing capabilities on our own, we may be unable to generate sufficient product revenue to sustain our business.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Due to the novel nature of our technology and the potential for our product to offer lifetime therapeutic benefit in a single administration, we face additional challenges in obtaining adequate pricing and reimbursement for our product. Failure to obtain or maintain adequate coverage and reimbursement for any new or current product could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments, such as gene therapy products. Sales of our product and any future products will depend substantially, both domestically and abroad, on the extent to which the costs of our product and any future products 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 payers. There is no assurance that the approved prices or reimbursement levels that payers will be willing to pay will be acceptable to us. In addition, because our therapies represent new treatment approaches, the estimation of potential revenues will be complex.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including gene therapies that are potential one-time treatments. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. A number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. In addition, costs or difficulties with the reimbursement experienced by the initial gene therapies to receive marketing authorization may create an adverse environment for reimbursement of other gene therapies.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, or medicinal products, as they are commonly referred to in the European Union, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, the revenues from sales by us or our collaborators, and the potential profitability of our product and any future products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world, but have been most drastic in the European Union. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate or recognize from the sale of the product in that particular country.

Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates following marketing approval, if and when obtained. We expect to experience pricing pressures in connection with the sale of our product and any future products, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. Net prices for drugs may be reduced by

mandatory discounts or rebates required by government or private payers 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. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Furthermore, because our target patient populations are relatively small, the pricing and reimbursement of our product and any future products must be adequate to cover the costs to treat and support the treatment of patients. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product and any future products will be adversely affected. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In addition, the administration of autologous drug products requires procedures for the collection of HSCs or T cells from the patient, followed by chemotherapy and myeloablative treatments, before infusion of the engineered cell therapy product. The manner and level at which reimbursement is provided for these services is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our product.

Although we have proposed novel payment models, including outcomes-based arrangements with payments over time, to assist with realizing the value and sharing the risk of a potential one-time treatment, we did not reach agreement with payers on an acceptable price for reimbursement in our priority markets in Europe. In addition, to the extent reimbursement for our product is subject to outcomes-based arrangements, the total payments received from product sales may vary, our cash collection of future payments and revenue assumptions from product sales will be at risk, and the timing of revenue recognition may not correspond to the timing of cash collection. We plan on commercializing our product candidates in the United States once approved, and will be subject to price reporting obligations set forth by CMS. To the extent reimbursement for our product or any future products by U.S. governmental payers is subject to outcomes-based arrangements, the increased complexity increases the risk that CMS may disagree with the assumptions and judgments that we use in our price reporting calculations, which may result in significant fines and liability.

Collectively, these factors could affect our ability to successfully commercialize our product and any future products and generate or recognize revenues, which would adversely impact our business, financial condition, results of operations and prospects.

Risks related to the research and development of our product candidates

We cannot predict when or if we will obtain marketing approval to commercialize beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates in the United States, and the marketing approval of our product and any future products may ultimately be for more narrow indications than we expect. If our product candidates are not approved in a timely manner or at all for any reason, our business prospects, results of operations, and financial condition would be adversely affected.

Before obtaining marketing approval from regulatory authorities for the commercialization of our product candidates, we must conduct extensive clinical studies to demonstrate the safety, purity and potency, and efficacy, of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. There is a high failure rate for drugs and biologics proceeding through clinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical studies even after achieving promising results in earlier stage clinical studies. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory agencies on study design;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites or due to unforeseen safety issues;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites;
- failure to obtain sufficient cells from patients to manufacture enough drug product or achieve target cell doses;
- delays patient enrollment, or in having patients complete participation in a study or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We have experienced delays in some of our clinical studies in the past, and we may experience similar delays in the future.

Results from previous or ongoing studies are not necessarily predictive of our future clinical study results, and initial or interim results may not continue or be confirmed upon completion of the study. There is limited data concerning long-term safety and efficacy following treatment with our gene therapy and T cell-based product candidates. These data, or other positive data, may not continue or occur for these patients or for any future patients in our ongoing or future clinical studies, and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical studies. There can be no assurance that any of these studies will ultimately be successful or support further clinical advancement or marketing approval of our product candidates. For instance, while patients with SCD who have been treated with LentiGlobin may experience a reduction of vaso-occlusive events following successful engraftment, there can be no assurance that they will not experience vaso-occlusive events in the future. Similarly, patients with cancer who receive treatment with one of our oncology product candidates may experience disease progression. We have experienced unexpected results in the past, and we may experience unexpected results in the future.

Even if our product candidates demonstrate safety and efficacy in clinical studies, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. We may experience delays or rejections based upon additional government regulation from future legislation or administrative action, changes in regulatory agency policy, or additional regulatory feedback or guidance during the period of product development, clinical studies and the review process. The field of cell and gene therapy is evolving, and as more products are reviewed by regulatory authorities, they may impose additional requirements that were not previously anticipated. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates. For example, the development of our product candidates for pediatric use is an important part of our current business strategy, and if we are unable to obtain marketing approval for the desired age ranges, our business may suffer. Furthermore, approvals by the EMA and the European Commission may not be indicative of what the FDA may require for approval.

In general, the FDA requires the successful completion of two pivotal trials to support approval of a biologics licensing application, or BLA, but in certain circumstances, will approve a BLA based on only one pivotal trial. Because beti-cel has been granted the FDA's Fast Track and Breakthrough Therapy designations, we are engaged in discussions with the FDA regarding the development plans for beti-cel to enable a submission of a BLA prior to the completion of our ongoing studies. Based on these discussions, we believe the results from our ongoing Northstar-2 and Northstar-3 clinical studies, together with data from our Northstar study, the LTF-303 long-term follow up protocol, and completed HGB-205 study, could be sufficient to form the basis for a BLA submission for beti-cel to treat patients with TDT. However, it should be noted that our ability to submit and obtain approval of a BLA is ultimately an FDA review decision, which will be dependent upon the data available at such time, and the available data may not be sufficiently robust from a safety and/or efficacy perspective to support the submission or approval of a BLA. Depending on the outcome of these ongoing clinical studies, the FDA may require that we conduct additional or larger pivotal trials before we can submit or obtain approval of a BLA for beti-cel for the treatment of patients with TDT. Furthermore, we are required to submit data relating to certain release assays designed to confirm the quality, purity and strength (including potency) of beti-cel as a condition for completing the BLA submission, which has the potential for further delaying the completion of our BLA submission, with the potential consequence of delaying any approval and commercial launch of beti-cel in the United States.

Based on our discussions with the FDA, we believe that we may be able to seek approval for eli-cel for the treatment of patients with CALD in the United States on the basis of safety and efficacy data from our ongoing Starbeam study, safety data from our ongoing ALD-104 study, and the completed ALD-103 observational study. Whether eli-cel is eligible for approval will ultimately be determined at the discretion of the FDA, and will be dependent upon the data available at such time, and the available data may not be sufficiently robust from a safety and/or efficacy perspective to support approval. Depending on the outcome of our ongoing studies, and pending the resolution of the clinical hold on our eli-cel clinical studies, the FDA may require that we conduct additional or larger clinical trials before eli-cel is eligible for approval.

Based on our discussions with the FDA, we believe that we may be able to seek accelerated approval for our LentiGlobin for SCD product candidate in the United States on the basis of clinical data from Group C of our ongoing HGB-206 clinical study, with our ongoing HGB-210 clinical study providing confirmatory data for full approval. We cannot be certain that data from our HGB-206 or HGB-210 clinical studies will be sufficiently robust from a safety and/or efficacy perspective to support either accelerated approval or full approval. Our development plan in the United States is contingent upon LentiGlobin for SCD demonstrating complete resolution of severe vaso-occlusive events, with globin response as a key secondary endpoint, and an acceptable safety profile in the study participants. Depending on the outcome of our ongoing and planned studies, the FDA may

require that we conduct additional or larger clinical trials before our LentiGlobin product candidate is eligible for approval for the treatment of patients with SCD. In our discussions with FDA regarding the transition of manufacturing to the commercial setting from the clinical context, we are finalizing our plans for validating our commercial manufacturing processes and for providing the FDA with the comparability data that it requires. The FDA may not agree with these plans, or may require additional validation or comparability data as a condition for completing the BLA submission and filing. In addition, in light of reported safety events in our HGB-206 clinical study, the conduct of our clinical studies of LentiGlobin for SCD was interrupted in 2021 as we worked with the FDA to lift the clinical hold on our studies. Taken together, these factors are likely to result in delays in our ability to submit a BLA for regulatory approval of LentiGlobin for SCD.

If our product candidates are ultimately not approved for any reason, our business, prospects, results of operations and financial condition would be adversely affected.

Changes in our manufacturing processes may cause delays in our clinical development and commercialization plans.

The manufacturing processes for our lentiviral vectors and our drug products are complex. We explore improvements to our manufacturing processes on a continual basis, as we evaluate clinical and manufacturing data and based on discussions with regulatory authorities. In some circumstances, changes in the manufacturing process may require us to perform additional comparability studies, collect additional data from patients, submit additional regulatory filings, or comply with additional requirements, which may lead to delays in our clinical development and commercialization plans. For instance, following the conditional approval of beti-cel by the European Commission, we continued to refine our commercial drug product manufacturing process to narrow some of the manufacturing process parameters and to tighten the range of commercial drug product release specifications, based on an ongoing discussion with the EMA and evolving clinical data. Implementing these changes to the beti-cel commercial manufacturing process had the effect of delaying our ability to treat the first patient in the commercial context in Europe. In LentiGlobin for SCD, we plan to seek regulatory approval for drug product utilizing lentiviral vector manufactured using the scalable suspension manufacturing process, rather than the adherent manufacturing process. The FDA may not agree with our proposed plans for demonstrating the comparability of the two processes, and may require us to conduct additional studies, collect additional data, develop additional assays, or modify release specifications, which may delay our ability to submit a BLA for regulatory approval of LentiGlobin for SCD. Over time, we also intend to transition the lentiviral vector manufacturing process for beti-cel in the United States to the suspension manufacturing process, and the timing in which we are able to make the transition will be dependent upon reaching agreement with the FDA, which may require us to conduct additional studies, collect additional data, develop additional assays, or modify release specifications.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced, safer or effective than ours, which may adversely affect our financial condition and our ability to successfully develop and commercialize beti-cel, eli-cel, LentiGlobin for SCD, and oncology product candidates. If our competitors obtain orphan drug exclusivity for products that regulatory authorities determine constitute the same drug and treat the same indications as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

We are engaged in the development of gene therapies for severe genetic diseases and cancer, and both fields are competitive and rapidly changing. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, more experienced manufacturing capabilities, or more established commercial infrastructure. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, safer, or less costly than any products that we may develop, or achieve patent protection, marketing approval, product commercialization and market penetration earlier than us. Additionally, technologies developed by our competitors may render our potential products uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors. For additional information regarding our competition, see “Item 1. Business—Competition” in our Annual Report on Form 10-K.

Even if we are successful in achieving marketing approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be “highly similar,” or biosimilar, to or “interchangeable” with an FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data from biological products already approved, but will not be able to get on the market until 10 years after the time of approval. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing

authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

In addition, although beti-cel, eli-cel, and LentiGlobin for SCD have been granted orphan drug status by the FDA and EMA, there are limitations to the exclusivity. In the United States, the exclusivity period for orphan drugs is seven years, while pediatric exclusivity adds six months to any existing patents or exclusivity periods. In Europe, orphan drugs may be able to obtain 10 years of marketing exclusivity and up to an additional two years on the basis of qualifying pediatric studies. However, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria. Additionally, a marketing authorization holder may lose its orphan exclusivity if it consents to a second orphan drug application or cannot supply enough drug. Orphan drug exclusivity also can be lost when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. Generally, if a product with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Commission from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the exclusivity period for the applicable indication.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our competitors’ products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize products based on our platform technologies, including our gene editing technology and cancer immunotherapy capabilities. Our research programs in oncology and severe genetic diseases may fail to identify other potential product candidates for clinical development for a number of reasons. We may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If any of these events occur, we may be forced to abandon our research, development or commercialization efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

****Insertional oncogenesis is a risk of gene therapies using viral vectors that can integrate into the genome, and a patient with CALD treated with eli-cel in one of our clinical studies has been diagnosed with myelodysplastic syndrome likely mediated by Lenti-D lentiviral vector insertion. These events may require us to halt or delay further clinical development of our product candidates, such as eli-cel, or to suspend or cease commercialization following marketing approval, and the commercial potential of our product candidates may be materially and negatively impacted.***

A potentially significant risk in any gene therapy product using viral vectors that can integrate into the genome is that the vector will insert in or near cancer-causing genes, leading to the proliferation of certain cellular clones that can cause cancer in the patient, known as insertional oncogenesis. Clonal predominance and vector insertion into or near genes associated with cancer in the general population has been detected in some patients treated with eli-cel. In August 2021, we reported that one of these patients has been diagnosed with myelodysplastic syndrome (MDS) likely mediated by Lenti-D lentiviral vector insertion, and dysplastic cells have been observed in another patient. As a result, the FDA has placed our clinical studies of eli-cel on clinical hold, and we have no assurance as to what the FDA may require for lifting the clinical hold, the timing of when the clinical hold may be lifted, and whether the timeline for our BLA submission for eli-cel may be delayed. It is possible that the FDA may also place a clinical hold on our clinical studies for beti-cel and LentiGlobin for SCD, or may require additional information, testing, or monitoring that results in delays to the timeline of our BLA submissions for these programs. In addition, we cannot make assurances that additional patients treated with eli-cel, beti-cel or LentiGlobin for SCD in the clinical or commercial setting will not exhibit clonal predominance in the future, that additional patients will not be diagnosed with MDS, or that the patient diagnosed with MDS or any other patient will not develop leukemia or lymphoma. It is possible that upon occurrence of any of these events, FDA may place one or more of our programs on hold, impose requirements that result in the delay of the BLA submissions for one or more of our programs, or may cause us to cease commercialization following the receipt of any marketing approval. If any of these were to occur, the commercial potential of our programs may be materially and negatively impacted.

.

There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. The FDA has stated that lentiviral vectors possess characteristics that may pose high risks of delayed adverse events. If any such adverse events occur, further advancement of our clinical studies could be halted or delayed, and we may be unable to continue to commercialize our approved product. Furthermore, treatment with our gene therapy product and product candidates involve chemotherapy or myeloablative treatments which can cause side effects or adverse events that may impact the perception of the potential benefits of our product and any future products. For instance, myelodysplastic syndrome leading to acute myeloid leukemia is a known risk of certain myeloablative regimens. Additionally, beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates, the procedures associated with their administration, or with the collection of patients' cells, could potentially cause other adverse events that have not yet been predicted. The inclusion of patients with significant underlying medical problems in our clinical studies may result in deaths, or other adverse medical events, due to other therapies or medications that such patients may be using, or the progression of their disease.

For instance, it is possible that the events of myelodysplastic syndrome and acute myeloid leukemia previously reported in our HGB-206 clinical study were caused by the LentiGlobin for SCD drug product, in combination with underlying sickle cell disease, transplant procedure, and stress on the bone marrow following drug product infusion. Even if a product such as LentiGlobin for SCD, eli-cel or beti-cel is ultimately approved, such safety events may result in the product being removed from the market or its market opportunity being significantly reduced. Other patients receiving our product or product candidates may develop leukemia, lymphoma, or myelodysplastic syndrome in the future, which may negatively impact the commercial prospects of our product or product candidates. Any of these events could impair our ability to develop or commercialize our product candidates, and their commercial potential may be materially and negatively impacted.

Patients receiving T cell-based immunotherapies, such as ide-cel and the bb21217 product candidate, may experience serious adverse events, including neurotoxicity and cytokine release syndrome. If our product candidates are revealed to have high and unacceptable severity and/or prevalence of side effects or unexpected characteristics, their clinical development, marketing approval, and commercial potential will be negatively impacted, which will significantly harm our business, financial condition and prospects.

Ide-cel and the bb21217 product candidate are chimeric antigen receptor, or CAR, T cell-based immunotherapies. In previous and ongoing clinical studies involving CAR T cell products, including those involving ide-cel and the bb21217 product candidate, patients experienced side effects such as neurotoxicity and cytokine release syndrome. There have been life-threatening events related to severe neurotoxicity and cytokine release syndrome, requiring intense medical intervention such as intubation or pressor support, and in several cases, resulted in death. Severe neurotoxicity is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures, or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. In some cases, severe neurotoxicity was thought to be associated with the use of certain lymphodepletion regimens used prior to the administration of the CAR T cell products. Cytokine release syndrome is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills, low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant vasopressor support. The exact cause or causes of cytokine release syndrome and severe neurotoxicity in connection with treatment of CAR T cell products is not fully understood at this time. In addition, patients have experienced other adverse events in these studies, such as a reduction in the number of blood cells (in the form of neutropenia, thrombocytopenia, anemia or other cytopenias), febrile neutropenia, chemical laboratory abnormalities (including elevated liver enzymes), and renal failure.

Undesirable side effects caused by ide-cel or the bb21217 product candidate, other CAR T product candidates targeting BCMA, or our other T cell-based immunotherapy product candidates, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. In some cases, side effects such as neurotoxicity or cytokine release syndrome have resulted in clinical holds of ongoing clinical trials and/or discontinuation of the development of the product candidate. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell-based immunotherapies are not normally encountered in the general patient population and by medical personnel. Medical personnel may need additional training regarding T cell-based immunotherapy product candidates to understand their side effects. Inadequate training in recognizing or failure to effectively manage the potential side effects of T cell-based immunotherapy product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product and any future products or adversely affect our ability to conduct our business or obtain and maintain marketing approvals for our product and product candidates.

Public perception may be influenced by claims that gene therapy, including gene editing technologies, is unsafe or unethical, and research activities and adverse events in the field, even if not ultimately attributable to us or our product or product candidates, could result in increased governmental regulation, unfavorable public perception, challenges in recruiting patients to participate in our clinical studies, potential regulatory delays in the testing or approval of our potential products, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any approved products.

Risks related to our reliance on third parties

We are dependent on BMS for the successful commercialization and further development of ide-cel. If BMS does not devote sufficient resources to the commercialization or further development of ide-cel, is unsuccessful in its efforts, or chooses to terminate its agreements with us, our business will be materially harmed.

We are co-developing and co-promoting ide-cel, marketed as ABECMA, in the United States with BMS under our amended and restated co-development and co-promotion agreement with BMS, or the Ide-cel CCPS. Under the Ide-cel CCPS, we and BMS share the obligation to develop and commercialize ide-cel in the United States. In addition, we have exclusively licensed to BMS the right to develop and commercialize the bb21217 product candidate, and we retain an option to co-develop and co-promote bb21217 in the United States under our license agreement with BMS. With respect to bb21217, we are responsible for completing the ongoing CRB-402 study, but BMS is responsible for further clinical development and commercialization costs, unless we choose to exercise our option to co-develop and co-promote bb21217 in the United States. If we exercise our option to co-develop and co-promote bb21217 in the United States, we and BMS will share the obligation to develop and commercialize bb21217 in the United States.

In our partnership with BMS, BMS is obligated to use commercially reasonable efforts to develop and commercialize ide-cel and bb21217 in the United States. BMS may determine however, that it is commercially reasonable to de-prioritize or discontinue the development of ide-cel and bb21217. These decisions may occur for many reasons, including internal business reasons (including due to the existence of other BMS programs that are potentially competitive with ide-cel and bb21217), results from clinical trials or because of unfavorable regulatory feedback. Further, on review of the safety and efficacy data, the FDA may impose requirements on one or both of the programs that render them commercially nonviable. In addition, under our agreements with BMS, BMS has certain decision-making rights in determining the development and commercialization plans and activities for the programs. We may disagree with BMS about the development strategy it employs, but we will have limited rights to impose our development strategy on BMS. Similarly, BMS may decide to seek marketing approval for, and limit commercialization of, ide-cel or bb21217 to narrower indications than we would pursue. More broadly, if BMS elects to discontinue the development of ide-cel or bb21217, we may be unable to advance the product candidate ourselves.

This partnership may not be scientifically or commercially successful for us due to a number of important factors, including the following:

- BMS has wide discretion in determining the efforts and resources that it will apply to its partnership with us. The timing and amount of any development milestones and downstream commercial profits that we may receive under such partnership will depend on, among other things, BMS's efforts, allocation of resources and successful development and commercialization of ide-cel.
- BMS may develop and commercialize, either alone or with others, products that are similar to or competitive with ide-cel. For example, BMS is currently commercializing a number of its existing products, including lenalidomide and pomalidomide, for certain patients with relapsed and refractory multiple myeloma and is also developing another CAR-T product candidate targeting ide-cel that it obtained through its acquisition of Juno Therapeutics, Inc.
- BMS may terminate its partnership with us without cause and for circumstances outside of our control, which could make it difficult for us to attract new strategic partners or adversely affect how we are perceived in scientific and financial communities.
- BMS may develop or commercialize our product candidates in such a way as to elicit litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.
- BMS may not comply with all applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements.

- If BMS were to breach its arrangements with us, we may need to enforce our right to terminate the agreement in legal proceedings, which could be costly and cause delay in our ability to receive rights back to the relevant product candidates. If we were to terminate an agreement with BMS due to BMS's breach or BMS terminated the agreement without cause, the development and commercialization of ide-cel or bb21217 product candidates that are the subject of its collaboration with us could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of these product candidates on our own if we choose not to, or are unable to, enter into a new collaboration for these product candidates.

BMS may enter into one or more transactions with third parties, including a merger, consolidation, reorganization, sale of substantial assets, sale of substantial stock or other change in control, which could divert the attention of its management and adversely affect BMS's ability to retain and motivate key personnel who are important to the continued development of the programs under the strategic partnership with us. In addition, the third-party to any such transaction could determine to re-prioritize BMS's development programs such that BMS ceases to diligently pursue the development of our programs and/or cause the respective collaboration with us to terminate.

We rely on third parties to conduct some or all aspects of our lentiviral vector production, drug product manufacturing, and testing, and these third parties may not perform satisfactorily.

We do not independently conduct all aspects of our lentiviral vector production, drug product manufacturing, and testing. We currently rely, and expect to continue to rely, on third parties with respect to these items, including manufacturing and testing in the commercial context.

Our reliance on these third parties for manufacturing, testing, research and development activities reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study protocols. For example, for products that we develop and commercialize on our own, we will remain responsible for ensuring that each of our IND-enabling studies and clinical studies are conducted in accordance with the study plan and protocols, and that our lentiviral vectors and drug products are manufactured in accordance with GMP as applied in the relevant jurisdictions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, or manufacture our lentiviral vectors and drug products in accordance with GMP, whether due to the impacts of COVID-19 or otherwise, we will not be able to complete, or may be delayed in completing, the preclinical and clinical studies and manufacturing process validation activities required to support future IND, MAA and BLA submissions and approval of our product candidates, or to support commercialization of our products, if approved. Many of our agreements with these third parties contain termination provisions that allow these third parties to terminate their relationships with us at any time. If we need to enter into alternative arrangements, our product development and commercialization activities could be delayed.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the products ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- the risk that these activities are not conducted in accordance with our study plans and protocols;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

We may be forced to manufacture lentiviral vector and drug product ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills required to manufacture our lentiviral vector or drug product candidates may be unique or proprietary to the original manufacturer, and we may have difficulty or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Any of these events could lead to clinical study delays or failure to obtain marketing approval, or impact our ability to successfully commercialize our product or any future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product and product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product and product candidates, are subject to extensive regulation. Some components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product and product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or MAA on a timely basis and where required, must adhere to the FDA's or other regulator's good laboratory practices, or GLP, and GMP regulations enforced by the FDA or other regulator through facilities inspection programs. Some of our contract manufacturers have not produced a commercially-approved product and therefore have not obtained the requisite FDA or other marketing approvals to do so. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product and potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA or other marketing approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulators can impose regulatory sanctions including, among other things, refusal to approve a pending application for a biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. The number of manufacturers with the necessary manufacturing capabilities is limited. In addition, an alternative manufacturer would need to be qualified through a BLA supplement or similar regulatory submission which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical studies, regulatory submissions, required approvals or commercialization of our product and any future products, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenues.

We expect to rely on third parties to conduct, supervise and monitor our clinical studies, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We expect to rely on CROs and clinical study sites to ensure our clinical studies are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's and other regulatory authorities' GCPs for conducting, recording and reporting the results of clinical studies to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical study participants are protected. If we or our CROs fail to comply with applicable

GCPs, the clinical data generated in our future clinical studies may be deemed unreliable and the FDA and other regulatory authorities may require us to perform additional clinical studies before approving any marketing applications.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain marketing approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to manufacture our vectors and our drug products, and because we collaborate with various organizations and academic institutions on the advancement of our gene therapy platform, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks related to our financial condition and capital requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have incurred net losses in each year since our inception in 1992, including net losses of $447.5 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $3.35 billion. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to generate revenues. We have devoted significant financial resources to research and development, including our clinical and preclinical development activities, which we expect to continue for the foreseeable future. To date, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, through collaboration agreements and grants from governmental agencies and charitable foundations. We have not generated material revenues from the sale of beti-cel in the European Union, and we do not expect to generate meaningful product revenues in the foreseeable future until we obtain marketing approval for products in the United States. Following marketing approval, our future revenues will depend upon the size of any markets in which our product and any future products have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payers and adequate market share for our product and any future products in those markets. We are dependent upon the commercialization efforts of BMS for any collaboration revenue from sales of ide-cel through our profit-loss sharing arrangement.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and preclinical and clinical development of our product candidates, including ide-cel, which we are co-developing with BMS;

- establish capabilities to support our commercialization efforts, including establishing a sales, marketing and distribution infrastructure in the United States, and to commercialize products for which we may obtain marketing approval;
- obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;
- initiate additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We have not generated material revenue from product sales and may never be profitable.

Our ability to generate revenues and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory, pricing and reimbursement approvals necessary to commercialize beti-cel, eli-cel, or LentiGlobin for SCD. Our ability to generate revenues from product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- developing a sustainable, commercial-scale, reproducible, and transferable manufacturing process for our vectors and drug products;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development for our product candidates and commercial demand for any approved product;
- launching and commercializing any approved product, either by collaborating with a partner or, if launched independently, by establishing a field-based team, marketing and distribution infrastructure;
- obtaining sufficient pricing and reimbursement for any approved product from private and governmental payers;
- obtaining market acceptance and adoption of any approved product and gene therapy as a viable treatment option;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how.

We expect to continue to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase, which costs may increase further as competitors enter the market. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate material product revenues, we may not become profitable and may need to obtain additional funding to continue operations.

****From time to time, we will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.***

We are currently advancing our late-stage programs in severe genetic diseases through clinical development and several oncology product candidates through preclinical development. Developing and commercializing gene therapy products is expensive, and we expect our research and development expenses and our commercialization expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates and progress our

commercialization readiness efforts in the United States. We do not expect to recognize material revenue from commercial sales of beti-cel or eli-cel in Europe prior to our planned wind down of our European operations. We can make no assurances as to when we, or any future licensee or commercialization partner, will resume marketing of beti-cel or begin marketing eli-cel in Europe, if ever.

As of June 30, 2021, our cash, cash equivalents and marketable securities were $941.6 million. Based on our current business plan, we expect our cash, cash equivalents and marketable securities will be sufficient to fund planned operations for at least the next twelve months from the date of issuance of these financial statements. Our current business plan assumes the completion of our planned separation, continued rigorous prioritization and focus on our expenses, real estate optimization, and exploration of additional sources of funding, including through public or private equity or debt financings, to further strengthen our financial position. However, our operating plan may change further as a result of the COVID-19 pandemic and the surrounding economic conditions, as well as many other factors currently unknown to us. In addition, we may seek additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances and licensing arrangements or a combination of these approaches, during this period. In any event, we will require additional capital to obtain marketing approval for, and to commercialize, our product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic objectives.

Our fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our approved product and product candidates. In addition, we cannot guarantee that financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, or if revenues from collaboration arrangements or product sales are less than we have projected, we may be required to further revise our business plan and strategy, which may result in us significantly curtailing, delaying or discontinuing one or more of our research or development programs or the commercialization of any product candidates or may result in our being unable to expand our operations or otherwise capitalize on our business opportunities, beyond our current plans. As a result, our business, financial condition and results of operations could be materially affected.

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements are incorrect, our actual results may vary from those reflected in our projections and accruals.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct. We may be incorrect in our assumptions regarding the applicability of drug pricing programs and rebates that may be applicable to our product or any future products, which may result in our under- or over-estimating our anticipated product revenues especially as applicable laws and regulations governing pricing evolve over time. In addition, to the extent payment for our product or any future products is subject to outcomes-based arrangements over time, the total payments received from product sales may vary, our cash collection of future payments and revenue assumptions from product sales will be at risk, and the timing of revenue recognition may not correspond to the timing of cash collection.

Further, from time to time we issue financial guidance relating to our expectations for our cash, cash equivalents, and marketable securities available for operations, which guidance is based on estimates and the judgment of management. If, for any reason, our expenses differ materially from our guidance or we utilize our cash more quickly than anticipated, we may have to adjust our publicly announced financial guidance. If we fail to meet, or if we are required to change or update any element of, our publicly disclosed financial guidance or other expectations about our business, our stock price could decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We expect that following marketing approval, if and when obtained, revenues from product sales will be difficult to predict from period to period, given the absence of historical sales data for beti-cel, eli-cel and LentiGlobin for SCD.

In addition, we have entered into licensing and collaboration agreements with other companies that include research and development funding and milestone payments to us, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will also depend on research and development funding, the achievement of milestones under our existing collaboration and license agreements, and profit-sharing arrangements for any approved products, including, in particular, our collaborations with BMS and Regeneron, as well as entering into potential new collaboration and license agreements. These payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

Further, changes in our operations, such as increased development, manufacturing and clinical trial expenses in connection with expanding our pipeline programs, or our undertaking of additional programs, or business activities, or entry into strategic transactions, including potential future acquisitions of products, technologies or businesses may also cause significant fluctuations in our expenses.

The cumulative effects of these factors, further exacerbated by the impacts of the ongoing COVID-19 pandemic on healthcare systems and economic conditions, will likely result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Risks related to our business operations

Even if we receive marketing approval for a product candidate, any approved product will remain subject to regulatory scrutiny.

Even if we obtain marketing approval in a jurisdiction, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of any approved products, or impose ongoing requirements for potentially costly post-approval studies, post-market surveillance or patient or drug restrictions. For example, the FDA typically advises that patients treated with gene therapy undergo follow-up observations for potential adverse events for a 15-year period. Additionally, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. We have experienced interruptions in our marketing of beti-cel in Europe due to safety concerns arising from our LentiGlobin for SCD program, and we can make no assurance that we will not experience interruptions in any marketing or other commercialization activities in the future, whether due to safety concerns in any approved products, or due to events arising from programs that utilize technologies similar to or related to ours.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with good manufacturing practices, or GMP, and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following marketing approval for a product, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;

- suspend any ongoing clinical studies;
- refuse to approve a pending marketing application, such as a BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved product and generate revenues.

We are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties, reputational harm, and diminished profits and future earnings.

In the United States, the research, manufacturing, distribution, sale, and promotion of drugs and biologic products are subject to regulation by various federal, state, and local authorities in addition to FDA, including CMS, other divisions of the HHS, (e.g., the Office of Inspector General), the United States Department of Justice offices of the United States Attorney, the Federal Trade Commission and state and local governments. Our operations are directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations described in more detail under *"Item 1. Business--Government regulation"* in our Annual Report. These include the federal Anti-Kickback Statute, federal civil and criminal false claims laws and civil monetary penalty laws (including False Claims Laws), HIPAA, transparency requirements created under the Affordable Care Act, as well as analogous state and foreign laws.

These laws apply to, among other things, our sales, marketing and educational programs. State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have recently increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co-pay support, funding of independent charitable foundations and other programs that offer benefits for patients. Several investigations into these programs have resulted in significant civil and criminal settlements.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions In addition to HIPAA, as amended by HITECH, and their respective implementing regulations, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business

activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

In the European Union, interactions between pharmaceutical companies, healthcare professionals, and patients are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU member states. The provision of benefits or advantages to healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Also, direct-to-consumer advertising of prescription-only medicinal products is prohibited at the European Union level and in the individual member states. In addition, the UK Bribery Act applies to any company incorporated in or "carrying on business" in the UK, irrespective of where in the world the alleged bribery activity occurs, which could have implications for our interactions with physicians both in and outside of the UK. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

EU member states, Switzerland and other countries have also adopted data protection laws and regulations, which impose significant compliance obligations. In the European Union, the collection and use of personal health data is currently governed by the provisions of the General Data Protection Regulation, or the GDPR. The GDPR, together with the national legislation of the individual EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals for the consent to be considered valid, the transfer of personal data out of the European Economic Area, security breach notifications, the use of third-party processors in connection with the processing of the personal data, confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU member states may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in the European Union. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. 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. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any activities falling within the scope of the GDPR. Further, 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.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our approved product or product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our approved product or product candidates, our marketing approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients participating in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product or product candidates. There is a risk that our product or product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;

- substantial monetary awards to patients or other claimants;
- the inability to develop our product candidates or commercialize any approved product; and
- decreased demand for any approved product.

We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs and approved product; however, we may not be able to maintain insurance coverage at commercially reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our approved product and product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our approved product or product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain marketing approval for any approved product, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our marketing approval process in other countries, or impact and limit the type of marketing approval our product candidates may receive or any approved product maintains. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, expanded the types of entities eligible for the 340B drug discount program, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Various portions of the Affordable Care Act are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court. It is unclear whether the Affordable Care Act will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the Affordable Care Act would have on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. These reductions were extended through

2029 through subsequent legislative amendments. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payers.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Our computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates' development programs and have a material adverse effect on our reputation, business, financial condition or results of operations.

Our computer systems and those of our current or future third-party collaborators, service providers, contractors and consultants may fail and are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The size and complexity of our information technology systems, and those of our collaborators, service providers, contractors and consultants, and the large amounts of information stored on those systems make those systems vulnerable to service interruptions, security breaches, or other failures, resulting from inadvertent or intentional actions by our employees or those of third-party business partners, or from cyber-attacks by malicious third parties. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to extracting sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices also increases the risk of data security incidents. If we experience a material system failure, accident or security breach that causes interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in significant reputational, financial, legal, regulatory, business or operational harm. For example, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. In addition, we rely on third-party service providers for management of the manufacture and delivery of drug product to patients in

the commercial context, including for chain of identity and chain of custody. We also rely on third-party service providers for aspects of our internal control over financial reporting and such service providers may experience a material system failure or fail to carry out their obligations in other respects, which may impact our ability to produce accurate and timely financial statements, thus harming our operating results, our ability to operate our business, and our investors' view of us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to material failures, security breaches, cyberattacks and other related breaches.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations to third parties, or any data security incidents or other security breaches that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us. These events could cause third parties to lose trust in us or could result in claims by third parties asserting that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

Risks related to the proposed separation of our business

The proposed separation of our business into two independent, publicly traded companies is subject to various risks and uncertainties and may not be completed on the terms or timeline currently contemplated, if at all, and will involve significant time, effort and expense, which could harm our business, results of operations and financial condition.

In January 2021, we announced our intent to separate our oncology programs from our severe genetic disease programs, resulting in two independent, publicly traded companies, bluebird bio and 2seventy bio. Following the separation, bluebird bio is expected to focus on the development and commercialization of therapies in β-thalassemia, cerebral adrenoleukodystrophy and sickle cell disease. 2seventy bio is expected to focus on the research and development efforts in our oncology pipeline, as well as supporting the commercialization of ide-cel and development of the bb21217 product candidate through the BMS collaboration.

The separation is expected to be completed by the end of 2021, subject to receipt of a favorable IRS ruling and the satisfaction of certain conditions. Unexpected developments, including adverse market conditions or tax consequences or delays or difficulties effecting the proposed separation, could delay, prevent or otherwise adversely impact the anticipated benefits from the proposed separation. Consummation of the separation also will require final approval from our board of directors. We may not complete the separation on the terms or on the timeline that we announced, or may, for any or no reason and at any time until the proposed separation is complete, abandon the separation or modify or change its terms. Any of the foregoing may result in our not achieving the operational, financial, strategic and other benefits we anticipate realizing as a result of the separation, and in each case, our business, results of operations and financial condition could be adversely affected.

We will incur significant expenses in connection with the proposed separation, and such costs and expenses may be greater than we anticipate. In addition, completion of the separation will require a significant amount of management time and effort, which may disrupt our business or otherwise divert management's attention from other aspects of our business, including strategic initiatives, discovery, development and commercialization efforts and relationships with our partners and other third parties. Any of the foregoing could adversely affect our business, results of operations and financial condition.

We may fail to realize some or all of the anticipated benefits of the proposed separation.

Even if the separation is completed, the anticipated operational, financial, strategic and other benefits of the separation may not be achieved. The combined value of the common stock of the two publicly-traded companies may not be equal to or greater than what the value of our common stock would have been had the separation not occurred. The combined value of the common stock of the two companies could be lower than anticipated for a variety of reasons, including the failure of either company to operate and compete effectively as an independent company. The common stock price of each company may experience periods of extreme volatility. In addition, the two independent companies will be smaller and less diversified, with a narrower business focus, and may be more vulnerable to changing market conditions. The separation also presents a number of significant risks to our internal processes, including the failure to maintain an adequate control environment due to changes to our infrastructure technology systems and financial reporting processes.

If the distribution of shares of 2seventy bio, together with certain related transactions, does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, our stockholders and we could be subject to significant tax liabilities.

In connection with the distribution of shares in 2seventy bio, we are seeking a private letter ruling from the IRS (the "IRS Ruling") and an opinion from our tax advisor (the "Tax Opinion") to the effect that, among other things, the distribution of shares in 2seventy bio, together with certain related transactions, will generally qualify as tax-free for U.S. federal income tax purposes under Sections 368(a)(1)(D) and 355 of the U.S. Internal Revenue Code of 1986, as amended (the “Code”). The IRS Ruling and the Tax Opinion will rely on certain facts, assumptions, representations, and undertakings from us and 2seventy bio, including those regarding the past and future conduct of the companies' respective businesses and other matters. Notwithstanding the IRS Ruling and the Tax Opinion, the IRS could determine that the distribution or any such related transaction is taxable if it determines that any of these facts, assumptions, representations or undertakings are not correct or have been violated, or that the distribution should be taxable for other reasons, including if the IRS were to disagree with the conclusions in the Tax Opinion. The Tax Opinion will not be binding on the IRS or the courts. Accordingly, the IRS or the courts may challenge the conclusions stated in the Tax Opinion and such challenge could prevail.

If the distribution were determined to be taxable for U.S. federal income tax purposes, our stockholders that receive shares of 2seventy bio in the distribution would be treated as having received a distribution of property in an amount equal to the fair value of such 2seventy bio shares on the distribution date and could incur significant income tax liabilities. Such distribution would be taxable to our stockholders as a dividend to the extent of our current and accumulated earnings and profits. Any amount that exceeded our current and accumulated earnings and profits would be treated first as a non-taxable return of capital to the extent of the relevant stockholder’s tax basis in its shares of stock, with any remaining amount being taxed as capital gain. We would recognize a taxable gain in an amount equal to the excess, if any, of the fair market value of the shares of 2seventy bio common stock held by us on the distribution date over our tax basis in such shares.

Risks related to our intellectual property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patent applications we hold or have in-licensed with respect to our programs or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. Several patent applications covering our product candidates have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by a third-party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available however the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-

how, and information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex part*e reexaminations, post-grant review, and *inter partes* review proceedings before the U.S. Patent and Trademark Office, or U.S. PTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to gene therapy product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates and commercialize our approved product. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or clinical development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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 lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may need to obtain licenses from third parties to advance the development of our product candidates or allow commercialization of our approved product, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates, approved product, or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected approved product or product candidates.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. 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 re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we 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 approved product and/or product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors 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 our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We have had in the past, and we may also have in the future, ownership disputes

arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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 non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the U.S. PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The U.S. PTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, 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.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. 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 products 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 products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. 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 or license.

Risks related to ownership of our common stock

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the price at which you purchase them.

Companies trading in the stock market in general, and The NASDAQ Global Select Market 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 biotechnology and pharmaceutical industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

The market price of our common stock has been volatile in the past, and may continue to be volatile for the foreseeable future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in preclinical or clinical studies;
- reports of adverse events in our product, product candidates or other gene therapy products, or in clinical studies of such products;
- inability to obtain additional funding;
- any delay in filing an IND, MAA or BLA for any of our product candidates, and any adverse development or perceived adverse development with respect to the regulatory authority's review of that IND, MAA or BLA;
- failure to successfully manage the commercial launch of beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates following marketing approval, if and when obtained, including failure to manage our supply chain operations in the coordination and delivery of drug product to patients at qualified treatment centers;
- failure to obtain sufficient pricing and reimbursement for beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates from private and governmental payers;
- failure to obtain market acceptance and adoption of beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates following marketing approval, if and when obtained;
- developments concerning the proposed separation of our programs into two independent, publicly-traded companies;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to future products;
- inability to obtain adequate product supply for beti-cel, eli-cel, LentiGlobin for SCD, or our oncology product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partner or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

Actual or potential sales of our common stock by our employees, including our executive officers, pursuant to pre-arranged stock trading plans could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, and our policies regarding stock transactions, a number of our employees, including executive officers and members of our board of directors, have adopted and may continue to adopt stock trading plans pursuant to which they have arranged to sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors require public filings. Actual or potential sales of our common stock by such persons could cause the price of our common stock to fall or prevent it from increasing for numerous reasons.

****Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 Stock Option and Incentive Plan, or the 2013 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2013 Plan automatically increases each year by up to 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors or compensation committee to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2013 Plan each year. If our board of directors or compensation committee elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall. We make equity grants to certain new employees joining the company pursuant to an inducement plan, and our compensation committee may elect to increase the number of shares available for future grant without stockholder approval. We also have an Employee Stock Purchase Plan and any shares of common stock purchased pursuant to that plan will also cause dilution.

****We are subject to securities class action litigation, which may result in substantial costs and a diversion of management's attention and resources, which could harm our business.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and we are litigating class action complaints in the United States District Court for the District of Massachusetts and for the District of Delaware, filed by purported stockholders against us and certain of our directors and officers. We may face additional securities class action litigation in the future. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years, and we expect to experience continued stock price volatility. Defending against the current litigation and any future litigation could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have completed several financings since our inception and prior to our initial public offering in 2013, which we believe have resulted in a change in control as defined by IRC Section 382. We completed a study through September 2019 confirming no ownership changes have occurred since our initial public offering in 2013. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We do not intend to pay cash dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and by-laws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation, amended and restated by-laws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and by-laws, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer or our president;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

****Changes in tax law could adversely affect our business and financial condition.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. On December 27, 2020, President Trump signed into law the "Consolidated Appropriations Act", which included additional stimulus relief for the COVID-19 pandemic in the form of modifications to the refundable employee retention credit under the CARES Act and credit extenders, and spending bill for the 2021 fiscal year. On March 11, 2021, President Biden signed into law the "American Rescue Plan Act" ("ARPA"), which included extenders to the refundable employee retention credit under the CARES Act and limitations to executive

compensation effective for tax years beginning after 2026. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

Our policy governing transactions in our securities by our directors, officers, and employees permits our officers, directors and certain other persons to enter into trading plans complying with Rule 10b5-1 under the Securities Exchange Act of 1934, as amended. We have been advised that none of our officers have entered into trading plans covering periods after the date of this Quarterly Report on Form 10-Q in accordance with Rule 10b5-1 and our policy governing transactions in our securities. Generally, under these trading plans, the individual relinquishes control over the transactions once the trading plan is put into place. Accordingly, sales under these plans may occur at any time, including possibly before, simultaneously with, or immediately after significant events involving our company. We do not undertake to report Rule 10b5-1 trading plans that may be adopted by any officers or directors in the future, or to report any modifications or termination of any publicly announced trading plan, except to the extent required by law.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth in the Exhibit Index below, which is incorporated herein by reference.

Exhibit Index

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File no.	Exhibit	Filing Date
2.1	Stock Purchase Agreement by and between the Registrant and Precision Genome Engineering, Inc.	8-K	001-35966	2.1	June 30, 2014
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-35966	3.1	June 24, 2013
3.2	Amended and Restated By-laws of the Registrant	10-K	001-35966	3.2	February 23, 2021
4.1	Specimen Common Stock Certificate	S-1/A	333-188605	4.1	June 4, 2013
10.1#	Second Amended and Restated 2002 Employee, Director and Consultant Stock Plan, as amended, and forms of award agreement thereunder	S-1	333-188605	10.1	May 14, 2013
10.2#	2010 Stock Option and Grant Plan, as amended, and forms of award agreement thereunder	S-1	333-188605	10.2	May 14, 2013
10.3#	2013 Stock Option and Incentive Plan and forms of award agreement thereunder	S-1/A	333-188605	10.3	June 4, 2013
10.4	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors	S-1	333-188605	10.4	May 14, 2013
10.5†	Patent License Agreement, dated December 11, 1996, by and between the Registrant (formerly known as Genetix Pharmaceuticals Inc., successor-in-interest to Innogene Pharmaceuticals, Inc.) and Massachusetts Institute of Technology, as amended	S-1	333-188605	10.6	May 14, 2013
10.6†	Fourth Amendment to Patent License Agreement, dated October 28, 2016, by and between the Registrant and Massachusetts Institute of Technology	10-K	001-35966	10.7	February 22, 2017
10.7†	Patent and Know-How License Agreement No. 07554F30, dated May 14, 2009, by and between the Registrant (formerly known as Genetix Pharmaceuticals Inc.) and INSERM-TRANSFERT, as amended	S-1	333-188605	10.7	May 14, 2013
10.8†	License Agreement, dated September 13, 2011, by and between the Registrant and Institut Pasteur, as amended	S-1	333-188605	10.8	May 14, 2013
10.9†	Amendment No. 3 to License Agreement, dated September 10, 2013, by and between the Registrant and Institut Pasteur	10-Q	001-35966	10.2	November 14, 2013
10.10†	Amendment No. 4 to License Agreement, dated April 1, 2015, by and between the Registrant and Institut Pasteur	10-Q	001-35966	10.10	May 6, 2015
10.11†	License Agreement, dated December 7, 2011, by and between the Registrant and Research Development Foundation	S-1	333-188605	10.9	May 14, 2013
10.12†	Novation Agreement, dated April 2, 2012, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University	S-1	333-188605	10.10	May 14, 2013
10.13†	Master Collaboration Agreement by and between the Registrant and Celgene Corporation, dated March 19, 2013	S-1	333-188605	10.11	May 14, 2013
10.14†	Amended and Restated Master Collaboration Agreement by and between the Registrant and Celgene Corporation, dated June 3, 2015	10-Q	001-35966	10.14	August 7, 2015
10.15	Amendment No. 1 to Amended and Restated Master Collaboration Agreement by and between the Registrant and Celgene Corporation, dated February 17, 2016	10-Q	001-35966	10.15	May 4, 2016
10.16	Amendment No. 2 to Amended and Restated Master Collaboration Agreement by and between the Registrant and Celgene Corporation, dated September 28, 2017	10-Q	001-35966	10.17	November 1, 2017
10.17††	Amended and Restated License Agreement by and between the Registrant and Celgene Corporation, dated February 16, 2016	—	—	—	Filed herewith

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File no.	Exhibit	Filing Date
10.18††	Second Amended and Restated License Agreement by and between the Registrant and Celgene Corporation and Celgene European Investment Company LLC, dated May 8, 2020	10-Q	001-35966	10.18	August 5, 2020
10.19†	Amended and Restated Co-Development, Co-Promote and Profit Share Agreement by and between the Registrant and Celgene Corporation and Celgene European Investment Company LLC, dated March 26, 2018	10-Q	001-35966	10.20	May 2, 2018
10.20††	First Amendment to Amended and Restated Co-Development, Co-Promote and Profit Share Agreement by and between the Registrant and Celgene Corporation and Celgene European Investment Company LLC, dated May 8, 2020	10-Q	001-35966	10.20	August 5, 2020
10.21††	License Agreement by and between the Registrant and Biogen Idec MA Inc., dated August 13, 2014	—	—	—	Filed herewith
10.22†	Letter Agreement by and between the Registrant and Biogen MA Inc., dated September 29, 2017	10-Q	001-35966	10.21	November 1, 2017
10.23††	Exclusive Patent License Agreement by and between the Registrant and the National Institutes of Health, dated August 31, 2015	—	—	—	Filed herewith
10.24†	License Agreement, dated December 23, 2015, by and between the Registrant and SIRION Biotech GmbH	10-K	001-35966	10.23	February 21, 2019
10.25††	Toll Manufacturing and Service Agreement, dated November 18, 2016 by and between the Registrant and Minaris Regenerative Medicine GmbH (formerly APCETH Biopharma GmbH), as amended	10-Q	001-35966	10.24	August 1, 2019
10.26††	Amendment Agreement No. 3 to the Toll Manufacturing and Service Agreement by and between bluebird bio (Switzerland) GmbH and Minaris Regenerative Medicine GmbH (formerly Apceth Biopharma GmbH)	8-K	001-35966	10.1	March 12, 2020
10.27††	Clinical and Commercial Supply Agreement – Viral Vector Product, dated November 27, 2017, by and between the Registrant and SAFC Carlsbad, Inc., as amended	10-Q	001-35966	10.25	August 1, 2019
10.28††	Amendment No. 2 to Clinical and Commercial Supply Agreement Viral Vector Product by and between bluebird bio (Switzerland) GmbH and SAFC Carlsbad, Inc.	8-K	001-35966	10.1	January 21, 2020
10.29	Amendment No. 3 to Clinical and Commercial Supply Agreement Viral Vector Product by and between bluebird bio (Switzerland) GmbH and SAFC Carlsbad, Inc.	10-K	001-35966	10.28	February 23, 2021
10.30#	Amended and Restated Employment Agreement by and between the Registrant and Nick Leschly	S-1/A	333-188605	10.12	June 4, 2013
10.31#	Amended and Restated Employment Agreement by and between the Registrant and Jeffrey T. Walsh	S-1/A	333-188605	10.13	June 4, 2013
10.32#	Amended and Restated Employment Agreement by and between the Registrant and David M. Davidson, M.D.	S-1/A	333-188605	10.15	June 4, 2013
10.33#	Employment Agreement, dated February 3, 2014, by and between the Registrant and Jason F. Cole	10-Q	001-35966	10.18	May 13, 2014
10.34#	Amendment to Employment Agreement, dated March 7, 2016, by and between the Registrant and Jason F. Cole	10-Q	001-35966	10.25	May 4, 2016
10.35#	Amendment No. 2 to Employment Agreement, dated November 3, 2016, by and between the Registrant and Jason F. Cole	10-K	001-35966	10.27	February 22, 2017
10.36#	Employment Agreement, dated May 30, 2015, by and between the Registrant and Philip D. Gregory	10-Q	001-35966	10.21	August 7, 2015
10.37#	Amendment to Employment Agreement, dated November 3, 2016, by and between the Registrant and Philip D. Gregory	10-K	001-35966	10.31	February 22, 2017
10.38#	2013 Employee Stock Purchase Plan	S-1/A	333-188605	10.17	June 4, 2013

Exhibit Number	Exhibit Title	Incorporated by Reference			
		Form	File no.	Exhibit	Filing Date
10.39#	First Amendment of the Bluebird Bio, Inc. 2013 Employee Stock Purchase Plan	10-K	001-35966	10.38	February 21, 2018
10.40#	Second Amendment of the Bluebird Bio, Inc. 2013 Employee Stock Purchase Plan	S-8	333-257135	99.1	June 15, 2021
10.41#	2021 Inducement Plan and forms of award agreements thereunder	S-8	333-257135	99.2	June 15, 2021
10.42#	Offer Letter, dated November 16, 2017, by and between the Registrant and Kory Wentworth	10-K	001-35966	10.39	February 21, 2018
10.43#	Executive Cash Incentive Bonus Plan	S-1	333-188605	10.18	May 14, 2013
10.44#	Employment Agreement, dated December 18, 2018, by and between the Registrant and William ("Chip") Baird	8-K	001-35966	10.1	February 11, 2019
10.45†	Lease, dated September 21, 2015, by and between the Registrant and ARE-MA Region No. 40 LLC	10-Q	001-35966	10.30	November 5, 2015
10.46	First Amendment to Lease, dated June 21, 2016, by and between the Registrant and ARE-MA Region No. 40 LLC	10-Q	001-35966	10.37	August 3, 2016
10.47	Second Amendment to Lease, dated November 14, 2016, by and between the Registrant and ARE-MA Region No. 40 LLC	10-K	001-35966	10.44	February 22, 2017
10.48††	Sublease, dated April 16, 2019, by and between the Registrant and Aventis Inc.	10-Q	001-35966	10.42	August 1, 2019
10.49	Amendment to Sublease, dated April 19, 2019, by and between the Registrant and Aventis Inc.	10-Q	001-35966	10.43	August 1, 2019
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Furnished herewith
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)	—	—	—	Filed herewith

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the SEC.

†† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the SEC.

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

bluebird bio, Inc.

Date: August 9, 2021

By: /s/ Nick Leschly

Nick Leschly

President, Chief Executive Officer and Director (Principal Executi Officer and Duly Authorized Officer)

Date: August 9, 2021

By: /s/ Chip Baird

Chip Baird

Chief Financial Officer (Principal Financial Officer, Principal Accounting Officer and Duly Authorized Officer)

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.17

Execution Version

Amended and Restated License Agreement

by and between

bluebird bio, Inc.

and

Celgene Corporation

and

Celgene European Investment Company LLC

February 16, 2016

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Table of Contents

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

List of Appendices

Amended and Restated License Agreement

This Amended and Restated License Agreement (this "License Agreement"), dated as of February 16, 2016 (the "License Agreement Effective Date"), is made by and between bluebird bio, Inc., a Delaware corporation ("Bluebird"), and Celgene Corporation, a Delaware Corporation ("Celgene Corp"), with respect to all rights and obligations under this License Agreement in the United States (subject to Section 11.18), and Celgene European Investment Company LLC, a Delaware limited liability company, with respect to all rights and obligations under this License Agreement outside of the United States (subject to Section 11.18) ("Celgene Europe" and together with Celgene Corp, "Celgene"). Each of Bluebird and Celgene may be referred to herein as a "Party" or together as the "Parties."

WHEREAS, Bluebird has developed and owns or has rights to certain Patents and technology relating to developing innovative gene therapies for genetic disorders;

WHEREAS, Celgene is a biopharmaceutical company focused on acquiring, Developing and Commercializing innovative anti-cancer agents; and

WHEREAS, Bluebird and Celgene are parties to that certain Master Collaboration Agreement, dated as of March 19, 2013, pursuant to which the Parties entered into a global strategic collaboration to research, develop and commercialize therapeutic products in the Field (the "Original MCA");

WHEREAS, the Parties entered into an Amended and Restated Collaboration Agreement, dated as of June 3, 2015 (the "Master Collaboration Agreement"), pursuant to which the Parties amended and restated the Original MCA in order to continue the research and development of the Product Candidates pursuant to the terms set forth therein;

WHEREAS, pursuant to the terms of the Master Collaboration Agreement, Celgene has exercised its option to select a Product Candidate to be an Optioned Candidate by delivering to Bluebird a Celgene Option Notice and payment of the applicable Initial Option Fee and Additional Option Fee (such Optioned Candidate, as defined more fully in Appendix A, the "Elected Candidate"); and

WHEREAS, the Parties now wish to enter into an exclusive licensing arrangement whereby Celgene will have exclusive rights to Develop Elected Candidate and Commercialize Licensed Product, all on the terms and conditions set forth here.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Definitions.

The following terms and their correlatives will have the meanings set forth below. Capitalized terms used, but not defined, herein will have the meanings ascribed to such terms in the Master Collaboration Agreement.

1.1 "Applicable Bluebird In-Licenses" means the Applicable Pre-Existing In-Licenses and the Applicable New In-Licenses.

1.2 "Applicable New In-Licenses" means all New In-Licenses of Bluebird or its Affiliates necessary or useful for the research, Development and/or Commercialization of

Elected Candidate and Licensed Product that Celgene has elected to list on Appendix B as of the License Agreement Effective Date, plus any other New In-License of Bluebird or its Affiliates that Celgene has elected to include as an Applicable New In-License pursuant to Section 3.2(b).

1.3 "Applicable Pre-Existing In-Licenses" means all Pre-Existing In-Licenses necessary or useful for the research, Development and/or Commercialization of Elected Candidate and Licensed Product, and any extensions or expansions of the scope of such Pre-Existing In-Licenses, including those listed on Appendix C.

1.4 "Biosimilar Product" means, with respect to a Licensed Product in any country, any biosimilar product sold by a Third Party not authorized by or on behalf of Celgene, its Affiliates or Sublicensees, (a) that is a biosimilar biological product, as defined in 21 USC 379j-51 (or any successor or replacement thereof), a similar biological medicinal product, as defined in Annex I to Directive 2001/83/EC (or any successor or replacement thereof), or any similar biosimilar or generic product under the Laws of any country or jurisdiction, or (b) regarding which Regulatory Approval is obtained by referencing Regulatory Data of such Licensed Product.

1.5 "Bluebird In-Licensed IP" means all Patents, Materials and Know-How in-licensed by Bluebird pursuant to Applicable Bluebird In-Licenses, including any extensions or expansions of the scope thereof.

1.6 "Bluebird Technology" means all Bluebird Solely Owned IP and all of Bluebird's right, title and interest in and to Joint IP.

1.7 "Celgene Development & Commercialization Program" means a Development and Commercialization program for Licensed Product in the Field worldwide.

1.8 "Celgene Licensed Product In-License" means any Applicable Celgene In-License or other agreement between Celgene or any of its Affiliates and a Third Party entered into under Section 4.3(d) pursuant to which Celgene or any of its Affiliates in-licenses any Know-How, Materials or Patents that directly relate to or Cover the Elected Candidate and/or Licensed Product or its Manufacture or use.

1.9 "Celgene Licensed Product In-Licensed IP" means any Patents, Materials and Know-How Controlled at any time during the License Agreement Term by Celgene or any of its Affiliates pursuant to a Celgene Licensed Product In-License or Celgene Other In-License that directly relate to or Cover the Elected Candidate and/or Licensed Product or its Manufacture or use.

1.10 "Celgene Licensed Product IP" means (a) Celgene Technology, (b) Collaboration IP solely owned by Celgene and Celgene's interest in jointly owned Collaboration IP, and (c) Patents, Materials or Know-How (to the extent not included in subsection (a) or (b)) owned by Celgene or its Affiliates that are Controlled at any time during the License Agreement Term by Celgene or any of its Affiliates, in each case that directly relate to or Cover the Elected Candidate and/or Licensed Product or its Manufacture or use.

1.11 "Celgene Other In-License" means any agreement between Celgene or any of its Affiliates and a Third Party, other than Applicable Celgene In-Licenses and any agreement between Celgene or any of its Affiliates and a Third Party entered into under Section 4.3(d), pursuant to which Celgene or any of its Affiliates in-licenses any Know-How, Materials or

Patents that directly relate to or Cover the Elected Candidate and/or Licensed Product or its Manufacture or use.

1.12 "Celgene Regulatory Rights" means all Regulatory Data, Regulatory Filings and Regulatory Approvals for Elected Candidate and Licensed Product worldwide Controlled by Celgene or any of its Affiliates.

1.13 "Celgene Technology" means all Celgene Solely Owned IP and all of Celgene's right, title and interest in and to Joint IP.

1.14 "Clinical Study" means any human clinical trial of a Product Candidate.

1.15 "Commercialization" means any and all activities directed to the Manufacturing, marketing, detailing, promotion and securing of reimbursement of a product after Regulatory Approval has been obtained (including making, having made, using, importing, selling and offering for sale such product), and will include post-approval clinical studies, post-launch marketing, promoting, detailing, marketing research, distributing, customer service, administering and commercially selling such product, importing, exporting or transporting such product for commercial sale, and all regulatory compliance with respect to the foregoing.

1.16 "Commercially Reasonable Efforts" means, with respect to the Development or Commercialization of Licensed Product by a Party, that level of efforts and resources that such Party would normally devote to the Development or Commercialization, as the case may be, of a product owned by it or to which it has rights of the type it has hereunder, which is of a similar commercial potential at a similar stage in its lifecycle, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then current competitive environment for such product and the likely timing of such product's entry into the market, the pricing and launching strategy for the respective product, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors.

1.17 "Control" or "Controlled" means, with respect to any Know-How, Material, Patent, Regulatory Data, Regulatory Filings and Regulatory Approvals, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this License Agreement) by a Party or its Affiliates of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party or, other than under Applicable Bluebird In-Licenses, being obligated to pay any royalties or other consideration therefor ("Additional Payments"). For clarity, Other In-Licenses are not "Controlled" for purposes of this License Agreement, unless and only after such Other In-License is converted into an Applicable New In-License pursuant to Section 3.2(b). Notwithstanding the foregoing, as provided in Section 3.2(a), if on or after the License Agreement Effective Date and for such time as the other Party agrees to pay and does in fact pay all Additional Payments with respect to such Party's access or license to any Know-How, Material, Patent, Regulatory Data, Regulatory Filings and Regulatory Approvals (other than that in-licensed by Bluebird pursuant to an Other In-License), such Know-How, Material, Patent, Regulatory Data, Regulatory Filings and Regulatory Approvals will be deemed to be included in the definition of "Control".

1.18 "Covers", with reference to (a) a Patent, means that the making, using, selling, offering for sale or importing of a product or practice of a method would infringe a Valid Claim of such Patent in the country in which such activity occurs, and (b) Materials or Know-How,

means that the Manufacture, Development or Commercialization of a product incorporates, embodies or otherwise makes use of such Materials or Know-How.

1.19 "EU" means the organization of member states of the European Union as it may be constituted from time to time.

1.20 "EU Regulatory Event" means, with respect to a Licensed Product, the earlier to occur of [***].

1.21 "Field" means the targeting of the Target Antigen by the use of (a) T-cells expressing a CAR (with or without other engineering to enhance functionality and/or safety), including virus specific genetically modified T-cells expressing a synthetic CAR, and (b) T-cells expressing native antigen receptors or engineered antigen receptors in which the T-cells are genetically modified to enhance their performance, persistence or safety, in each case under (a) and (b) for the treatment, modulation, palliation or prevention of cancer in humans.

1.22 "First Commercial Sale" means the first sale for use or consumption of any Licensed Product in a country after all required Regulatory Approvals for commercial sale of such Licensed Product have been obtained in such country.

1.23 "First Indication" means the first disease condition for which a particular Licensed Product has been approved by a Regulatory Authority.

1.24 "GAAP" means U.S. generally accepted accounting principles or International Financial Reporting Standards, consistently applied, as designated and used by the applicable Party.

1.25 "Gene Editing" means homing endonuclease (HE) and megaTAL gene editing technologies, including HE/megaTAL-mediated homology directed recombination and Bluebird's proprietary DARIC cell signaling technology.

1.26 "In-License Payments" means any amounts paid or payable under any Applicable Bluebird In-License that are incurred by Bluebird solely and directly as a result of the grant of a sublicense thereunder under this License Agreement to Celgene, any of Celgene's contract Third Parties under Section 3.5, or any further Sublicensees of Celgene (including of Celgene's Affiliates that are granted sublicenses) under this License Agreement. Any such payments will include [***] but excluding [***].

1.27 "Licensed IP" means all (a) Patents, Materials and Know-How Controlled at any time during the term of this License Agreement by Bluebird or any of its Affiliates (including any applicable Collaboration IP and Bluebird Technology), other than pursuant to an Applicable Bluebird In-License, and (b) Bluebird In-Licensed IP, in each case to the extent necessary or useful to Develop Elected Candidate and Develop and Commercialize Licensed Product. [***]

1.28 "Licensed Product" means any product that constitutes or incorporates an Elected Candidate (including all modified and improved versions thereof), in all forms, presentations, and formulations (including manner of delivery and dosage). A modified or improved version of an Elected Candidate constituted or incorporated in a product will be deemed a "Modified Licensed Product" for purposes of Section 4.2 if it is Covered by patentable technology Controlled by Bluebird that (a) is first discovered, created, conceived, developed or reduced to practice after the later of (i) the License Agreement Effective Date and (ii) the end of the Collaboration Program Term, (b) requires the submission of a new BLA with respect to such modified or improved Elected Candidate, and (c) materially contributes to the Elected Candidate

being approved for a new indication or new patient population. For clarity, "Modified Licensed Products" are Licensed Products hereunder for all purposes other than Section 4.2.

1.29 "Manufacturing" means the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control. With reference to Elected Candidate and Licensed Product, Manufacturing includes Vector and associated Payload supply.

1.30 "Net Sales" means [***].

1.31 "Pivotal Study" means (a) a Phase 3 Study that is intended by Celgene to be submitted (together with any other registration trials that are prospectively planned when such Phase 3 Study is initiated) for Regulatory Approval in the U.S. or the EU, or (b) any other clinical study that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which clinical study is a registration trial intended to be sufficient for filing an application for a Regulatory Approval for the Licensed Product in the U.S. or another country or some or all of an extra-national territory, solely as evidenced by the acceptance for filing for a Regulatory Approval for such product after completion of such study.

1.32 "Regulatory Exclusivity Period" means with respect to a Licensed Product in a country, the period of time during which (a) Celgene or any of its Affiliates or Sublicensees has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Law) in such country to market and sell the Licensed Product, or (b) the data and information submitted by Celgene or any of its Affiliates or Sublicensees to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval may not be disclosed, referenced or relied upon in any way by such Regulatory Authority (including by relying upon the Regulatory Authority's previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval or marketing of any product by a Third Party in such country.

1.33 "Second Indication" means [***].

1.34 "Selling Party" means Celgene and its Sublicensees (including Celgene's Affiliates that are granted sublicenses pursuant to Section 3.3).

1.35 "Sublicensee" means any person or entity (including Affiliates of Celgene) that is granted a sublicense as permitted by Section 3.3 (or an option to take such a sublicense), either directly by Celgene or indirectly by any other Sublicensee hereunder.

1.36 "Target Antigen" means the antigen designated as B-cell maturation antigen (BCMA) as further set forth on Appendix D, and naturally occurring variants thereof.

1.37 "Valid Claim" means, with respect to a particular country, (a) any claim of an issued and unexpired Patent in such country that (i) has not been held revoked, unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country, or (b) a claim of a pending Patent application that has

not been finally abandoned or finally rejected or expired and which has been pending [***] from the date of filing of the earliest priority Patent application to which such pending Patent application is entitled to claim benefit.

1.38 "Vector Supplies" means supplies of Vectors and associated Payloads Manufactured for incorporation into Elected Candidate and Licensed Product for Development or Commercialization thereof.

Definitions for each of the following terms are found in the body of this License Agreement or the Appendices hereto as indicated below:

Defined Terms	***Location***
Additional IP	Section 3.2(a)
Additional Payments	Section 1.17
Applicable Bluebird In-License	Section 1.1
Applicable New In-License	Section 1.2
Applicable Pre-Existing In-License	Section 1.3
Bankruptcy Code	Section 3.7
Biosimilar Application	Section 7.2(f)
Biosilimar Product	Section 1.4
Biosimilar Product Competition	Section 4.3(e)
Bluebird	Preamble
Bluebird In-Licensed IP	Section 1.5
Bluebird Indemnitees	Section 9.6(a)
Bluebird Technology	Section 1.6
Business Acquisition	Section 3.4(b)
Business Party	Section 3.4(b)
Business Program	Section 3.4(b)
Celgene	Preamble
Celgene Corp	Preamble
Celgene Development & Commercialization Program	Section 1.7
Celgene Europe	Preamble
Celgene Indemnitees	Section 9.6(b)
Celgene Licensed Product In-License	Section 1.8
Celgene Licensed Product In-Licensed IP	Section 1.9
Celgene Licensed Product IP	Section 1.10
Celgene Other In-License	Section 1.11
Celgene Regulatory Rights	Section 1.12
Celgene Technology	Section 1.13
Clinical Study	Section 1.14
Combination Product	Section 1.30

Defined Terms	***Location***
Commercialization	Section 1.15
Commercially Reasonable Efforts	Section 1.16
Competitive Infringement	Section 7.1
Control	Section 1.17
Covers	Section 1.18
Elected Candidate	Appendix A
EU	Section 1.19
EU Regulatory Event	Section 1.20
Field	Section 1.21
First Commercial Sale	Section 1.22
First Indication	Section 1.23
Fully Burdened Manufacturing Cost	Appendix H
GAAP	Section 1.24
Gene Editing	Section 1.25
In-License Payment	Section 1.26
Indemnification Claim Notice	Section 9.6(c)
Indemnified Party	Section 9.6(c)
Joint IP	Section 5.2
License Agreement	Preamble
License Agreement Effective Date	Preamble
License Agreement Term	Section 10.1
Licensed IP	Section 1.27
Licensed Product	Section 1.28
Litigation Conditions	Section 9.6(d)(i)
Losses	Section 9.6(a)
Major EU Countries	Section 1.20
Manufacturing	Section 1.29
Manufacturing and Supply Agreement	Section 2.4(c)(ii)
Master Collaboration Agreement	Preamble
Milestone Event	Section 4.2
Milestone Payment	Section 4.2
Modified Licensed Product	Section 1.28
Net Sales	Section 1.30
Original MCA	Preamble
Party(ies)	Preamble
Patent Challenge	Section 10.2(b)
PHSA	Section 7.2(f)
Pivotal Study	Section 1.31
Regulatory Exclusivity Period	Section 1.32
Second Indication	Section 1.33
Selling Party	Section 1.34

Defined Terms	*Location*
Solely Owned IP	Section 5.1
Specific Patent	Section 6.3
Sublicensee	Section 1.35
Third Party Claims	Section 9.6(a)
Valid Claim	Section 1.37
Vector Supplies	Section 1.38

2. Development and Commercialization.

2.1 Development. As of and after the License Agreement Effective Date, Celgene will assume sole responsibility for, and control of, Developing Elected Candidate and Licensed Product in the Field worldwide, and will establish a Celgene Development & Commercialization Program for that purpose. As of and after the License Agreement Effective Date, Celgene will have sole responsibility for all costs and expenses arising from the Development and Commercialization of Elected Candidate and Licensed Product in the Field worldwide. Notwithstanding the foregoing, if the initial Phase 1 Study with respect to Optioned Candidate has not been completed as of the License Agreement Effective Date, Bluebird will continue to be responsible for the performance of such initial Phase 1 Study under the oversight of the JSC under the Master Collaboration Agreement until completion of such initial Phase 1 Study. In the event Bluebird continues to be responsible for the performance of such initial Phase 1 Study, Bluebird will be responsible for the costs of performing such initial Phase 1 Study on the terms set forth in the Master Collaboration Agreement.

2.2 Regulatory. Subject to the last sentence of Section 2.1, (a) as of and after the License Agreement Effective Date, Celgene will lead and have sole control of all efforts with Regulatory Authorities regarding the Development and Commercialization of Elected Candidate and Licensed Product in the Field worldwide, including taking full responsibility for preparing and filing the relevant Regulatory Filings and seeking Regulatory Approval and (b) promptly following the License Agreement Effective Date, Bluebird will, at Celgene's expense, assign to Celgene all Regulatory Filings with respect to Elected Candidate and Licensed Product. For clarity, in the event Bluebird continues to be responsible for the performance of an initial Phase 1 Study following the License Agreement Effective Date in accordance with Section 2.1, Bluebird will retain ownership of any Regulatory Filings (including the IND) for Optioned Candidate until completion of such initial Phase 1 Study. In the event of failure to assign such Regulatory Filings to Celgene, Bluebird hereby consents and grants to Celgene the right to access and reference (without any further action required on the part of Bluebird, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such Regulatory Filing.

2.3 Technical Assistance. During the Collaboration Program Term, Bluebird will reasonably cooperate with Celgene to provide all technical assistance, and to transfer to Celgene any additional Know-How licensed to Celgene under Section 3.1, requested by Celgene to facilitate the transfer of Development efforts related to Elected Candidate and Licensed Product. Such cooperation will include providing Celgene with reasonable access by teleconference or in-person at Bluebird's facilities to Bluebird personnel involved in the research and Development of Elected Candidate to provide Celgene with a reasonable level of technical assistance and consultation in connection with the transfer of such Know-How. Following the Collaboration Program Term, Bluebird will reasonably cooperate with Celgene to provide reasonable amounts

of technical assistance, including to transfer to Celgene any additional Know-How licensed to Celgene under Section 3.1, with respect to Elected Candidate or Licensed Product as reasonably requested by Celgene with reasonable advance notice to Bluebird. Any dispute with respect to the amount and completeness of the technical assistance and cooperation to be provided by Bluebird under this Section 2.3 will be referred to and finally resolved by binding arbitration by a mutually agreeable, disinterested, conflict-of-interest-free individual not affiliated or consulting with either Party. Any such arbitration will be conducted under the then-current rules of the American Arbitration Association.

2.4 Manufacture and Supply.

(a) *Manufacturing*. Subject to Section (b), Celgene will be solely responsible for, and will bear all the costs and expenses of, Manufacturing and supplying all Elected Candidate and Licensed Product for Development and Commercialization in the Field worldwide and, subject to Section 2.4(c), Celgene will purchase Vector Supply from Bluebird or its designee for such purpose.

(b) *Vector Supply*. Bluebird will have the sole right to Manufacture or have Manufactured Vector Supply, and Celgene will have no rights with respect thereto except as provided in Section 2.4(c)(iv). Except as provided in Section 2.4(c)(iv) or in the Manufacturing and Supply Agreement, neither Celgene nor any Affiliate of Celgene (nor any others on behalf of or under license or sublicense from Celgene or any of its Affiliates) will Manufacture (i) any Vector and associated Payload for Licensed Product or (ii) Licensed Product, except for the Manufacture of Licensed Product using Vector Supply supplied by or on behalf of Bluebird. Except as provided in Section 2.4(c)(iv) or in the Manufacturing and Supply Agreement, Celgene and its Affiliates and Sublicensees will purchase all Vector Supply exclusively from Bluebird or its designee.

(c) *Vector Supply Terms*.

(i) Except as provided otherwise in this Section 2.4(c) or in the Manufacturing and Supply Agreement, Bluebird and its Affiliates will Manufacture, or cause a Third Party to Manufacture, all Vector Supply for all Elected Candidate and Licensed Product required for clinical Development and Commercialization in the Field worldwide, and will have the right to make all necessary decisions regarding arrangements with Third Party manufacturers, provided that Bluebird will reasonably consult with Celgene with respect to all such arrangements and obtain Celgene's prior written consent, which will not be unreasonably withheld, conditioned or delayed. [***]

(ii) The Parties will enter into a "Manufacturing and Supply Agreement," between each other or among the Parties and an Affiliate or a Third Party, covering Vector Supply as soon as reasonably practicable after the License Agreement Effective Date, which agreement will be consistent with and supersede the terms of this Section 2.4(c) and will otherwise be subject in all respects to the terms and conditions of this License Agreement.

(iii) The cost to Celgene of Vector Supply will equal [***] of Bluebird's Fully Burdened Manufacturing Cost for such Manufacture, plus [***], unless otherwise agreed by the Parties in writing.

(iv) The Manufacturing and Supply Agreement will include the terms set forth in Appendix I, including terms permitting Celgene to establish "back-up" and/or "second source" rights for Vector Supply and license grants from Celgene to Bluebird under the Celgene

Licensed Product IP and Celgene Licensed Product In-Licensed IP to the extent necessary or useful for Bluebird to Manufacture Vector Supply. [***] Any such arbitration will be conducted under the then-current rules of the American Arbitration Association. Each Party will prepare and submit a written summary of such Party's position with respect to the disputes issues and any relevant evidence in support thereof to the arbitrator within [***] days of selection of the arbitrator. Upon receipt of such summaries from both Parties, the arbitrator(s) will provide copies of the same to the other Party. The arbitrator will be authorized to solicit briefing or other submissions on particular questions. Within [***] days of the delivery of such summaries by the arbitrator, each Party will submit a written rebuttal of the other Party's summary and may also amend and re-submit its original summary. Oral presentations will not be permitted unless otherwise requested by the arbitrator. The arbitrator will make a final decision with respect to the disputed issues within [***] days following receipt of the last of such rebuttal statements submitted by the Parties and [***]. Immediately following such arbitration decision, the Parties will enter into the Manufacturing and Supply Agreement which includes the terms and conditions agreed to by the Parties and such other terms and conditions decided by such arbitrator with respect to the disputed issues.

(v) At Celgene's request, Bluebird will cooperate with Celgene's reasonable requests, at Celgene's cost and expense, to engage in a technology transfer to allow Celgene, in accordance with Section 2.4(c)(iv), to Manufacture Vector Supply (through the first commercial batch of Vector Supply) itself or by through its designated Third Party manufacturer, by transferring all Know-How, Materials, technology and trade secrets Controlled by Bluebird or its Affiliates that are necessary to Manufacture Vector Supply, thereby enabling Celgene (or such Third Party) to Manufacture the Vector Supply.

(vi) Any purchase of Vector Supply from Bluebird or its designee will expressly not include any license rights to any Know-How or Patents, but instead all licenses (implied, by exhaustion or otherwise) will arise under Section 3.1, if and as applicable.

(vii) For the purpose of this License Agreement, certain words and phrases (and their correlatives) relating to Manufacturing will have the meanings set forth on Appendix I.

2.5 Celgene Diligence. Celgene, directly or through one or more of its Sublicensees, will use Commercially Reasonable Efforts: (a) to Develop Licensed Product in the Field and to obtain Regulatory Approvals therefor; and (b) to Commercialize Licensed Product in the Field after obtaining such Regulatory Approval, in each country worldwide where Commercializing Licensed Product would be warranted by using Commercially Reasonable Efforts.

2.6 Annual Update Meetings. At least once during each consecutive twelve (12)-month period from the License Agreement Effective Date until the earlier of first approval of a BLA for Licensed Product by the FDA or first approval of an MAA for Licensed Product by the EMA, within thirty (30) days of Bluebird's written request, the Parties will meet in person at a U.S. site of Celgene for Celgene to provide Bluebird with an update on the Development of Licensed Product by Celgene and its Sublicensees. During such meeting, Celgene will disclose to Bluebird all material information regarding such Development.

2.7 Reports by Celgene. Celgene will prepare and maintain, and will cause its Sublicensees to prepare and maintain, reasonably complete and accurate records regarding the Development of Elected Candidate and Licensed Product, and Commercialization of Licensed Product worldwide after Regulatory Approval therefor. Celgene will provide to Bluebird a

reasonably detailed report regarding such efforts at least once every twelve (12)-month period from the License Agreement Effective Date. Such report will contain sufficient detail to enable Bluebird to assess Celgene's compliance with its Development and Commercialization obligations in Section 2.5, including information with respect to the following: (a) the design, status and results of any animal studies and clinical trials for Licensed Product; (b) any regulatory milestones, and any Regulatory Approvals achieved, for Licensed Product; and (c) activities with respect to selling, promoting, supporting, detailing and marketing of Licensed Product. In addition to the foregoing, Celgene will provide Bluebird with such additional information regarding any such activities as Bluebird may reasonably request from time to time.

2.8 Applicable Bluebird In-Licenses and Other IP.

(a) *Maintenance of Applicable Bluebird In-Licenses*. Bluebird (i) will duly perform and observe all of its obligations under the Applicable Bluebird In-Licenses in all material respects and maintain in full force and effect the Applicable Bluebird In-Licenses, and (ii) will not, without Celgene's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), (A) amend, modify, restate, cancel, supplement or waive any provision of any Applicable Bluebird In-License, or grant any consent thereunder, or agree to do any of the foregoing, or (B) exercise any right to terminate any Applicable Bluebird In-License in each case ((A) and (B)) that would reasonably be expected to adversely affect in any respect the rights of Celgene under this License Agreement, provided that Bluebird will provide prior written notice to Celgene of all of the foregoing notwithstanding whether or not any of the foregoing would reasonably be expected to adversely affect in any respect the rights of Celgene under this License Agreement. Bluebird will provide Celgene with written notice as promptly as practicable (and in any event within five (5) business days) after becoming aware of any of the following: (I) any material breach or default by Bluebird or any of its Affiliates of any covenant, agreement or other provision of any Applicable Bluebird In-License, (II) any notice or claim from the counterparty to any Applicable Bluebird In-License terminating or providing notice of termination of any Applicable Bluebird In-License, (III) any notice or claim alleging any breach of default under any Applicable Bluebird In-License, or (IV) the existence of any facts, circumstances or events which alone or together with other facts, circumstances or events could reasonably be expected (with or without the giving of notice or passage of time or both) to give rise to a breach of or default under or right to terminate any Applicable Bluebird In-License. If Bluebird fails to pay any amounts due under any Applicable Bluebird In-License and if such nonpayment would permit the counterparty to such Applicable Bluebird In-License to terminate or suspend the same or any rights thereunder, Celgene will have the right, but not the obligation, in its sole discretion, to pay such amounts on Bluebird's behalf, and any amounts so paid by Celgene may be taken by Celgene as a credit against any amounts payable to Bluebird under this License Agreement.

(b) *Maintenance of Celgene Licensed Product In-Licenses*. Celgene (i) will duly perform and observe all of its obligations under the Celgene Licensed Product In-Licenses in all material respects and maintain in full force and effect the Celgene Licensed Product In-Licenses, and (ii) will not, without Bluebird's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), [***]. Celgene will provide Bluebird with written notice as promptly as practicable (and in any event within [***]) after becoming aware of any of the following: [***] If Celgene fails to pay any amounts due under any Celgene Licensed Product In-License [***] Bluebird will have the right, but not the obligation, in its sole discretion, to [***]

(c) *Applicable Bluebird In-License Requirements*. Celgene will abide, and will cause all its Affiliates and applicable Sublicensees to abide, by all requirements of each Applicable Bluebird In-License in all material respects (and in any case in all respects in the case that failure to so abide would result in a breach under the Applicable Bluebird In-License), to the extent applicable to Sublicensees thereunder and to the extent disclosed by Bluebird to Celgene, with the understanding that disclosure by Bluebird of any Applicable Bluebird In-License to Celgene will be deemed disclosure of such requirements of such Applicable Bluebird In-License to Celgene. In the event of a termination of any Applicable Bluebird In-License, Bluebird agrees, to the extent requested by Celgene, to reasonably assist Celgene in securing a direct license from the applicable licensor under any Patents, Materials and Know-How that was licensed to Bluebird and sublicensed to Celgene hereunder prior to such termination. In addition, Bluebird agrees, if requested by Celgene, to reasonably assist Celgene in securing a standby license from the applicable licensor under any Patents, Materials and Know-How that are licensed to Bluebird and sublicensed to Celgene.

3. License Grants.

3.1 License by Bluebird. Subject to the terms and conditions of this License Agreement, Bluebird hereby grants to Celgene a worldwide, exclusive (even as to Bluebird) license, with the right to sublicense only as permitted by Section 3.4, under Licensed IP, to Develop Elected Candidate and to Develop and Commercialize Licensed Product. Further, (a) the license to Commercialize granted in this Section 3.1 will cover only the sale and offer for sale of Licensed Product in finished form and not the sale or offer for sale of Vectors (other than as and to the extent incorporated in the Licensed Product), and (b) rights to Manufacture Vectors and associated Payloads are included within the scope of the license granted to Celgene under this Section 3.1, which rights are subject to the terms and conditions of Section 2.4(c).

3.2 Additional IP; Other In-Licenses.

(a) *Additional IP*. Except as set forth in Section 3.2(b), Celgene may, on or after the License Agreement Effective Date, elect to include within the scope of the Licensed IP any Know-How, Material, Patent, Regulatory Data, Regulatory Filings or Regulatory Approvals ("Additional IP"), that would be Controlled by Bluebird but for required payments of Additional Payments to a Third Party, by (i) providing notice to Bluebird of same and (ii) agreeing to pay and in fact paying all Additional Payments with respect to Celgene's access or license to such Additional IP. Following Bluebird's receipt of such notice and subject to Celgene's performance of its obligations to pay any Additional Payments with respect to Celgene's access or license to such Additional IP, such Additional IP will be deemed Licensed IP hereunder. For avoidance of doubt, this Section 3.2(a) does not apply to Know-How, Materials, Patents, Regulatory Data, Regulatory Filings or Regulatory Approvals licensed to Bluebird under the Applicable Bluebird In-Licenses, all of which are deemed Controlled by Bluebird notwithstanding this Section 3.2(a).

(b) *Other In-Licenses*. Celgene may, on or after the License Agreement Effective Date, elect to convert any Other In-License to an Applicable New In-License by providing notice to Bluebird of same. Upon Bluebird's receipt of such notice, such Other In-License will be an Applicable New In-License hereunder, Appendix B will automatically be updated to include such New In-License and the provisions of this License Agreement applicable to New In-Licenses, including Section 4.1(b), will apply with respect to such New In-License.

3.3 Sublicensing Rights.

(a) *Transfer*. The licenses granted in Sections 3.1 are transferable only upon a permitted assignment of this License Agreement in accordance with Section 11.12.

(b) *Celgene Sublicenses*. The license granted in Section 3.1 may be sublicensed, in full or in part, by Celgene by a written agreement to its Affiliates and Third Parties (with the right to sublicense through multiple tiers), provided, that as a condition precedent to and requirement of any such sublicense:

(i) Celgene will provide Bluebird with a copy of any sublicense agreement with a non-Affiliated Sublicensee within thirty (30) days of execution thereof, and to the extent permitted under any Applicable Bluebird In-License, such sublicense agreement may be redacted as necessary to protect commercially sensitive information;

(ii) Celgene will be responsible for any and all obligations of such Sublicensee as if such Sublicensee were "Celgene" hereunder; and

(iii) Any such Sublicensee will agree in writing to be bound by substantially identical obligations as Celgene hereunder with respect to the activities of such Sublicensee hereunder (and not with respect to the activities of any other), including Know-How disclosure obligations Celgene has to Bluebird hereunder with respect to the activities of such Sublicensee hereunder (but excluding payment obligations).

3.4 Exclusivity.

(a) During the License Agreement Term, neither Party nor its Affiliates (nor any others on behalf of or with, or under license (including a covenant not to sue) or sublicense from, such Party or any its Affiliates) will research, Develop, Manufacture or Commercialize any actual or potential products (including Vectors and associated Payloads) to be used in the Field (which, for the purposes of this Section 3.4, will include all indications and will not be limited to cancer) that specifically target the Target Antigen, other than pursuant to this License Agreement (which includes, for avoidance of doubt, research, Development, Manufacture and Commercialization of improved and modified versions of the Licensed Product by Celgene) or any other Development & Commercialization Agreement (which includes, for avoidance of doubt, research, Development, Manufacture and Commercialization of improved and modified versions of the Licensed Product by Celgene).

(b) Notwithstanding Section 3.4(a), if (i) a Business Combination occurs with respect to either Party with a Third Party or (ii) a Party acquires a Third Party (including by a merger or consolidation) so that such Third Party becomes an Affiliate over which the acquiring Party has control (as defined in the definition of Affiliate), or (iii) a Party acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (i), (ii) and (iii), a "Business Acquisition"; such Party, the "Business Party"), and, in each case, the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than the Business Party and its Affiliates as of the Business Acquisition) (A) already has, or the acquired assets contain, as applicable, a program that existed prior to, or was planned prior to and is demonstrably to be implemented shortly after, the Business Acquisition or (B) initiates and pursues a new program following such Business Acquisition, in each case that would otherwise violate Section 3.4(a) (a "Business Program"), then such Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than the Business Party and its Affiliates as of the Business Acquisition), as applicable, will be permitted to initiate, pursue and continue

such Business Program after such Business Acquisition and such initiation, pursuit and continuation will not constitute a violation of Section 3.4(a); provided however that (I) none of the Licensed IP, or other Patents, Materials or Know-How Controlled by the other Party and, in each case, licensed to the Business Party will be used in the Business Program, and (II) the research or Development activities required under this License Agreement will be conducted separately from any research or Development activities directed to such Business Program, including the maintenance of separate lab notebooks and records (password-protected to the extent kept on a computer network) and separate personnel working on each of the activities under this License Agreement and the activities covered under such Business Program.

[***]

3.5 Contract Manufacturers. Subject to the terms and conditions of this License Agreement, either Party will have the right to appoint by a written agreement "contract manufacturers", meaning any Third Party or Affiliate of such Party that manufactures Licensed Product (or components therefor, including for Bluebird, Vectors and associated Payloads) for re-sale, but who itself is not a "Sublicensee" hereunder and thereby exercises "have made" rights granted by the other Party hereunder, as well as "contract research organizations" and other providers performing services on Celgene's behalf, none of which will be deemed a "Sublicensee" hereunder. Each Party will be responsible for any such contract manufacturer, contract research organization or service provider hereunder, and further will require any such contract manufacturer, contract research organization or service provider to agree in writing to comply with Sections 3.6 and 8.

3.6 No Implied Rights. No license, sublicense or other right is or will be created or granted hereunder by implication, estoppel or otherwise. Any licenses, sublicenses or rights will be granted only as expressly provided in this License Agreement. Celgene will not practice or otherwise use any Licensed IP other than in accordance with the licenses granted in Section 3.1.

3.7 Section 365(n) of the Bankruptcy Code. All rights and licenses granted pursuant to any section of this License Agreement are, and will be deemed to be, rights and licenses to "intellectual property" (as defined in Section 101(35A) of title 11 of the United States Code and of any similar provisions of applicable Laws under any other jurisdiction (the "Bankruptcy Code")). Bluebird agrees that Celgene, as a licensee of rights and licenses under this License Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Bluebird under the Bankruptcy Code or analogous provisions of applicable Law outside the United States, Celgene will be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to Celgene and all embodiments of such intellectual property, which, if not already in Celgene's possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon Celgene's written request therefor, unless Bluebird elects to continue to perform all of its obligations under this License Agreement or (b) if not delivered under clause (a), following the rejection of this License Agreement by Bluebird in the bankruptcy proceeding upon written request therefor by Celgene.

4. Payments and Royalties.

4.1 Applicable Bluebird In-Licenses and Celgene Licensed Product In-Licenses.

(a) *Applicable Pre-Existing In-Licenses*. If any In-License Payment becomes due under any Applicable Pre-Existing In-License during the License Agreement Term, Bluebird will pay same, provided that Celgene will reimburse Bluebird for any such In-License Payment within thirty (30) days of Celgene's receipt of Bluebird's written invoice therefor, which In-License Payment (other than payments that are royalties) will not exceed [***], and subject to Section 6.1. Any such reimbursement by Celgene to Bluebird (i) is in addition to and not in lieu of the other payments required by this Section 4 and (ii) will not be subject to Section 4.3(d).

(b) *Applicable New In-Licenses*. Celgene may elect to take a sublicense under any New In-License of Bluebird and its Affiliates and upon such election, such New In-License will be an Applicable New In-License hereunder for all purposes. For the purposes of determining the Parties' respective payment obligations, all Applicable New In-Licenses as of and following the License Agreement Effective Date will be listed on Appendix B. If any In-License Payment becomes due under any Applicable New In-License during the License Agreement Term, Bluebird will pay same and, subject to Section 6.1, Celgene will reimburse Bluebird for (i) [***] of such payment that are royalties, which royalties will be subject to Section 4.3(d), and (ii) [***] of such payment that are not royalties, in each case ((i) and (ii)) within thirty (30) days of receipt of Bluebird's written invoice therefor. If Celgene elects to convert an Other In-License to an Applicable New In-License pursuant to Section 3.2(b), Celgene will reimburse Bluebird for [***] of any In-License Payments that became due under such Applicable New In-License during the License Agreement Term to the same extent as if such Applicable New In-License was designated as such as of the License Agreement Effective Date, including with respect to applicable Patent Costs in accordance with Section 6.1, provided that Bluebird provides Celgene with a reasonable accounting of same. If any In-License Payments are royalties due under any Applicable New In-License during the License Agreement Term, such royalties will be subject to Section 4.3(d). To the extent that any grant of a sublicense by Celgene or any Sublicensees under an Applicable New In-License triggers a payment obligation under such Applicable New In-License, Bluebird will pay same and Celgene will reimburse Bluebird for [***] of such payment within thirty (30) days of receipt of Bluebird's written invoice therefor.

(c) *Celgene Licensed Product In-Licenses*. If any payments become due under any Celgene Licensed Product In-License with respect to the Licensed Product, Bluebird will be responsible for [***] of such payments as provided in Section 4.1(e) of the Master Collaboration Agreement, provided that if any such payments are royalties, such royalties will be subject to Section 4.3(d).

4.2 Milestone Payments. Celgene will make milestone payments (each, a "Milestone Payment") to Bluebird upon the occurrence of each of the milestones events (each, a "Milestone Event") as set forth below in this Section 4.2. Each of the Milestone Payments will be payable to Bluebird by Celgene within forty-five (45) days of the achievement of the specified Milestone Event, and such payments when owed or paid will be non-refundable and non-creditable, and not subject to set-off, except as otherwise set forth in Sections 2.8(a), 10.3(c) and 10.6 hereof, and Sections 4.1(e), 4.3 and 10.6 of the Master Collaboration Agreement. Except with respect to Modified Licensed Products, each of the Milestone Payments are payable only once in total under this License Agreement, whether achieved by one or more Licensed Products.

Notwithstanding the foregoing, Bluebird will be entitled to receive [***] of the Milestone Payments below, other than the Milestone Payment for the first Milestone Event (i.e., [***].

Milestone Event	***Milestone Payment***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]

4.3 Royalties.

(a) *Rates*. Subject to the remainder of this Section 4.3, Celgene will pay to Bluebird running royalties, on a Licensed Product-by-Licensed Product basis, based on the total aggregate annual Net Sales worldwide by Selling Parties of such Licensed Product in a given calendar year at the following royalty rates:

Annual Worldwide Net Sales of each Licensed Product	***Royalty Rate***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

By way of example, in a given calendar year, if the aggregate annual worldwide Net Sales for a Licensed Product is [***], the following royalty payment would be payable for those Net Sales under this Section 4.3(a): [***].

(b) *Royalty Term*. Royalties under Section 4.3(a) will be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, on the Net Sales of any Licensed Product if at least one of the following two (2) conditions apply:

(i) if one or more Valid Claims within any of Patents included within the Licensed IP (including, for clarity, Joint IP) Covers such Licensed Product in such country; or

(ii) on a country-by-country basis, for [***] years from the First Commercial Sale of such Licensed Product in such country, provided that, for the purposes of this Section 4.3(b)(ii), Licensed Products that have achieved Regulatory Approval under different BLAs will be deemed to be separate Licensed Products hereunder, and thus subject to separate [***] year periods on a country-by-country basis.

(c) *Royalty Reduction*. If Licensed Product is royalty-bearing only on account of Section 4.3(b)(ii), then the royalty rates set forth in Section 4.3(a) with respect to Net Sales attributable to Licensed Product will be reduced by [***].

(d) *Third Party Royalty Payments*. If Celgene or its Sublicensee, in its reasonable judgment, is required to obtain a license from any Third Party under any Patent Covering Licensed Product in order to Develop or Commercialize such Licensed Product, and if Celgene (or its Sublicensee) is required to pay to such Third Party under such license any royalties, and

the infringement of such Patent cannot reasonably be avoided by Celgene (or its Sublicensee), or if Celgene (or its Sublicensee) is required by a court of competent jurisdiction to pay royalties or lost profits to such a Third Party (and the infringement of such Patent cannot reasonably be avoided), then the amount of Celgene's royalty obligations under this Section 4.3 will be reduced by [***] of the amount of such royalties paid to such Third Party, provided however, that the royalties payable under Section 4.3(a) will not be reduced in any such event below [***] of the amounts set forth in Section 4.3(a) (but as may be further reduced pursuant to Section 4.3(c) or Section 4.3(e)) for each royalty tier. Any royalties payable under any Applicable Pre-Existing In-Licenses may not be deducted under this Section 4.3(d) from royalties owed to Bluebird. Any royalties payable under any Applicable New In-Licenses and Celgene Licensed Product In-Licenses may be deducted under this Section 4.3(d) from royalties owed to Bluebird. Celgene (or its Sublicensee) will use its commercially reasonable efforts to minimize the amount of any of the foregoing payments owed to Third Parties. Prior to Celgene or its Sublicensee exercising its reasonable judgment under this Section 4.3(d), Celgene will provide Bluebird with written notice of a potential need to obtain any license from Third Parties. The Parties will discuss the best course of action to resolve such potential license requirement(s).

(e) [***]

(f) *Additional Royalty Provisions*. The royalties payable under Section 4.3(a) will be subject to the following:

(i) only one (1) royalty will be payable hereunder with respect to each Licensed Product unit;

(ii) royalties when owed or paid hereunder will, except as provided in Section 4.3(d), be non-refundable and non-creditable and not subject to set-off (except as otherwise provided in Sections 2.8(a), 10.3(c) and 10.6 hereof, Section 17.6 of any Co-Development, Co-Promote and Profit Share Agreement, and Sections 4.1(e), 4.3 and 10.6 of the Master Collaboration Agreement); and

(iii) except as expressly set forth in Sections 4.3(c), 4.3(d) and 4.3(e), no other royalty deductions are permitted hereunder.

4.4 Payment Terms.

(a) *Manner of Payment*. All payments to be made by Celgene hereunder will be made in U.S. dollars by wire transfer to such bank account as Bluebird may designate.

(b) *Reports and Royalty Payments*. For as long as royalties or other payments are due under this Section 4, Celgene will furnish to Bluebird a written report, after the end of each calendar quarter, showing the amount of Net Sales and royalty due under Section 4.3, and any other payments accrued during such calendar quarter, which report will be furnished within [***] of the end of the quarter for Net Sales generated by Celgene and its Affiliates, and within [***] of the end of the quarter for Net Sales generated by Sublicensees. [***]. The reports will include, at a minimum, the following information for the applicable calendar quarter, each listed by country of sale and use: [***].

(c) *Records and Audits*. Celgene will keep, and will cause each of the other Selling Parties, as applicable, to keep, and Bluebird will keep, adequate books and records of accounting for the purpose of calculating all royalties and other amounts payable by either Party to the other Party hereunder and ensuring each Party's compliance hereunder. For the [***]

following the end of the calendar year to which each will pertain, such books and records of accounting (including those of the other Selling Parties, as applicable) will be kept at each of their principal place of business. At the request of either Party, the other Party will, and, with respect to Celgene, Celgene will cause each of the other Selling Parties to, permit the requesting Party and its representatives (including an independent auditor), at reasonable times and upon reasonable notice, to examine the books and records maintained pursuant to this Section 4.4(c). Such examinations may not [***]. Except as provided below, the cost of this examination will be borne by [***]. Unless disputed as described below, if such audit concludes that additional payments were owed or that excess payments were made during such period, [***]. In the event of a dispute regarding such books and records, [***] Bluebird and Celgene will work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***] such dispute will be resolved in accordance with [***].

(d) *Currency Exchange*. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Bluebird hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on [***].

(e) [***]

(f) *Blocked Payments*. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Celgene (or any other Selling Party) to transfer, or have transferred on its behalf, payments owed Bluebird hereunder, Celgene will [***].

(g) *Interest Due*. If any payment due to either Party under this License Agreement is overdue (and is not subject to a good faith dispute), then such paying Party will pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***].

(h) *Mutual Convenience of the Parties*. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Bluebird.

5. Ownership and Inventorship of IP.

5.1 Solely-Owned IP. Subject to Section 5.2, as between the Parties, each Party will own and retain all right, title and interest in and to any and all Know-How and Patents arising therefrom that are discovered, created, conceived, developed or reduced to practice solely by or on behalf of such Party under or in connection with this License Agreement, including as part the Celgene Development & Commercialization Program ("Solely Owned IP"). Subject to the licenses hereunder and the other terms and conditions of this License Agreement, each Party will be solely responsible for the Prosecution and Maintenance, and the enforcement and defense, of any Patents within its Solely Owned IP, and the other Party will have no rights with respect thereto.

5.2 Joint IP. The Parties will jointly own any and all Know-How and Patents arising therefrom that are discovered, created, conceived, developed or reduced to practice jointly by or on behalf of the Parties, under or in connection with this License Agreement, including as part of the Celgene Development & Commercialization Program ("Joint IP"). Each Party will have an undivided one-half interest in and to Joint IP. Each Party will exercise its ownership rights in

and to such Joint IP, including the right to license and sublicense or otherwise to exploit, transfer or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the licenses hereunder and the other terms and conditions of this License Agreement, including Section 3.4. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint IP. Each Party, for itself and on behalf of its Affiliates, licensees and Sublicensees, and employees, subcontractors, consultants and agents of any of the foregoing, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to the other Party a joint and undivided interest in and to all Joint IP. The Prosecution and Maintenance, and the enforcement and defense, of any Patents within Joint IP will be jointly managed by the Parties on mutually agreeable terms to be entered into by the Parties at the time any such Patents are first filed, provided that (a) all recoveries and Patent Costs arising from the enforcement or defense of any Patents within Joint IP, absent further agreement, will be shared by the Parties in accordance with Section 7.2(e) (provided that sufficient advance written notice of any such Patent Costs is given to the Party not incurring same) and (b) Patent Costs incurred in connection with the Prosecution and Maintenance of Patents within Joint IP will be apportioned as set forth in Sections 6.1 and 6.3, provided that in each case ((a) and (b)), if either Party elects not to pay any such Patent Costs for any such Patent, the Parties will meet and agree upon an equitable way to treat such Patent.

5.3 Inventorship. Inventorship determination for all Patents worldwide arising from any Know-How created, conceived or developed by or on behalf of the Parties under or in connection with this License Agreement and thus the ownership thereof will be made in accordance with applicable United States patent Laws.

5.4 Allocation. Notwithstanding Sections 5.1 – 5.3, the Patent Committee may allocate ownership of a particular item of intellectual property to improve the prospects of obtaining patent protection with respect to such item of intellectual property, even if such allocation is not in accordance with the terms of Sections 5.1 – 5.3, so long as the Parties mutually agree to such allocation.

6. Patent Prosecution and Maintenance.

6.1 Generally. Subject to Sections 6.2 and 6.3, Bluebird will have the sole right to Prosecute and Maintain Patents within the Licensed IP. Bluebird will use commercially reasonable efforts to, where applicable and upon Celgene's reasonable request, separate parent Patent applications within the Licensed IP into one or more separate Patent applications for Specific Patents, to the extent permitted under applicable Law, where doing so would not reasonably be expected to materially harm any Patent within the Licensed IP or other Patents owned by Bluebird or its Affiliates, provided that the foregoing limitation will not apply to Licensed IP that is Collaboration IP. Bluebird will be responsible for [***]. Celgene will be responsible for [***] Except for costs associated with [***] during the License Agreement Term Celgene will be responsible for [***].

6.2 Celgene Input. Bluebird will regularly provide Celgene with copies of all applications for Patents within the Licensed IP, and all other material submissions and correspondence with any patent authorities regarding such Patents, in sufficient time to allow for review and comment by Celgene. In addition, Bluebird will provide Celgene and its counsel with an opportunity to consult with Bluebird and its counsel regarding Prosecution and Maintenance of any such Patents in the Field, and Bluebird will consider in good faith all

comments timely made by Celgene and its counsel. In the event of any disagreement between any of Bluebird or Celgene, Bluebird will have the final decision-making authority with respect to the matter involved as long as Bluebird acts in good faith.

6.3 Specific Patents. For any Patent within the Licensed IP [***] (each "Specific Patent"), the following will apply: upon Celgene's written request, and provided that Bluebird reasonably agrees with Celgene that the following Prosecution and Maintenance activities would not materially harm any other Patent within the Licensed IP or other Patents owned by Bluebird or its Affiliates (other than Collaboration IP), Celgene will control the Prosecution and Maintenance of the Specific Patents, and notwithstanding anything in Section 6.1 to the contrary, Celgene will be solely responsible for the payment of all related Patent Costs. In addition, Celgene will provide Bluebird and its counsel with an opportunity to consult with Celgene and its counsel regarding Prosecution and Maintenance of any such Specific Patents, and Celgene will include or reflect all reasonable comments timely made by Bluebird and its counsel. Celgene acknowledges and agrees that Bluebird may grant similar rights to other exclusive Third Party licensees under any Patent within the Licensed IP that has claims Covering only a product that is not a Licensed Product (or its manufacture or use) and no other product (or its manufacture or use), other than Specific Patents. If the Parties cannot agree whether or not any Patent within the Licensed IP is a Specific Patent, or if Bluebird claims that the foregoing Prosecution and Maintenance activities would materially harm any other Patent within the Licensed IP or other Patents owned by Bluebird or any of its Affiliates, either of the Parties may refer such dispute to a mutually agreeable, disinterested, conflict-of-interest-free individual not affiliated or consulting with either Party and who has at least fifteen (15) years of patent prosecution experience in the pharmaceutical field. Any such arbitration will be conducted under the then-current rules of the American Arbitration Association, and the decision of the arbitrator will be final.

6.4 Election Not to Prosecute or Maintain or Pay Patent Costs. If Bluebird elects not (a) to Prosecute or Maintain any Patents within the Licensed IP in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (b) to pay the Patent Costs associated with Prosecution or Maintenance of any Patents within the Licensed IP, then in each such case Bluebird will so notify Celgene, promptly in writing and in good time to enable Bluebird to meet any deadlines by which an action must be taken to preserve such Patent in such country, if Celgene so requests. Upon receipt of each such notice by Bluebird, Celgene will have the right, but not the obligation, to notify Bluebird in writing on a timely basis that Celgene will assume control of the Prosecution or Maintenance of such Patent, and bear the Patent Costs thereafter incurred by Celgene with respect thereto. In addition, Celgene will provide Bluebird and its counsel with an opportunity to consult with Celgene and its counsel regarding Prosecution and Maintenance of any such Patents, and Celgene will include or reflect all reasonable comments timely made by Bluebird and its counsel. If after making such election, Celgene elects not to pay the Patent Costs associated with Prosecution or Maintenance of any such Patent, then in each such case Celgene will so notify Bluebird and on the ninetieth (90^{th}) day after Bluebird's receipt of such notice such Patent will no longer be licensed to Celgene hereunder and will no longer be included within the "Licensed IP" hereunder.

6.5 Third Party Rights. To the extent that a Third Party licensor of Bluebird has retained any right to Prosecute or Maintain any Patent within the Licensed IP licensed to Celgene hereunder (including pursuant to an Applicable Bluebird In-License), or otherwise be involved in such activities, Bluebird will use commercially reasonable efforts to cause such Third Party

licensor to take the actions specified by this Section 6 (including Sections 6.6 and 6.7) in a manner consistent with the in-license applicable thereto, but Bluebird will not be deemed to be in breach of its obligations under this Section 6 if, after using such commercially reasonable efforts, it is unable to comply with such obligations because of actions taken or not taken by such Third Party licensor.

6.6 Patent Extensions. Subject to the remainder of this Section 6.6, if any election for patent term restoration or extension, supplemental protection certificate or any of their equivalents may be made with respect to any Patent within the Licensed IP, after consultation with Celgene, the Parties will discuss and seek to reach mutual agreement whether or not to take such action. If the Parties are not able to reach mutual agreement, (a) Celgene will have the sole right to make the final decision whether or not to seek such patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to Specific Patents and Patents within the Collaboration IP licensed to Celgene hereunder and (b) Bluebird will have the sole right to make the final decision whether or not to seek such patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to all other Patents within the Licensed IP.

6.7 Regulatory Exclusivity Periods. With respect to any Patent listings required for any Regulatory Exclusivity Periods for Product, the Parties will mutually agree on which Patents within the Licensed IP to list, provided that if the Parties are not able to agree, Celgene will have the right to make the final decision, and provided further that the exercise of such right by Celgene will not increase or otherwise change the rights or obligations of the Parties hereunder.

6.8 Cooperation. Each Party will reasonably cooperate with the other Party in the Prosecution and Maintenance of Patents within the Licensed IP. Such cooperation includes promptly executing all documents, or requiring inventors, subcontractors, employees and consultants and agents of Celgene and Bluebird and their respective Affiliates and Sublicensees to execute all documents, as reasonable and appropriate so as to enable the Prosecution and Maintenance of any such Patents in any country.

6.9 Patent Marking. Celgene will mark, and will cause all other Selling Parties to mark, Product with all Patents within the Licensed IP in accordance with applicable Law, which marking obligation will continue for as long as (and only for as long as) required under applicable Law.

6.10 Common Interest Disclosures. With regard to any information or opinions disclosed pursuant to this License Agreement by one Party to the other Party regarding Prosecution and Maintenance of Patent within the Licensed IP, or enforcement of intellectual property and/or technology by or against Third Parties, Bluebird and Celgene agree that they have a common legal interest in determining the ownership, scope, validity and/or enforcement of the Licensed IP, and whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Development and Commercialization of any Licensed Product, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the Development or Commercialization of any Licensed Product. Accordingly, the Parties agree that all such information and materials obtained by the Parties from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement. All such information and materials will be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be

applicable. By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Neither Party will have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor will the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party. This Section 6.10 will be subject to any right granted by either Party to any Third Party, provided that the grant of such right to such Third Party does not conflict with the other Party's rights or the first Party's obligations under this License Agreement.

7. Patent Enforcement and Defense.

7.1 Notice. Each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected Competitive Infringement of any Patents within the Licensed IP by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of any Patents within the Licensed IP, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto. For purposes of this License Agreement, "Competitive Infringement" means any allegedly infringing activity in the Field (which, for the purposes of this definition, will include all indications and will not be limited to cancer) with respect to a Patent within the Licensed IP, which activity (a) falls within the scope then in effect of the licenses granted by Bluebird to Celgene as set forth in Sections 3.1, (b) is subject to Section 7.2(f), or (c) would be competitive with a Licensed Product and targets the same Target Antigen as such Licensed Product.

7.2 Enforcement and Defense.

(a) *Patents within the Licensed IP and Competitive Infringement*.

(i) As between the Parties, [***] will have the first right, but not the obligation, to seek to abate any Competitive Infringement of the Patents within the Licensed IP by a Third Party, or to file suit against any such Third Party for such Competitive Infringement. If [***] does not take steps to abate such Competitive Infringement, or file suit to enforce the Patents within the Licensed IP against such Third Party with respect to such Competitive Infringement, within a commercially reasonably time, [***] will have the right (but not the obligation) to take action to enforce the Patents within the Licensed IP against such Third Party for such Competitive Infringement. [***] will pay all its Patent Costs incurred for such enforcement.

(ii) Neither Party will exercise any of its enforcement rights under this Section 7.2(a) without first consulting with the other Party, provided that this consultation requirement will not limit either Party's rights under this Section 7.2(a).

(b) *Defense*. As between the Parties, [***] will have the first right, but not the obligation, to defend against a declaratory judgment action or other action challenging any Patents within the Licensed IP, other than with respect to [***]. If [***] does not take steps to defend within a commercially reasonably time, or elects not to continue any such defense (in which case it will promptly provide notice thereof to [***]), then [***] will have the right (but not the obligation) to defend any such Patent.

(c) *Withdrawal, Cooperation and Participation*. With respect to any infringement or defensive action identified above in this Section 7.2:

[***]

(d) [***]

(e) *Damages*. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in Section 7.2(a) or any action described in Section 7.2(b) will be used first to [***] with the balance of any such recovery to be divided as follows:

(i) To the extent such recovery reflects [***]

(ii) To the extent such recovery reflects [***]

(iii) For the remainder of any such recovery [***]

(f) *Biosimilar Applications.* If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the Public Health Service Act ("PHSA") (a "Biosimilar Application") naming Licensed Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(1)(9)(C) of the PHSA), such Party will, [***].

7.3 Third Party Rights. To the extent that a Third Party licensor of Bluebird has retained any right to (a) defend against a declaratory judgment action or other action challenging any Patents within the Licensed IP, (b) seek to abate any Competitive Infringement of the Patents within the Licensed IP by a Third Party, or (c) take any other actions described in Section 7.2(f) for any Patent within the Licensed IP licensed to Celgene hereunder (including pursuant to an Applicable Bluebird In-License), or otherwise be involved in such activities, Bluebird will use commercially reasonable efforts to cause such Third Party licensor to take the actions specified by this Section 7.3 in a manner consistent with the in-license applicable thereto, but Bluebird will not be deemed to be in breach of its obligations under this Section 7.3 if, after using such commercially reasonable efforts, it is unable to comply with such obligations because of actions taken or not taken by such Third Party licensor.

8. Confidentiality.

The Parties acknowledge and agree that terms of this License Agreement and all Materials, ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by a Party or at the request of a Party, including any of the foregoing of Third Parties, will be subject to the provisions of Section 10 of the Master Collaboration Agreement. The Parties agree to issue the joint press release on Appendix E promptly following the License Agreement Effective Date. A redacted version of this License Agreement will be agreed to by the Parties and shall be consistent with the corresponding redacted version of this License Agreement in such manner as is provided in Section 8.3 of the Master Collaboration Agreement.

9. Warranties; Limitations of Liability; Indemnification.

9.1 Representations and Warranties. Each Party represents and warrants to the other as of the License Agreement Effective Date that it has the legal right and power to enter into this License Agreement, to extend the rights and licenses granted or to be granted to the other in this License Agreement, and to fully perform its obligations hereunder.

9.2 Additional Representations and Warranties of Bluebird. Except as set forth in Schedule 9.2, Bluebird represents and warrants to Celgene that, as of the License Agreement Effective Date:

(a) *Licensed IP*. Appendix F sets forth a complete and accurate list of all Patents included in the Licensed IP, indicating the owner, licensor and/or co-owner(s), if applicable, and, for any Elected Candidate and Licensed Product-relevant subject matter or Materials, if no Patent is specifically licensed, a list of all subject matter or Materials that are included in the Licensed IP, including those licensed under a materials use license or equivalent. Bluebird Controls the Patents listed on Appendix F and the Know-How within the Licensed IP, and is entitled to grant the licenses specified herein. Bluebird has not granted to any Third Party any rights or licenses under such Patents or Know-How within the Licensed IP that would conflict with the licenses granted to Celgene hereunder.

(b) *Third Party Agreements*. The Applicable Bluebird In-Licenses are valid and binding obligations of Bluebird and, to the Knowledge of Bluebird, the applicable licensor, enforceable against Bluebird and, to the Knowledge of Bluebird, the applicable licensor, in accordance with their terms, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, moratorium and other similar Laws of general application relating to or affecting creditors' rights generally. Neither Bluebird nor any of its Affiliates has received any notice of any counterparty's intention to terminate any Applicable Bluebird In-License in whole or in part or any notice requesting any amendment, alteration or modification of such Applicable Bluebird In-License or any sublicense or assignment thereunder. There is no breach or default, or event which upon notice or the passage of time, or both, could give rise to any breach or default, in the performance of any Applicable Bluebird In-License by Bluebird or any of its Affiliates or, to the Knowledge of Bluebird, the counterparty thereto, and Bluebird has not received any notice of any such breach, default or event. Except for the Applicable Bluebird In-Licenses, neither Bluebird nor any of its Affiliates is a party to any license, sublicense or other agreement pursuant to which Bluebird or such Affiliate has received a license or other rights relating to the Elected Candidate or Licensed Product. All Patents and Know-How licensed to Bluebird under the Applicable Bluebird In-Licenses are Controlled by Bluebird for purposes of the licenses granted to Celgene under this License Agreement.

(c) *Patents*. To Bluebird's Knowledge, the Patents listed on Appendix F have been procured or are being procured from the respective patent offices in accordance with applicable Law. None of the Patents included in the Licensed IP is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and no Licensed IP is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation. Neither Bluebird nor any of its Affiliates has received any notice alleging that the Patents in the Licensed IP are invalid or unenforceable, or challenging Bluebird's ownership of or right to use any such rights.

(d) *No Conflicts*. The execution, delivery and performance by Bluebird of this License Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which Bluebird is a party or by which it is bound. Neither Bluebird nor any of its Affiliates has entered into any agreement or otherwise licensed, granted, assigned, transferred, conveyed or otherwise encumbered or disposed of any right, title

or interest in or to any of its assets, including any intellectual property rights, that would in any way conflict with or impair the scope of any rights or licenses granted to Celgene hereunder.

(e) *Outlicenses.* Appendix G sets forth a complete and accurate list of all agreements relating to the licensing, sublicensing or other granting of rights by Bluebird to any Person with respect to the Licensed IP and the Target Antigen, and Bluebird has provided complete and accurate copies of all such agreements to Celgene. Except for the Applicable Bluebird In-Licenses, Bluebird and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this License Agreement. Neither Bluebird nor any of its Affiliates has granted any liens or security interests on the Licensed IP and the Licensed IP is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien or charge of any kind.

(f) *No Proceedings*. There is no action, suit, proceeding or investigation pending or, to the Knowledge of Bluebird, currently threatened in writing against or affecting Bluebird that questions the validity of this License Agreement or the right of Bluebird to enter into this License Agreement or consummate the transactions contemplated hereby.

(g) *No Infringement*. Neither Bluebird nor any of its Affiliates has received any notice of any claim that any Patent, Know-How or other intellectual property Controlled by a Third Party would be infringed or misappropriated by the production, use, research, Development, Manufacture or Commercialization of the Elected Candidate or Licensed Product pursuant to this License Agreement, and, to the Knowledge of Bluebird, there are no Patents, Know-How or other intellectual property owned by a Third Party and not included in the Licensed IP or In-Licensed IP that are necessary for the production, use, research, Development, Manufacture or Commercialization of Elected Candidate or Licensed Product.

(h) Disclaimers. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that any Licensed Product will be successful, in whole or in part. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS LICENSE AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY PATENTS, KNOW-HOW, ELECTED CANDIDATE OR LICENSED PRODUCT, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENT RIGHTS, TITLE, QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.

9.4 [***]

9.5 Performance by Others. The Parties recognize that each Party may perform some or all of its obligations under this License Agreement through Affiliates and permitted subcontractors provided, however, that each Party will remain responsible and liable for the performance by its Affiliates and permitted subcontractors and will cause its Affiliates and permitted subcontractors to comply with the provisions of this License Agreement in connection therewith.

9.6 Indemnification.

(a) *Indemnification by Celgene*. Celgene will indemnify Bluebird, its Affiliates and their respective directors, officers, employees, Third Party licensors and agents, and their

respective successors, heirs and assigns (collectively, "Bluebird Indemnitees"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") against the Bluebird Indemnitees arising from or occurring as a result of: (i) the material breach by Celgene of any term of this License Agreement; (ii) any gross negligence or willful misconduct on the part of Celgene in performing its obligations under this License Agreement; or (iii) the Development or Commercialization by or on behalf of Celgene or any of its Affiliates or Sublicensees of Elected Candidate or Licensed Product, except in each case for those Losses for which Bluebird has an obligation to indemnify Celgene pursuant to Section 9.6(b), as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, however, that Celgene will not be obligated to indemnify Bluebird Indemnitees for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of an Bluebird Indemnitee.

(b) *Indemnification by Bluebird*. Bluebird will indemnify Celgene, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, "Celgene Indemnitees"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims against Celgene Indemnitees arising from or occurring as a result of: (i) the material breach by Bluebird of any term of this License Agreement; (ii) any gross negligence or willful misconduct on the part of Bluebird in performing its obligations under this License Agreement; or (iii) the Development by or on behalf of Bluebird or any of its Affiliates or Sublicensees of Elected Candidate or Licensed Product, except in each case for those Losses for which Celgene has an obligation to indemnify Bluebird pursuant to Section 9.6(a), as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses; provided, however, that Bluebird will not be obligated to indemnify Celgene Indemnitees for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of a Celgene Indemnitee.

(c) *Notice of Claim*. All indemnification claims provided for in Sections 9.6(a) and 9.6(b) will be made solely by such Party to this License Agreement (the "Indemnified Party"). The Indemnified Party will promptly notify the indemnifying Party (an "Indemnification Claim Notice") of any Losses or the discovery of any fact upon which the Indemnified Party intends to base a request for indemnification under Sections 9.6(a) and 9.6(b), but in no event will the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and estimated amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

(d) *Defense, Settlement, Cooperation and Expenses*.

(i) *Control of Defense*. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice, provided however that (A) the Third Party Claim solely seeks monetary damages and (B) the indemnifying Party expressly agrees in writing that as between the indemnifying Party and the Indemnified Party, the indemnifying Party will be solely obligated to satisfy and discharge the

Third Party Claim in full and is able to reasonably demonstrate that it has sufficient financial resources (the matters described in (A) and (B), the "Litigation Conditions"). The assumption of the defense of a Third Party Claim by the indemnifying Party will not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party (the indemnifying Party will consult with the Indemnified Party with respect to a possible conflict of interest of such counsel retained by the indemnifying Party). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 9.6(d)(ii), the indemnifying Party will not be liable to the Indemnified Party for any legal costs or expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. The Indemnified Party may, at any time, assume the defense of a Third Party Claim if at any time the Litigation Conditions are not satisfied with respect to such Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party will reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Third Party Claims incurred by the indemnifying Party in its defense of the Third Party Claim.

(ii) *Right to Participate in Defense*. Without limiting Section 9.6(d)(i), any Indemnified Party will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnified Party's own cost and expense unless (A) the employment thereof has been specifically authorized by the indemnifying Party in writing, (B) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.6(d)(i) (in which case the Indemnified Party will control the defense), (C) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable Law, ethical rules or equitable principles, or (D) the indemnifying Party no longer satisfies the Litigation Conditions, in which case the indemnifying Party will assume [***] percent ([***]) of any such costs and expenses of counsel for the Indemnified Party.

(iii) *Settlement*. With respect to any Third Party Claims that relate solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, and subject to the Litigation Conditions being satisfied, the indemnifying Party will have the sole right to agree to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.6(d)(i), the indemnifying Party will have authority to agree to the entry of any judgment, enter

into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (such consent not to be unreasonably withheld, delayed or conditioned). The indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld, delayed or conditioned.

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

(v) *Costs and Expenses*. Except as provided above in this Section 9.6(d), the costs and expenses, including attorneys' fees and expenses, incurred by the Indemnified Party in connection with any claim will be reimbursed on a calendar quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

9.7 Insurance. Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this License Agreement, and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the U.S. pharmaceutical industry for the activities to be conducted by such Party under this License Agreement. Subject to the preceding sentence, such liability insurance or self-insurance program will insure against all types of liability, including personal injury, physical injury or property damage arising out of the manufacture, sale, use, distribution or marketing of Licensed Product. The coverage limits set forth herein will not create any limitation on a Party's liability to the other under this License Agreement.

10 Term and Termination.

10.1 Term. This License Agreement will commence as of the License Agreement Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, will continue on a country-by-country basis, until there are no more payments owed Bluebird on Licensed Product in such country (the longest such period of time for any Licensed Product hereunder, the "License Agreement Term"). Upon there being no more such payments hereunder for any such Licensed Product in such country, the licenses contained in

Section 3.1 for such Licensed Product will become fully paid up and will remain exclusive with respect to such Licensed Product in such country.

10.2 Termination by Bluebird.

(a) *Breach*. Bluebird will have the right to terminate this License Agreement in full upon delivery of written notice to Celgene in the event of any material breach by Celgene of any terms and conditions of this License Agreement in a manner that fundamentally frustrates the transactions contemplated by this License Agreement, provided that such termination will not be effective if such breach, has been cured within [***] after written notice thereof is given by Bluebird to Celgene specifying the nature of the alleged breach (or, if such default cannot be cured within such [***] period, within [***] after such notice if Celgene commences actions to cure such default within such [***] period and thereafter diligently continues such actions, but fails to cure the default by the end of such [***]); provided, however, that to the extent such material breach involves the failure to make a payment when due, such breach must be cured within [***] after written notice thereof is given by Bluebird to Celgene.

(b) *Termination for IP Challenge*. Bluebird will have the right to terminate this License Agreement in full upon written notice to Celgene in the event that Celgene or any of its Affiliates or Sublicensees directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Patents within the Licensed IP (except as a defense against a claim, action or proceeding asserted by Bluebird against Celgene or its Affiliates or Sublicensees) (a "Patent Challenge"); provided that with respect to any such Patent Challenge by any Sublicensee of Celgene, (i) Bluebird will not have the right to terminate this License Agreement under this Section 10.2(b) if Celgene (A) causes such Patent Challenge to be terminated or dismissed or (B) terminates such Sublicensee's sublicense to the Patents being challenged by the Sublicensee, in each case ((A) and (B)) within [***] Bluebird's notice to Celgene under this Section 10.2(b), and (ii) Bluebird may terminate this License Agreement only with respect to the country or countries in which such Sublicensee has commenced a Patent Challenge unless such country or countries are the United States, France, Germany, Italy, Spain and/or the United Kingdom, in which case Bluebird may terminate this entire License Agreement. In the event Celgene intends to assert a Patent Challenge in any forum, not less than [***] prior to making any such assertion, Celgene will provide to Bluebird a complete written disclosure of each basis known to Celgene for such assertion. Notwithstanding the foregoing, Bluebird's termination right under this Section 10.2(b) will not apply to any Affiliate of Celgene that first becomes an Affiliate of Celgene after the Effective Date of this License Agreement in connection with a Business Combination, where such Affiliate of Celgene was undertaking activities in connection with a Patent Challenge prior to such Business Combination; provided however that Celgene causes such Patent Challenge to terminate within forty-five (45) days after such Business Combination.

10.3 Termination by Celgene.

(a) *Breach*. Celgene will have the right to terminate this License Agreement in full upon delivery of written notice to Bluebird in the event of any material breach by Bluebird of any terms and conditions of this License Agreement in a manner that fundamentally frustrates the transactions contemplated by this License Agreement, provided that such termination will not be effective if such breach has been cured within [***] after written notice thereof is given by Celgene to Bluebird specifying the nature of the alleged breach (or, if such default cannot be cured within such [***] period, within [***] after such notice if Bluebird commences actions to

cure such default within such [***] period and thereafter diligently continues such actions, but fails to cure the default by the end of such [***].

(b) *Discretionary Termination*. Beginning with the [***], Celgene will have the right to terminate this License Agreement in full at its discretion for any reason by delivering written notice to Bluebird, such termination to be effective [***] following the date of such notice.

(c) *Alternative to Termination Under Section* 10.3(a). If Celgene has the right to terminate this License Agreement under Section 10.3(a) (including expiration of all applicable cure periods thereunder), in lieu of exercising such termination right, Celgene may elect once by written notice to Bluebird before the end of such applicable cure period to have this License Agreement continue in full force and effect and instead have, starting immediately after the end of such applicable cure period, any future Milestone Payments set forth in Section 4.2 and the royalty rates set forth in the table set forth in Section 4.3(a) be reduced by [***], provided that such reduction will not apply if such future Milestone Payments and royalty rates have already been reduced pursuant to Section 11.4(c) of the Master Collaboration Agreement.

10.4 Effects of Termination. Upon termination (but not expiration pursuant to Section 10.1) of this License Agreement for any reason:

(a) *Wind Down*. Celgene will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced or, if reasonably practicable and requested by Bluebird, allow Celgene, its Affiliates or its Sublicensees to complete such trials. Celgene will be responsible for any costs associated with such wind-down. Bluebird will pay all costs incurred by either Party to complete such studies should Bluebird request that such studies be completed.

(b) *Sublicenses*. A termination of this License Agreement will not automatically terminate any sublicense granted by Celgene pursuant to Section 3.3 for Commercialization rights with respect to a non-Affiliated Sublicensee, provided that (i) such Sublicensee is not then (A) in material breach of any provision of this License Agreement or (B) in material breach of the applicable sublicense agreement or otherwise in breach of such sublicense agreement in a manner that would give rise to a right of termination on the part of Celgene, (ii) if Bluebird terminates this License Agreement pursuant to Section 10.2(a) for Celgene's failure to fulfill its payment obligations hereunder, such Sublicensee agrees to and does pay to Bluebird all outstanding amounts that accrued as a result of such Sublicensee's activities under the sublicense, (iii) Bluebird will have the right to step into the role of Celgene as sublicensor under any such sublicense executed after the License Agreement Effective Date, with all the rights that Celgene had under such sublicense, solely with respect to the Licensed IP, prior to termination of this License Agreement (including the right to receive any payments to Celgene by such Sublicensee that accrue from and after the date of the termination of this License Agreement solely with respect to the Licensed IP), (iv) such Sublicensee will pay to Bluebird all amounts that Celgene would have been obligated to pay to Bluebird hereunder with respect to such Sublicensee's activities had this License Agreement not terminated (less any amounts received by Bluebird in clause (iii) above) and (v) the survival of such sublicense will not result in an imposition of any additional obligations on the part of Bluebird that are not included within the scope of this License Agreement. Celgene will include in any sublicense agreement executed after the License Agreement Effective Date that relates solely to the Licensed IP a provision in which said Sublicensee acknowledges its obligations to Bluebird under this Section 10.4(b).

(c) *Cessation of Rights*. Except as otherwise expressly provided in Section 10.4(b), all rights and licenses granted by Bluebird to Celgene in Section 3 will terminate, and Celgene and its Affiliates and Sublicensees will cease all use of Licensed IP and all Development, Manufacture and Commercialization of Elected Candidate and Licensed Product.

(d) *Regulatory Approvals*. To the extent permitted by applicable Law, and subject to Bluebird paying commercially reasonable compensation to Celgene for the assets to be transferred pursuant to this Section 10.4(d) (such compensation to either be mutually agreed to or determined through arbitration as provided in Section 10.4(g) below, and such compensation to be reduced by [***] from what would be commercially reasonable compensation if this License Agreement is terminated by Bluebird pursuant to Section 10.2(a)), all Regulatory Approvals and other regulatory filings and communications owned (in whole or in part) or otherwise Controlled by Celgene and its Affiliates and Sublicensees solely relating to the Elected Candidate and/or Licensed Product, and all other documents solely relating to and necessary to further Develop and Commercialize Elected Candidate and Licensed Product, as such items exist as of the effective date of such termination (including all solely related completed and ongoing clinical studies) will be assigned to Bluebird, and Celgene will provide to Bluebird one (1) copy of the foregoing and all documents contained in or referenced in any such items, together with the raw and summarized data for any clinical studies (and where reasonably available, electronic copies thereof). In the event of failure to obtain assignment, subject to the Parties agreeing on commercially reasonable compensation for the right to access and reference, Celgene hereby consents and grants to Bluebird the right to access and reference (without any further action required on the part of Celgene, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item.

(e) *Licenses*. Subject to Bluebird paying (i) commercially reasonable compensation to Celgene for the licenses to be granted pursuant to subsection (A) of this Section 10.4(e) (such compensation to either be mutually agreed to or determined through arbitration as provided in Section 10.4(g) below, and such compensation to be reduced by [***] from what would be commercially reasonable compensation if this License Agreement is terminated by Bluebird pursuant to Section 10.2(a)), and (ii) amounts payable to Celgene's applicable licensors as set forth below, Celgene will grant to Bluebird and its Affiliates (A) a worldwide, perpetual and irrevocable, nontransferable (except in connection with a permitted assignment of this License Agreement in accordance with Section 11.12), exclusive license, with the right to grant sublicenses through multiple tiers (subject to Section 3.3(b), *mutatis mutandis*), under the Celgene Licensed Product IP, and (B) an exclusive sublicense under the Celgene Licensed Product In-Licensed IP, in each case ((A) and (B)) to the extent such Celgene Licensed Product IP and Celgene Licensed Product In-Licensed IP are used in or Cover the Licensed Product as of the effective date of termination and to the extent such Celgene Licensed Product IP and Celgene Licensed Product In-Licensed IP exist as of the effective date of such termination (including in each case any additions, divisions, continuations, continuations-in-part, invention certificates, substitutions, reissues, reexaminations, extensions, registrations, supplementary protection certificates and renewals of such Celgene Licensed Product IP and Celgene Licensed Product In-Licensed IP) solely to the extent necessary to research, Develop, Manufacture and Commercialize the Elected Candidate and Licensed Product. With respect to grants of a sublicense under subsection (B) above, Bluebird will be responsible for all amounts payable to the applicable licensor, excluding maintenance fee payments, payments that are trigged by the grant of a sublicense (but including payments triggered by further grants of sublicenses by

Bluebird or its sublicensees) and Patent Costs, that are attributable to Bluebird as a sublicensee thereunder under this License Agreement and Celgene will pay same and Bluebird will reimburse Celgene for [***] of such payments within thirty (30) days of receipt of Celgene's written invoice therefor. Celgene will provide Bluebird with copies of all applicable Celgene Licensed Product In-Licenses promptly following the effective date of the termination of this License Agreement. The Prosecution and Maintenance and enforcement and defense rights and obligations of the Parties with respect to any Patents licensed or sublicensed to Bluebird pursuant to this Section 10.4(e) will be discussed and agreed to by the Parties, with the understanding that such Prosecution and Maintenance and enforcement and defense rights and obligations will be substantially similar to those set forth in Section 6, with the roles of Bluebird and Celgene reversed (and such other changes as are appropriate from the context, and taking into account any rights retained by a Third Party licensor of Celgene to Prosecute and Maintain or enforce and defend any Patent sublicensed to Bluebird under this Section 10.4(e)). Bluebird will abide, and will cause all its Affiliates and applicable sublicensees to abide, by all requirements of each Celgene Licensed Product In-License under which Bluebird is sublicensed under this Section 10.4(e) in all material respects (and in any case in all respects in the case that failure to so abide would result in a breach under the Celgene Licensed Product In-License), to the extent applicable to sublicensees thereunder and to the extent disclosed by Celgene to Bluebird, with the understanding that disclosure by Celgene of any Celgene Licensed Product In-License to Bluebird will be deemed disclosure of such requirements of such Celgene Licensed Product In-License to Bluebird.

(f) *Trademarks*. Subject to Bluebird paying commercially reasonable compensation to Celgene for the license to be granted pursuant to this Section 10.4(f) (such compensation to either be mutually agreed to or determined through arbitration as provided in Section 10.4(g) below, and such compensation to be reduced by [***] from what would be commercially reasonable compensation if this License Agreement is terminated by Bluebird pursuant to Section 10.2(a)), Celgene will exclusively license to Bluebird any registered or unregistered trademarks or internet domain names that are specific to and solely used for the Licensed Product worldwide (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name(s) of Celgene).

(g) *Commercially Reasonable Compensation.* If the Parties are unable to agree on the amount of commercially reasonable compensation payable by Bluebird to Celgene pursuant to Sections 10.4(d), 10.4(e) or 10.4(f) within ten (10) days of the effective date of termination of this License Agreement, [***].

(h) *Country Termination*. If this License Agreement is terminated only with respect to a specific country pursuant to Section 10.2(b), the provisions of this Section 10.4 will apply only with respect to such terminated country.

10.5 Survival. In addition to the termination consequences set forth in Section 10.4, the following provisions will survive termination or expiration of this License Agreement: Sections 1, 3.3 (mutatis mutandis with respect to licenses granted to Bluebird under Section 10.4), 3.6, 3.7, 4.4, 5, 8, 9.3, 9.4, 9.6, 9.7, 10.4, 10.5 and 11. Termination or expiration of this License Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this License Agreement nor prejudice either Party's right to obtain performance of

any obligation. All other rights and obligations will terminate upon expiration of this License Agreement.

10.6 Right to Set-off. Notwithstanding anything to the contrary in this License Agreement, each Party has the right at all times to retain and set off against all amounts due and owing to the other Party as determined in a final judgment any damages recovered by such Party for any Losses incurred by such Party.

11. General Provisions.

11.1 Cumulative Remedies and Irreparable Harm. All rights and remedies of the Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this License Agreement would cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages.

11.2 Business Combination and IP.

(a) *Bluebird Business Combination*. Notwithstanding anything to the contrary herein, for purposes of this License Agreement, no Know-How, Materials, Patents, Regulatory Data, Regulatory Filings or Regulatory Approvals not Controlled by Bluebird or any of its Affiliates prior to a Business Combination of Bluebird will be Controlled for purposes of this License Agreement after such Business Combination of Bluebird, other than (i) Applicable Bluebird In-Licenses to the extent in effect immediately prior to such Business Combination of Bluebird, (ii) Collaboration IP, and (iii) any Patent that claims priority, directly or indirectly, to any other Patent first Controlled before such Business Combination of Bluebird will be Controlled thereafter no matter when such Patent is filed or issued.

(b) *Celgene Business Combination*. Notwithstanding anything to the contrary herein, for purposes of this License Agreement, no Know-How, Materials, Patents Regulatory Data, Regulatory Filings or Regulatory Approvals not Controlled by Celgene or any of its Affiliates prior to a Business Combination of Celgene will be Controlled for purposes of this License Agreement after such Business Combination of Celgene, other than Collaboration IP, and except that any Patent that claims priority, directly or indirectly, to any other Patent first Controlled before such Business Combination of Celgene will be Controlled thereafter no matter when such Patent is filed or issued.

11.3 Relationship of Parties. Nothing in this License Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. There are no express or implied third party beneficiaries hereunder (except for Bluebird Indemnitees and Celgene Indemnitees for purposes of Section 9.6).

11.4 Compliance with Law. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law. Without limiting the foregoing, Bluebird

will comply with comply with all applicable Laws and regulations (including U.S. Foreign Corrupt Practices Act and any other applicable anti-bribery or anti-kickback laws or regulations).

11.5 Force Majeure. Neither Party will be liable to the other for failure of or delay in performing obligations set forth in this License Agreement (other than any obligation to pay monies when due), and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of such Party; provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

11.6 Governing Law. This License Agreement will be governed by and construed in accordance with the Laws of the State of New York, without respect to its conflict of laws rules, provided that any dispute relating to the scope, validity, enforceability or infringement of any Patents or Know-How will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents or Know-How apply.

11.7 Counterparts; Facsimiles. This License Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this License Agreement by either Party will constitute a legal, valid and binding execution and delivery of this License Agreement by such Party

11.8 Headings. All headings in this License Agreement are for convenience only and will not affect the meaning of any provision hereof.

11.9 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this License Agreement. Accordingly, the rule of construction that any ambiguity in this License Agreement will be construed against the drafting party will not apply.

11.10 Interpretation. Whenever any provision of this License Agreement uses the term “including” (or “includes”), such term will be deemed to mean “including without limitation” (or ”includes without limitations”). “Herein,” “hereby,” “hereunder,” “hereof” and other equivalent words refer to this License Agreement as an entirety and not solely to the particular portion of this License Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Appendices in this License Agreement are to Sections and Appendices of this License Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered “Section 2.1” would be part of “Section 2”, and references to “Section 2.1” would also refer to material contained in the subsection described as “Section 2.1(a)”).

11.11 Binding Effect. This License Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.

11.12 Assignment. This License Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this License Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned; provided that without consent (a) Celgene may assign this License Agreement to (i)

an Affiliate or (ii) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets, and (a) Bluebird may assign this License Agreement to (i) an Affiliate or (ii) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this License Agreement; provided further that, except in the case where a Party is involved in a merger or consolidation where it is the surviving entity and no assets of such Party that are subject to this License Agreement have been transferred as a result of such merger or consolidation, (A) such assigning Party provides the other Party to this License Agreement with at least thirty (30) business days advance written notice of such assignment(s) and the assigning Party agrees in a written agreement delivered prior to such assignment(s) to the non-assigning Party (and upon which such non-assigning Party may rely) to remain fully liable for the performance of its obligations under this License Agreement by its assignee(s), (B) the assignee(s) agree in a written agreement delivered prior to such assignment(s) to the non-assigning Party (and upon which such non-assigning Party may rely) to assume performance of all such assigned obligations, (C) in the case of any assignment by Bluebird, all Licensed IP licensed to Celgene under this License Agreement will be transferred to such assignee(s) effective as of such assignment(s), (D) all of the matters referred to in clauses (A), (B) and (C), as applicable, will be set forth in documentation reasonably acceptable to the non-assigning Party prior to any such assignment(s) (and with such reasonable acceptance not to be unreasonably withheld, conditioned or delayed) and in all cases will provide the non-assigning Party with the full benefits of its rights under this License Agreement (after taking into account all risks involving applicable counter-party performance and bankruptcy and insolvency risks, including those involving contractual rejection under 11 USC §365) as if no such assignment(s) had occurred, and (E) in the case of any assignment, the assigning Party will reimburse the non-assigning Party for all of the legal fees and expenses incurred by such non-assigning Party in connection with the matters set forth in clause (D) of this sentence in an aggregate amount not to exceed [***], and provided, further, that if Bluebird wishes to assign any Licensed IP to its Affiliates, it will be permitted to do so conditioned on each such Affiliate becoming a party to this License Agreement, in the form of an amendment to this License Agreement executed by Celgene, Bluebird and such Affiliate, pursuant to which such Affiliate would agree to assume all obligations hereunder, and grant to Celgene all rights hereunder, with respect to the Licensed IP. The terms of this License Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 11.12 will be null and void *ab initio*.

11.13 Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this License Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the applicable address or facsimile number set forth in Section 13.14 of the Master Collaboration Agreement. Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 11.13.

11.14 Amendment and Waiver. This License Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate

only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

11.15 Severability. In the event that any provision of this License Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and the Parties will negotiate in good faith to modify this License Agreement to preserve (to the extent possible) their original intent.

11.16 Entire Agreement. This License Agreement, together with the Master Collaboration Agreement, is the sole agreement with respect to the subject matter and supersedes all other agreements and understandings between the Parties with respect to same (including Confidential Agreement). In the event of any conflict between the terms of this License Agreement and the terms of the Master Collaboration Agreement, the terms of this License Agreement will control.

11.17 Force Majeure. Neither Celgene nor Bluebird will be liable for failure of or delay in performing obligations set forth in this License Agreement (other than any obligation to pay monies when due), and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of Celgene or Bluebird and without the fault or negligence of the Party so failing or delaying; provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

11.18 **Celgene Parties**. The Parties hereby acknowledge and agree that (a) Celgene Corp is the party to this License Agreement with respect to all rights and obligations under this License Agreement in the United States, provided that with respect to payment obligations under this License Agreement, Celgene Corp is the responsible party with respect to all such payment obligations; (b) Celgene Europe is the party to this License Agreement with respect to all rights and obligations under this License Agreement outside of the United States, provided that with respect to payment obligations under this License Agreement, Celgene Europe is not a responsible party with respect to any such payment obligations; and (c) as between Bluebird, on the one hand, and Celgene Corp and Celgene Europe, on the other, Celgene Corp shall undertake all actions permitted or required to be taken by Celgene Corp and/or Celgene Europe.

[*Remainder of this Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the License Agreement Effective Date.

BLUEBIRD BIO, INC.

By: /s/ Jason F. Cole
(Signature)

Name: Jason F. Cole

Title: SVP, and General Counsel

Date:

CELGENE CORPORATION

By: /s/ Peter N. Kellogg
(Signature)

Name: Peter N. Kellogg

Title: EVP and CFO

Date: 2/8/2016

CELGENE EUROPEAN INVESTMENT COMPANY LLC (CEICO)

By: Celgene International Sarl, the sole member of CEICO

By: /s/ Jonathan Biller
Print: Jonathan Biller

and

By: /s/ Jürg Oehen
Print: Jürg Oehen, Director

Appendix A
Additional Defined Terms

"Elected Candidate" means the following Optioned Candidate selected by Celgene under the Master Collaboration Agreement that specifically targets the Target Antigen: bb2121.

Appendix B

Applicable New In-Licenses

[***]

Appendix C

Applicable Pre-Existing In-Licenses

[***]

Appendix D

Target Antigen

B cell maturation antigen (BCMA, gene name TNFRSF17)

Approved symbol
TNFRSF17

Approved name
Tumor necrosis factor receptor superfamily, member 17

Appendix E

Press Release

bluebird bio Announces First Patient Treated with bb2121 in CRB-401 Phase 1 Study in Patients with Relapsed/Refractory Multiple Myeloma

Celgene has agreed to exercise its option to exclusively license bb2121 under global strategic collaboration

bluebird bio to receive $10 million option exercise payment from Celgene

Cambridge, MA, February 17, 2016 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical- stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies for cancer, announced treatment of the first patient in a Phase 1 study of its product candidate bb2121 in patients with relapsed/refractory multiple myeloma. bb2121 is a chimeric antigen receptor T cell (CAR T) therapy targeting B cell maturation antigen (BCMA), and bluebird bio is developing bb2121 in collaboration with Celgene Corporation. bluebird bio also announced today that Celgene has exercised its option to exclusively license bb2121, under the terms of the collaboration agreement between the two companies.

“bb2121 is bluebird bio’s first oncology program to enter the clinic, and the treatment of this first patient marks an important milestone for us as we build a broad, fully integrated T cell immunotherapy franchise,” said Nick Leschly, chief bluebird. “We are pleased that Celgene has exercised their option to license bb2121. We believe our combined manufacturing, development and commercial expertise will enable us to rapidly advance bb2121 through clinical trials.”

“Despite many recent advances in the field, multiple myeloma remains incurable, with almost all patients becoming refractory to therapy eventually,” said James N. Kochenderfer, M.D., National Cancer Institute, an investigator for the CRB-401 study. “BCMA is one of the most exciting targets in multiple myeloma, and we are eager to explore the potential of bb2121 to become an important new treatment option for patients living with multiple myeloma.”

bluebird bio and Celgene amended and restated their collaboration agreement in June 2015 to focus on developing product candidates targeting BCMA during a three-year collaboration term. By exercising its exclusive option under the terms of the agreement, Celgene will be responsible for worldwide development and commercialization of bb2121 after Phase 1. bluebird bio is responsible for the development of bb2121 through the completion of the CRB-401 Phase 1 study and has an option to share in the development, promotion and profits in the United States. bluebird bio will receive a $10 million option exercise payment from Celgene, and bluebird bio is also eligible to receive specified development, regulatory and commercial milestone payments and royalty payments on net sales.

About the CRB-401 Study

The primary objective of the CRB-401 study is to evaluate the maximum tolerated dose of bb2121 and determine the recommended Phase 2 dose. The secondary objective is patient response, measured using the International Myeloma Working Group (IMWG) Response Criteria

for Multiple Myeloma. The first portion of the study includes a dose- escalation phase in which cohorts of patients will receive ascending doses of bb2121 to determine the maximum tolerated dose and establish a recommended Phase 2 dose. The second portion of the study is a dose expansion phase where patients will receive bb2121 to further evaluate the safety, tolerability and clinical activity at the recommended Phase 2 dose.

About bluebird bio, Inc.

With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and cancer. bluebird bio's gene therapy clinical programs include its Lenti-D™ product candidate, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin® BB305 product candidate, currently in three clinical studies for the treatment of transfusion-dependent ß-thalassemia, also known as ß-thalassemia major, and severe sickle cell disease. bluebird bio's oncology pipeline is built upon the company's leadership in lentiviral gene delivery and T cell engineering, with a focus on developing novel T cell-based immunotherapies, including chimeric antigen receptor (CAR T) and T cell receptor (TCR) therapies. bluebird bio's lead oncology program, bb2121, is an anti-BCMA CAR T program partnered with Celgene. bb2121 is currently being studied in a Phase 1 trial for the treatment of relapsed/refractory multiple myeloma. bluebird bio also has discovery research programs utilizing megaTALs/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, and Paris, France.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the clinical and market potential of the Company's anti-BCMA oncology program, including its bb2121 product candidate. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the preclinical efficacy and safety data for our bb2121 product candidate will not be observed in the CRB-401 clinical study, the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates, the risk of a delay in the enrollment of patients in our clinical studies, the risk that our collaboration with Celgene Corporation will not continue or will not be successful, and the risk that any one or more of our product candidates will not be successfully developed and commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange

Commission. All information in this press release is as of the date of the release, and bluebird bio undertakes no duty to update this information unless required by law.

Contact:

bluebird bio, Inc.

Manisha Pai, 617-245-2107
mpai@bluebirdbio.com

or

Pure Communications, Inc.
Dan Budwick, 973-271-6085

Appendix F

Certain Patents within the Licensed IP Controlled by Bluebird as of the License Agreement Effective Date

[***]

Appendix G

Bluebird Agreements

None.

Appendix H

Certain Manufacturing Definitions

"Fully Burdened Manufacturing Costs" means costs to supply applicable therapeutic ingredients, finished products, related inputs and services (a) supplied by an unaffiliated Third Party or (b) manufactured directly by Bluebird; it being understood and agreed that (i) in the case of costs referred to in clause (a) of this sentence where an unaffiliated Third Party is the manufacturer, Fully Burdened Manufacturing Costs will equal [***], and (ii) in the case of costs referred to in clause (b) of this sentence where Bluebird is the manufacturer, Fully Burdened Manufacturing Costs will equal [***]

Appendix I

Manufacturing and Supply Agreement Terms

1. ***Supply*:**
   - Vector Supply will be governed by the Manufacturing and Supply Agreement. The terms of the Manufacturing and Supply Agreement will be consistent with the terms of Section 2.4 and will include, but will not be limited to, the following:

     [***]
   - Quality of the Vector Supplies supplied will be governed by a separate Quality Service Agreement, to be agreed between the Parties.
2. ***Forecasts*:**
   - The Supply Agreement will define the conditions for non-binding and binding forecasts.

     [***]
3. ***Minimum Supply Quantities*:**

   [***]
4. ***Manufacture*:**
   - As indicated in Section 2.4(c)(i) of the License Agreement, Bluebird will Manufacture Vector Supply in-house or utilize Third Party contract manufacturers. Bluebird will have the right to make all necessary decisions regarding arrangements with Third Party manufacturers, provided that Bluebird will reasonably consult with Celgene with respect to all such arrangements and obtain Celgene's prior written consent, which will not be unreasonably withheld, conditioned or delayed.

     [***]

Schedule 9.2

Exceptions to Bluebird's Representations and Warranties in Section 9.2

Execution Version

EXHIBIT 10.21

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "**Agreement**") is made effective as of the 13 day of August, 2014 (the "**Effective Date**"), by and between bluebird bio, Inc., a Delaware corporation having its principal place of business at 150 Second Street, Third Floor, Cambridge, MA 02141 ("**Bluebird**"), and Biogen Idec MA Inc., a Massachusetts corporation having its principal place of business at 225 Binney Street, Cambridge, MA 02142 ("**Biogen**"). Bluebird and Biogen may, from time-to-time, be individually referred to as a "**Party**" and collectively referred to as the "**Parties**".

RECITALS

WHEREAS, Biogen Controls the Licensed Patent Rights (hereinafter defined); and

WHEREAS, Bluebird wishes to obtain, and Biogen wishes to grant, certain licenses under the Licensed Patent Rights on the terms and conditions set forth herein.

NOW, THEREFORE, the Parties, intending to be legally bound hereby, agree as follows:

1. DEFINITIONS

1.1. "**Affiliate**" means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise; or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.

1.2. "**Applicable Laws**" means all applicable laws, statutes, rules, regulations and guidelines, including all good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority.

1.3. "**BCMA**" means B-Cell Maturation Antigen.

1.4. "**Business Day**" means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York are authorized or required by law to remain closed.

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

1.6. "**Calendar Year**" means any twelve (12) month period commencing on January 1.

1.7. "**COM IP**" means (a) the patents and patent applications listed on **Schedule A** attached hereto; and (b) (i) all continuations, divisionals, renewals and continuations-in-part (to the extent the claims thereof are entirely supported by one or more of the patents and patent applications listed on **Schedule A** to which it claims priority) claiming priority to the patents and patent applications described in clause (a), (ii) any other subsequent filings in any country worldwide

claiming priority to the patents and patent applications described in clause (a) (to the extent the claims thereof are entirely supported by one or more of the patents and patent applications listed on **Schedule A** to which it claims priority); and (iii) all letters of patent granted with respect to any of the foregoing and patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, reissues and re-examinations of any of the foregoing described in clauses (b)(i) and (b)(ii), each of the foregoing (b)(i) through (b)(iii), to the extent (x) Biogen or its Affiliates Controls such patents and patent applications and (y) such patents and patent applications have claims Covering Licensed Products then in Development or Commercialization within the Field.

1.8. "**Commercialize**" or "**Commercialization**" means to manufacture for sale, market, promote, otherwise offer for sale, distribute, and sell.

1.9. "**Commercially Reasonable Efforts**" means [***].

1.10. "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, the legal authority or right (whether by ownership, license or otherwise other than pursuant to this Agreement) of a Party or any of its Affiliates to grant a license or a sublicense of or under such Intellectual Property Rights to the other Party without breaching the terms of any agreement with a Third Party. For clarity, if a Party or any of its Affiliates only can grant a license or sublicense to Intellectual Property Rights, or provide access to a material or document, of a limited scope due to an encumbrance imposed by a Third Party, "**Control**" or "**Controlled**" shall be construed to so limit the license or sublicense to such Intellectual Property Rights or the provision of, or provision of access to, such materials or documents (as applicable).

1.11. "**Cover**", "**Covering**" or "**Covered**" means, with respect to a given Licensed Product in a given country in the Territory, that, in the absence of ownership of or a license granted under a Valid Claim, the research, Development, manufacture, Commercialization, use, import, offer for sale or sale of such Licensed Product in such country would infringe such Valid Claim (or, in the case of a claim that has not yet issued, would infringe such claim if it were to issue without modification).

1.12. "**Develop**" or "**Development**" means to conduct research and development activities (including related manufacturing activities) under conditions designed to yield data suitable for inclusion in, or otherwise necessary to support, an application for Regulatory Approval of a Licensed Product by a Regulatory Authority within the Territory.

1.13. "**Distributor**" means a Third Party, other than a Third Party to which any sublicense hereunder is granted, that (a) purchases any Licensed Products in finished form from Bluebird or any of its Affiliates or sublicensees with the intent or purpose of reselling such Licensed Products; and (b) has the right to Commercialize such Licensed Products in one or more regions.

1.14. "**EMA**" means the European Medicines Agency, or any successor agency thereto.

1.15. "**EU**" means the European Union member states as of the applicable time during the Term.

1.16. "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.17. "**Field**" means all human diagnostic, therapeutic and prophylactic uses in [***].

1.18. "**First Clinical Trial**" means the first human clinical trial of a Licensed Product.

1.19. "**First Commercial Sale**" means with respect to a Licensed Product, the first sale for use or consumption of the Licensed Product following receipt of Regulatory Approval for such Licensed Product in a country in the Territory.

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

1.21. "**IND**" means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of a Licensed Product; or (b) any foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.22. "**Intellectual Property Rights**" means all trade secrets, copyrights, Patent Rights, Trademarks, moral rights, know-how and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.23. "**Licensed Patent Rights**" means collectively, the COM IP and MOT IP.

1.24. "**Licensed Product**" means [***].

1.25. "**MAA**" means (a) a Marketing Authorization Application for a Licensed Product filed with (i) the EMA under the centralized European procedure (including amendments and supplements thereto) or (ii) a Regulatory Authority in any country in the EU if the centralized European procedure is not used to obtain Regulatory Approval of such Licensed Product; or (b) any other equivalent or related Regulatory Filing, such as a Type II variation, to gain Regulatory Approval of a Licensed Product in any country in the EU.

1.26. "**MOT IP**" means (a) the patents and patent applications listed on **Schedule B** attached hereto; and (b) (i) all continuations, divisionals, renewals and continuations-in-part (to the extent the claims thereof are entirely supported by one or more of the patents and patent applications listed on **Schedule B** to which it claims priority) claiming priority to the patents and patent applications described in clause (a), (ii) any other subsequent filings in any country worldwide claiming priority to the patents and patent applications described in clause (a) (to the extent the claims thereof are entirely supported by one or more of the patents and patent applications listed on **Schedule B** to which it claims priority); and (iii) all letters of patent granted with respect to any of the foregoing and patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, reissues and re-examinations of any of the foregoing described in clauses (b)(i) and (b)(ii), each of the foregoing (b)(i) through (b)(iii), to the extent (x) Biogen or its Affiliates Controls such patents and patent applications and (y) such patents and patent applications have claims Covering Licensed Products then in Development or Commercialization within the Field.

1.27. "**NDA**" means: (a) a new drug application filed with the FDA for authorization for marketing the Licensed Product; or (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.

1.28. "**Net Sales**" means [***]

1.29. "**Patent Rights**" means the rights and interests in and to issued patents and pending patent applications in any country, jurisdiction or region (including inventor's certificates and utility models), including all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisionals, renewals and all patents granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including supplementary protection certificates, PCTs, pediatric exclusivity periods and any foreign equivalents to any of the foregoing.

1.30. "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.31 "**Phase III Clinical Trial**" means a human clinical trial of a Licensed Product which is intended to be a pivotal trial for obtaining Regulatory Approval, or otherwise is designed and conducted according to 21 C.F.R. §312.21(c), as amended, or its equivalent, as appropriate, in foreign jurisdictions.

1.32.. "**Regulatory Approval**" means, with respect to a Licensed Product in any country or regulatory jurisdiction, any approval registration, license or authorization that is required by the applicable Regulatory Authority to market and sell such Licensed Product in such country or regulatory jurisdiction.

1.33. "**Regulatory Authority**" means any governmental agency or authority responsible for granting Regulatory Approvals for a Licensed Product in the Territory.

1.34. **"Regulatory Exclusivity"** means any rights or protections which are recognized, afforded or granted by any Regulatory Authority in any country or region of the Territory in association with the Regulatory Approval of a Licensed Product in the Field, providing such Licensed Product: (i) a period of marketing exclusivity during which a Regulatory Authority that recognizes, affords or grants such marketing exclusivity shall refrain from either reviewing or approving a marketing authorization application or similar regulatory submission submitted by a Third Party seeking to market a product containing the same active pharmaceutical ingredient as such Licensed Product; or (ii) a period of data exclusivity during which a Third Party seeking to market a product containing the same active pharmaceutical ingredient as such Licensed Product is precluded from either referencing or relying upon, without an express right of reference from the dossier holder, such Licensed Product's clinical dossier or relying on previous Regulatory Authority findings of safety or effectiveness with respect to such Licensed Product to support the submission, review or approval of a

marketing authorization application or similar regulatory submission before the applicable Regulatory Authority.

1.35. "**Regulatory Filings**" means, with respect to a Licensed Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, any NDA, any submission to a regulatory advisory board, any marketing authorization application (including any MAA), any BLA (biologics license application) and any supplement or amendment thereto.

1.36. "**Related Party**" means any of a Party's Affiliates and permitted sublicensees.

1.37. "**ROFO Field**" means [***].

1.38. "**Royalty Term**" means, on a Licensed Product-by-Licensed Product and country-by country basis, the period commencing on the First Commercial Sale of such Licensed Product in such country and expiring upon the later of: (a) ten (10) years following the date of First Commercial Sale of such Licensed Product in such country; (b) the expiration of Regulatory Exclusivity for such Licensed Product or (c) the expiration or abandonment of the last Valid Claim included in the Licensed Patent Rights that Covers the Licensed Product in such country.

1.39. **"T-Cell**" means any of the lymphocytes that mature in the thymus and have the ability to recognize specific peptide antigens presented by major histocompatibility complex antigens through the receptors on their cell surface.

1.40. "**Territory**" means worldwide.

1.41. "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.42. "**Trademarks**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

1.43. "**Valid Claim**" means either: (a) a claim of an issued and unexpired patent included within the Licensed Patent Rights, which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a pending patent application included within the Licensed Patent Rights, which claim was filed in good faith and has not been cancelled, withdrawn, abandoned or finally disallowed without the possibility of appeal or refiling of such application.

1.44. **Additional Definitions**. Each of the following definitions is set forth in the Section indicated below:

Definition	Section
Agreement	Preamble
Annual 5-Year Forecast	5.1.6(b)
Bankruptcy Code	13.4

Definition	Section
Bankruptcy Event	13.4
Biogen	Preamble
Biogen Indemnitees	11.1
Bluebird	Preamble
Bluebird Indemnitees	11.2
Bluebird Withholding Tax Action	5.3.2
Cap	12.2
CDA	17.11
Change in Control	17.1
Claims	11.1
Confidential Information	9.1
Combination Product	1.28
Deductions	1.28
Defense Action	8.1
Developed IP	7.2
Effective Date	Preamble
Fees	6.1.1
Force Majeure Event	17.4
government	10.3
Government Official	10.3
Gross Sales	1.28
Indemnified Party	11.3
Indemnifying Party	11.3
Milestone Event	5.1.2
Milestone Payment	5.1.2
Party(ies)	Preamble
Recipients	9.2
Relevant Records	6.1.1
Restricted Information	14.2
ROFO Exercise Notice	4.1
ROFO Exercise Period	4.1
ROFO Notice	4.1
Term	13.1
Third Party Infringement	8.1

2. LICENSE GRANT EXCLUSIVITY

2.1. **License Grant**. Subject to the terms and conditions of this Agreement, Biogen hereby grants to Bluebird a co-exclusive (with Biogen), sublicensable (subject to Section 2.2), royalty-bearing right and license under the Licensed Patent Rights to research, Develop, manufacture, Commercialize, use, import, offer for sale and sell the Licensed Products in the Field in the Territory.

2.2. Bluebird Sublicense Rights. Bluebird may sublicense the rights granted to it by Biogen under this Agreement (a) to any of its Affiliates or Celgene Corporation or any of its Affiliates, in each case without Biogen's prior approval, or (b) to any other Third Party upon Biogen's prior written approval, which approval shall not be unreasonably withheld or delayed. Any and all sublicenses shall be subject to the following requirements:

2.2.1. All sublicenses shall be subject to and consistent with the terms and conditions of this Agreement and shall: (a) preclude the assignment of such sublicense without the prior written approval of Biogen, (b) include Biogen as an intended third party beneficiary under the sublicense with the right to enforce the terms of such sublicense, and (c) preclude the granting of further sublicenses in contravention with the terms and conditions of this Agreement. In no event shall any sublicense relieve Bluebird of any of its obligations under this Agreement.

2.2.2. Except for any sublicenses to an Affiliate of Bluebird or Celgene Corporation, prior to the execution of any sublicense agreement (including any further sublicense by an existing sublicensee), Bluebird shall provide to Biogen a draft of the proposed sublicense agreement and Biogen shall approve, disapprove or require modifications to such proposed sublicense agreement, which approval, disapproval or required modifications shall be communicated to Bluebird within [***] by Biogen, or, if Biogen does not provide any such communication within such [***] period, such proposed sublicense agreement shall be deemed to have been approved by Biogen.

2.2.3. Bluebird shall furnish to Biogen a true and complete copy of each sublicense agreement and each amendment thereto, within [***] after the sublicense or amendment has been executed.

2.3. Retained Rights. Bluebird acknowledges and agrees that Biogen retains, on behalf of itself and its Affiliates, all rights in the Licensed Patent Rights other than those specifically granted to Bluebird in Section 2.1, including, subject to Section 2.5, the right to practice the Licensed Patents in the Field in the Territory. As between Biogen and Bluebird, Biogen will exclusively own the results of any use of the Licensed Patent Rights by Biogen not in violation of this Agreement and, subject to Section 4, will have no obligation under this Agreement to disclose or license to Bluebird any developments or Intellectual Property Rights that may arise with respect to such uses.

2.4. No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon Bluebird by implication, estoppel, or otherwise as to any active pharmaceutical ingredients, compounds, products, technology or Intellectual Property Rights of Biogen or its Affiliates other than the rights under the Licensed Patent Rights expressly granted herein.

2.5. Exclusivity. During the Term, Biogen shall not grant any rights under the Licensed Patent Rights to a Third Party to Develop or Commercialize Licensed Products in the Field in the Territory, except that Biogen may grant any such rights to any Third Party acting on behalf of Biogen in such Development or

Commercialization, including contract research organizations, contract manufacturing organizations and distributors.

3. DEVELOPMENT, MANUFACTURING, REGULATORY AND COMMERCIALIZATION

3.1. Development. Bluebird shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop Licensed Products in the Field in the Territory, and Bluebird shall undertake all Development activities at its sole expense. Without limiting the foregoing, in connection with its efforts to Develop Licensed Products, Bluebird shall bear all responsibility and expense for filing Regulatory Filings in Bluebird's name and obtaining Regulatory Approval for Licensed Products in the Field in the Territory.

3.2. Commercialization.

3.2.1. Bluebird shall itself, or through its Affiliates, sublicensees or Distributors, use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Field throughout the Territory in those countries in which Regulatory Approval has been obtained for the marketing of the Licensed Products, it being understood that Bluebird, in the exercise of such Commercially Reasonable Efforts, may determine to not seek Regulatory Approval for and Commercialize the Licensed Product in certain countries in the Territory. Bluebird shall undertake such activities at its sole expense and shall have sole decision-making authority with respect to such activities.

3.2.2. Prohibition on Sales Outside of the Field. To the extent permitted by Applicable Laws in each country in the Territory, Bluebird shall not, and shall ensure that its Related Parties agree not to, Commercialize any Licensed Product outside of the Field in the Territory or provide or sell Licensed Product for or to any Third Party if Bluebird or its Related Party knows or has reason to believe that such Third Party, either directly or indirectly, will provide or sell such Licensed Product for use outside of the Field in the Territory. Biogen shall be a third party beneficiary of any agreements between or among Bluebird and its Related Parties with respect to such restriction, with the right to enforce such agreements. Bluebird shall provide Biogen with a copy of the relevant sections of each such agreement promptly after the execution thereof.

3.3. Reporting. [***]

3.4. Manufacturing. Subject to Section 2.2, Bluebird shall have the sole right to manufacture, or have manufactured, Licensed Products for use in the Field in the Territory, and it shall be entitled to use, and to sublicense the manufacturing rights under the Licensed Patent Rights, for such purposes. Bluebird shall be responsible for all aspects of manufacturing of Licensed Products.

4. RIGHT OF FIRST OFFER

4.1. If at any time during the Term and [***], Biogen seeks to grant rights to a Third Party under the Licensed Patent Rights to Develop or Commercialize one or more

Licensed Products for the ROFO Field in any country in the Territory, then before granting such rights, Biogen shall provide Bluebird with written notice thereof (such notice, the "**ROFO Notice**"). In the event that Bluebird wishes to exercise its right of first offer with respect to the ROFO Field for all of the countries in the Territory, it shall do so in writing (the "**ROFO Exercise Notice**") no later than [***] after Bluebird's receipt of the ROFO Notice (the "**ROFO Exercise Period**").

4.2. Upon Biogen's receipt of the ROFO Exercise Notice, this Agreement shall be amended promptly as follows:

(a) the definition of "Field" shall be amended to include the ROFO Field;

(b) as a result of updating the definition of "Field" pursuant to the foregoing clause (a), Net Sales of Licensed Products in the ROFO Field in the Territory shall be included in the aggregate annual Net Sales of Licensed Products for royalty calculation purposes pursuant to Sections 5.1.3(a) and 5.1.3(b);

(c) a new provision shall be added pursuant to which Bluebird shall pay to Biogen an upfront payment of [***] with respect to the ROFO Exercise Notice for the ROFO Field within [***] after the effective date of the amendment;

(d) [***]; and

(e) any additional terms as may be agreed by the Parties with respect to the addition of the ROFO Field shall be included in this Agreement.

4.3. If Bluebird notifies Biogen that it elects not to exercise such right or fails to respond during the ROFO Exercise Period, Biogen shall thereafter have no further obligation to Bluebird with respect to the ROFO Field and may enter into a definitive agreement granting a Third Party, a license or other right under the Licensed Patent Rights to Develop or Commercialize one or more Licensed Products in the ROFO Field.

5. PAYMENT TERMS

5.1. Payment Terms.

5.1.1. Upfront Payment. In partial consideration of the licenses and rights granted to Bluebird hereunder, Bluebird shall pay to Biogen [***] within ten (10) days after the Effective Date. Such payment shall be non-refundable and non-creditable.

5.1.2. Milestone Payments. Bluebird shall notify Biogen as soon as practicable upon (and in any event within ten (10) days after) achievement of each of the following events by Bluebird or its Affiliates or sublicensees (each such event, a "**Milestone Event**"). In further consideration of the licenses and rights granted to Bluebird, within [***] after achievement of each Milestone Event set forth below, Bluebird shall pay to Biogen the

corresponding non-creditable and non-refundable milestone payment (each, a "**Milestone Payment**"). If any Milestone Payment has not been paid by the time that the subsequent (based on the row numbers in the table below) Milestone Event is achieved, then all unpaid earlier Milestone Payments will be due and payable on the due date for payment of the Milestone Payment for such subsequent Milestone Event, and Bluebird shall pay to Biogen all such unpaid earlier Milestone Payments in addition to the Milestone Payment for such subsequent Milestone Event on such due date.

(a) Development Milestone Events.

Row	Milestone Event	Milestone Payment
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(b) For the avoidance of doubt and except as set forth in Section 4.2(d): (i) each Milestone Payment shall be payable only once upon the first achievement of the applicable Milestone Event for a Licensed Product in the Field [***]; and (ii) satisfaction of a Milestone Event by a sublicensee or assignee of, or Third Party retained by, Bluebird or its Affiliates shall be deemed to have been satisfied by Bluebird for purposes of this Section 5.1.2.

5.1.3. Calculation of Royalties. In consideration of the licenses and rights granted to Bluebird hereunder, Bluebird shall pay to Biogen in accordance with Section 5.1.4(b) the royalties set forth in Sections 5.1.3(a) and 5.1.3(b), as applicable, with respect to aggregate annual Net Sales of Licensed Products in the Field in the Territory during the applicable Royalty Term.

(a) Royalty in countries of the Territory where there is no Valid Claim that Covers the Licensed Product. Bluebird shall pay Biogen a royalty of [***] of aggregate annual Net Sales of Licensed Products in the Field in countries of the Territory where there is no Valid Claim included in the Licensed Patent Rights in such countries that Covers such Licensed Products.

(b) Royalty in countries of the Territory where there is a Valid Claim that Covers the Licensed Product. Bluebird shall pay Biogen a royalty on Net Sales of Licensed Products in the Field in countries of the Territory where there is a Valid Claim included in the Licensed Patent Rights in such countries that covers such Licensed Products calculated as the percentages of the applicable portion of annual Net Sales of Licensed Products in the Field in the Territory set forth in the table below.

	Annual Net Sales of Licensed Products in the Field in the Territory	Royalty Rate to be applied to Net Sales from countries where there is a Valid Claim
[***]		[***]
[***]		[***]
[***]		[***]

For example, if (a) annual Net Sales of Licensed Products in the Field in countries **without** a Valid Claim are $700 million and (b) annual Net Sales of Licensed Products in the Field in countries **with** a Valid Claim are $1.2 billion, the royalties under Sections 5.1.3(a) and 5.1.3(b) would be calculated as follows:

[***]

5.1.4. Royalty Reports and Payments. Commencing with the beginning of the first Royalty Term and thereafter during the Term, on a Calendar Year-by-Calendar Year basis and with respect to each Calendar Quarter of such Calendar Year, within [***] after the end of the applicable Calendar Quarter, Bluebird shall:

(a) provide to Biogen a report of gross sales (including any foreign exchange rates used) and Net Sales of Licensed Products (detailing all Deductions) in the Field in the Territory for such Calendar Year broken down by Calendar Quarter on an aggregate and country-by-country basis, which Net Sales shall include Net Sales for such Calendar Quarter and Net Sales for each of the previous Calendar Quarters in such Calendar Year, as applicable, and including lists of countries that fall under each of Sections 5.1.3(a) and 5.1.3(b), with calculations of aggregate annual Net Sales under each of Sections 5.1.3(a) and 5.1.3(b); and

(b) pay to Biogen the royalties due under Section 5.1.3(a) and Section 5.1.3(b) with respect to such Net Sales for such Calendar Quarter.

5.1.5. Payment Reduction in the event of [***].

5.1.6. [***]

(a) In order to enable Biogen [***] within [***] of each Calendar Quarter [***] Bluebird shall deliver to Biogen [***] provided that Biogen acknowledges [***].

(b) Within [***] after Bluebird submits an application for Regulatory Approval of the first Licensed Product in any country in the Territory [***].

5.1.7. Late Payments. Any late payments shall bear interest [***].

5.2. Payment Method.

5.2.1. **Currency**. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due for royalties under Section 5.1.3 will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on amounts converted to U.S. dollars using currency exchange rates for the Calendar Quarter for which remittance is made for such royalties. [***]

5.2.2. **Method of Payment**. All payments from Bluebird to Biogen shall be made by wire transfer in U.S. Dollars to the credit of such bank account as may be designated by Biogen in writing to Bluebird. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

5.3. Taxes.

5.3.1. **VAT.** It is understood and agreed between the Parties that any payments made under this Agreement are [***] (VAT), which shall be added thereon as applicable.

5.3.2. **Withholding Taxes.** If Bluebird is required to make a payment to Biogen subject to a deduction of tax or withholding tax, then [***].

5.3.3. **Tax Cooperation** [***] Each Party shall provide the other Party with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of [***].

5.3.4. **Tax Forms.** The Parties agree to cooperate and produce on a timely basis any tax forms or reports reasonably requested by the other Party in connection with [***].

6. RECORDS; AUDIT RIGHTS

6.1. Relevant Records.

6.1.1. **Relevant Records**. Bluebird shall keep, and will cause each of its Affiliates or sublicensees, as applicable, to keep, accurate books and records of accounting for the purpose of calculating all payments due to Biogen under Section 5.1 (such payments, collectively the "**Fees**" and such books and records, collectively the "**Relevant Records**"). For the [***] following the end of the Calendar Year to which each will pertain, such Relevant Records will be kept by Bluebird or such Affiliate or sublicensee at each of their principal place of business.

6.1.2. **Audit Request**. At the request of Biogen, Bluebird shall, and, shall cause each of its Affiliates or sublicensees to, permit Biogen and its representatives (including an independent auditor), at reasonable times and upon reasonable notice, to examine the Relevant Records. Such examinations may not (a) be conducted for any Calendar Year more than [***] after the end of such Calendar Year; (b) be conducted more than once in any [***] period; or (c) be repeated for any Calendar Year. Such audit shall be requested in writing at least [***] in advance, and shall be

conducted during Bluebird's normal business hours and otherwise in manner that minimizes any interference to Bluebird's business operations.

6.1.3. Audit Fees and Expenses. Biogen shall bear any and all fees and expenses incurred by it in connection with any such audit of the Relevant Records; ***provided***, ***however***, in the event an audit reveals an underpayment by Bluebird of more than [***] as to the period subject to the audit, Bluebird shall reimburse Biogen for any reasonable and documented out-of-pocket costs and expenses of the audit within [***] after receiving invoices thereof.

7. INTELLECTUAL PROPERTY RIGHTS

7.1. Pre-existing IP. Subject only to the rights expressly granted to the other Party under this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned, licensed or sublicensed by such Party prior to or independent of this Agreement.

7.2. Developed IP. Bluebird shall own all rights, title and interests in and to any Intellectual Property Rights that are conceived solely by Bluebird, its Affiliates or sublicensees following the Effective Date (collectively, "**Developed IP**").

7.3. Patent Prosecution and Maintenance of Licensed Patent Rights.

7.3.1. Prosecution and Maintenance of MOT IP.

(a) Subject to the rights of any Third Party with respect to the MOT IP, Biogen shall, at its expense and discretion, be responsible for prosecuting (including in connection with any reexaminations, oppositions and the like) and maintaining the MOT IP in the Territory. If Biogen files patent applications claiming priority to the patent listed in **Schedule B** subsequent to the Effective Date, Biogen shall make a determination in good faith as to whether such applications have claims that constitute MOT IP. If Biogen determines that such applications have claims that constitute MOT IP, then Biogen shall provide Bluebird drafts of any material filings or responses to be made to relevant patent offices which are related to such MOT IP, within a reasonable amount of time in advance of submitting such filings or responses to permit Bluebird an opportunity to review and comment thereon. Biogen shall consider in good faith the reasonable comments made by Bluebird with respect to the MOT IP, ***provided that*** Biogen does not reasonably determine such comments to be detrimental to the prosecution or enforcement of any Patent Rights owned or Controlled by Biogen or the rights of any Third Party with respect to the MOT IP.

(b) If Biogen elects to abandon the prosecution or maintenance of the MOT IP in any country in the Territory or as a PCT application (and does not elect to file one or more new patent applications claiming priority to such MOT IP), then unless Biogen has a good faith reasonable basis for determining that such prosecution or

maintenance not be continued by either Party, Biogen will promptly (but not less than thirty (30) days before any action is required) provide Bluebird with written notice, and will permit Bluebird, at Bluebird's sole discretion and expense, to continue prosecution or maintenance of any such MOT IP in the applicable country of the Territory, subject to the rights of any Third Party with respect to such MOT IP and ***provided that*** Bluebird shall consult with Biogen with respect to the prosecution or maintenance of such Patent Rights by Bluebird, including: (i) allowing Biogen a reasonable opportunity and reasonable time to review and comment regarding such drafts before any applicable filings are submitted to any relevant patent office or governmental authority, (ii) reflecting any reasonable comments offered by Biogen in any filings submitted by Bluebird to any relevant patent office or governmental authority and (iii) not taking any position with respect to such Patent Rights that would be reasonably likely to adversely affect the scope, validity or enforceability of any other Patent Rights being prosecuted or maintained by Biogen without the prior written consent of Biogen, which consent shall not be unreasonably withheld, delayed or conditioned.

7.3.2. Prosecution and Maintenance of COM IP.

(a) Biogen shall be responsible for prosecuting (including in connection with any reexaminations, oppositions and the like) and maintaining the COM IP in the Territory, and subject to Section 5.1.5, the Parties shall share equally the costs and expenses in connection with such prosecution and maintenance. Biogen shall provide Bluebird drafts of any material filings or responses related thereto to be made to relevant patent offices, within a reasonable amount of time in advance of submitting such filings or responses to permit Bluebird an opportunity to review and comment thereon. Biogen shall reflect any such reasonable comments with respect to COM IP, ***provided that*** in each case Biogen does not reasonably determine such comments to be detrimental to the prosecution or enforcement of any Patent Rights owned or Controlled by Biogen.

(b) If Biogen elects to abandon the prosecution or maintenance of any COM IP in any country in the Territory or as a PCT application (and does not elect to file one or more new patent applications claiming priority to such COM IP), then unless Biogen has a good faith reasonable basis for determining that such prosecution or maintenance not be continued by either Party, Biogen will promptly (but not less than thirty (30) days before any action is required) provide Bluebird with written notice, and will permit Bluebird, at Bluebird's sole discretion and expense, to continue prosecution or maintenance of such COM IP in the applicable country of the Territory; ***provided that*** Bluebird shall consult with Biogen with respect to the preparation, filing, prosecution and

maintenance of such Patent Rights by Bluebird, including: (i) allowing Biogen a reasonable opportunity and reasonable time to review and comment regarding such drafts before any applicable filings are submitted to any relevant patent office or governmental authority, (ii) reflecting any reasonable comments offered by Biogen in any filings submitted by Bluebird to any relevant patent office or governmental authority and (iii) not taking any position with respect to such Patent Rights that would be reasonably likely to adversely affect the scope, validity or enforceability of any other Patent Rights being prosecuted and maintained by Biogen without the prior written consent of Biogen, which consent shall not be unreasonably withheld, delayed or conditioned.

8. ACTUAL OR THREATENED INFRINGEMENT, DISCLOSURE OR MISAPPROPRIATION.

8.1. Notification. Each Party shall promptly notify the other Party in writing of its becoming aware of (a) any actual or threatened infringement, misappropriation or other violation or challenge to the validity, scope or enforceability by a Third Party of any Licensed Patent Rights in the Field ("**Third Party Infringement**"); or (b) initiation by a Third Party of an opposition proceeding against any Licensed Patent Rights in the Field, or initiation by Bluebird of an opposition against a Third Party related to the Licensed Patent Rights in the Field or any allegation by a Third Party that Intellectual Property Rights owned by it are infringed, misappropriated or violated by the Development, Commercialization or research, develop, make, have made, use, sell, offer for sale, market, distribute, import, export or otherwise exploit any Licensed Product in the Field ("**Defense Action**").

8.2. Third Party Infringements.

8.2.1. Enforcement of MOT IP. Subject to the rights of any Third Party with respect to MOT IP, [***] shall have the sole right (but not the obligation), at its own expense, to control enforcement of the MOT IP against any Third Party Infringement [***].

8.2.2. Enforcement of COM IP.

(a) Unless [***] shall have the [***] right (but not the obligation), [***] to control enforcement of the COM IP against any Third Party Infringement.

(b) [***] shall have the right (but not the obligation) to control enforcement of the COM IP against any Third Party Infringement if (i) [***] or (ii) [***] ***provided that***, in the case of clause (ii), [***].

8.2.3. Cooperation. Each Party shall provide to the Party enforcing any such rights under this Section 8.2 reasonable assistance in such enforcement, [***].

8.2.4. Recoveries. Any and all recoveries resulting from a suit, action or proceeding relating to a claim of Third Party Infringement shall first be [***]. Thereafter, any remaining recoveries shall be [***].

8.3. Defense Actions. [***] shall be [***] responsible for the costs of any Defense Action and shall have all authority with respect to any such Defense Action, including [***] ***provided that*** [***] shall keep [***] timely informed of the proceedings and filings, and provide [***] with copies of all material communications, pertaining to each Defense Action [***] shall not settle, stipulate to any facts or make any admission with respect to any Defense Action without [***] prior written consent (not to be unreasonably withheld or delayed) if such settlement, stipulation or admission would (a) [***] (b) [***] (c) [***].

9. CONFIDENTIALITY

9.1. Definition. "**Confidential Information**" means the terms and provisions of this Agreement and other proprietary information and data of a financial, commercial or technical nature that the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, which are disclosed in writing or orally, including with respect to Bluebird as the disclosing Party, Restricted Information and any Bluebird proprietary information or data in proposed publications or presentations submitted to Biogen pursuant to Section 14.1.3 or reports submitted pursuant to Section 3.3.

9.2. Obligations. During the Term and for five (5) years thereafter, the receiving Party will (a) protect all Confidential Information of the disclosing Party against unauthorized disclosure to Third Parties and (b) not use or disclose the Confidential Information of the disclosing Party, except as permitted by or in furtherance of exercising rights or carrying out obligations hereunder or for internal legal, accounting or finance purposes, for the avoidance of doubt, Biogen may not use Restricted Information in connection with its own research, Development, manufacture, Commercialization, use, import, or sale of products covered by the Licensed Patents in the Field in the Territory. The receiving Party shall treat all Confidential Information provided by the disclosing Party with the same degree of care as the receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The receiving Party may disclose the Confidential Information to its Affiliates, and their respective directors, officers, employees, subcontractors, sublicensees, consultants, attorneys, accountants, banks and investors (collectively, "**Recipients**") who have a need-to-know such information for purposes related to this Agreement, ***provided that*** the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

9.3. Exceptions to Confidentiality. The obligations under this Section 9 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain

through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;

(b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party;

(c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or

(d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

9.4 Permitted Disclosures.

9.4.1. Compliance with Law. The restrictions set forth in this Section 9 shall not apply to any Confidential Information that the receiving Party is required to disclose under Applicable Laws or a court order or other governmental order or to enforce any Licensed Patent Right under Section 8, ***provided that*** the receiving Party: (a) provides the disclosing Party with prompt notice of such disclosure requirement if legally permitted; (b) affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure; and (c) if the disclosing Party is unsuccessful in its efforts pursuant to Section 9.4.1(b), discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel.

9.4.2. Biogen Permitted Disclosures. Notwithstanding the restrictions set forth in this Section 9, in the event that Biogen wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Fees payable hereunder, Biogen may disclose to a Third Party Confidential Information of Bluebird in connection with any such proposed assignment, ***provided that*** Biogen shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

9.4.3. Bluebird Permitted Disclosures. Notwithstanding the restrictions set forth in this Section 9, in the event that Bluebird wishes to enter into a sublicense in accordance with Section 2.2, Bluebird may disclose to a Third Party Confidential Information of Biogen relating to the Licensed Products in the Field in connection with any such proposed sublicense, ***provided that*** Bluebird shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

9.4.4. Disclosure of Agreement Terms. Notwithstanding the restrictions set forth in this Section 9, a Party may, without the prior consent of the other Party, disclose the terms and provisions of this Agreement to any Third Party that is (a) performing diligence in connection with any permitted Change of Control or similar transaction or (b) a permitted sublicensee

under this Agreement or a permitted assignee of this Agreement, ***provided that*** such Party shall hold such Third Party to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.

9.5. Right to Injunctive Relief. Each Party agrees that breaches of this Section 9 may cause irreparable harm to the other Party and shall entitle such other Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

9.6. Ongoing Obligation for Confidentiality. Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy, delete or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one copy which may be retained in the confidential files of its legal department for archival purposes only.

10. REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1. Representations and Warranties by Each Party. Each Party represents and warrants to the other Party as of the Effective Date that:

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

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

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

(d) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

(e) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents; (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Laws.

10.2. Representations and Warranties by Biogen.

Biogen represents and warrants to Bluebird as of the Effective Date that:

(a) Biogen Controls the Licensed Patent Rights, and is entitled to grant the licenses specified herein; and

(b) Biogen has not granted to any Third Party any rights or licenses under any of the Licensed Patent Rights that would conflict with the licenses granted to Bluebird hereunder.

10.3. Covenants and Representations and Warranties by Bluebird.

Bluebird represents and warrants as of the Effective Date and covenants thereafter to Biogen that:

(a) it shall, and shall ensure all Third Parties that it engages, comply with all Applicable Laws with respect to the performance of its obligations hereunder;

(b) without limiting the generality of Section 10.3(a), Bluebird shall comply with the U.S. Foreign Corrupt Practices Act of 1977 (as modified or amended);

(c) it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence any Government Official; and

(d) if Bluebird is itself a Government Official, Bluebird represents warrants and covenants that it has not accepted, and will not accept in the future, such a payment or transfer.

As used in this Section 10.3, "**Government Official**" means: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office; (iv) an employee or person acting for or on behalf of a public international organization; or (v) any person otherwise categorized as a government official under local law. For the purposes of the definition of "**Government Official**", the terms "**government**" and the correlative term "**governmental**" are meant to include all levels and subdivisions of non-U.S. governments (i.e., local, regional, or national and administrative, legislative, or executive).

10.4. No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 10, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. ANY INFORMATION PROVIDED BY BIOGEN OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

11. INDEMNIFICATION

11.1. Indemnification by Bluebird. Bluebird agrees to indemnify, hold harmless and defend Biogen and its Affiliates, and their respective officers, directors and employees (collectively, "**Biogen Indemnitees**"), from and against any Claims arising or resulting from: (a) the Development of a Licensed Product by, on behalf of or under grant of rights from Bluebird, its Affiliates, subcontractors or sublicensees; (b) the Commercialization of a Licensed Product by, on behalf of or under grant of rights from Bluebird, its Affiliates, subcontractors or sublicensees; (c) any gross negligence or wrongful intentional acts or omissions of Bluebird, its Affiliates, subcontractors or sublicensees in connection with this Agreement; (d) breach by Bluebird of any representation, warranty, obligation or covenant as set forth in this Agreement; or (e) breach by Bluebird of the scope of the license set forth in Section 2.1. As used herein, "**Claims**" means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees).

11.2. Indemnification by Biogen. Biogen agrees to indemnify, hold harmless and defend Bluebird and its Affiliates and their respective officers, directors and employees (collectively, "**Bluebird Indemnitees**"), from and against any Claims arising or resulting from: (a) any gross negligence or wrongful intentional acts or omissions of Biogen, its Affiliates, or subcontractors in connection with this Agreement; or (b) breach by Biogen of any representation, warranty, obligation or covenant as set forth in this Agreement.

11.3. Indemnification Procedure. In connection with any Claim for which a Party (the "**Indemnified Party**") seeks indemnification from the other Party (the "**Indemnifying Party**") pursuant to this Agreement, the Indemnified Party shall: (a) give the Indemnifying Party prompt written notice of the Claim; ***provided, however,*** that failure to provide such notice shall not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, at the Indemnifying Party's expense, in connection with the defense and settlement of the Claim; and (c) permit the Indemnifying Party to control the defense and settlement of the Claim; ***provided, however,*** that the Indemnifying Party may not settle the Claim without the Indemnified Party's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts the Indemnified Party's rights or obligations. Further, the Indemnified Party shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

12. LIMITATION OF LIABILITY

[***]

13. TERM; TERMINATION

13.1. **Term**. The term of this Agreement (the "**Term**") shall commence as of the Effective Date and, unless earlier terminated as expressly provided herein, shall expire upon the last-to-expire Royalty Term.

13.2. **Termination for Cause**. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party breaches any of its material obligations hereunder and fails to cure such breach within [***] of receiving notice thereof; ***provided***, ***however***, that if such breach is capable of being cured, but cannot be cured within such [***] period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed [***]. Any termination by a Party under this Section 13.2 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. For the avoidance of doubt, Bluebird's failure to use Commercially Reasonable Efforts to Develop and Commercialize the Licensed Product shall constitute a material breach by Bluebird under this Agreement.

13.3. **Termination by Bluebird**. Bluebird may terminate this Agreement at will in its sole discretion, on not less than [***] prior written notice to Biogen.

13.4. Termination for a Bankruptcy Event. Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [***] after they are instituted; (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature; (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code; (d) the appointment of a receiver for all or substantially all of a Party's assets; or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

13.5. **Effect of Termination or Expiration**.

13.5.1. Upon termination or expiration of this Agreement, (a) Bluebird shall pay to Biogen [***] Biogen as of the effective date of termination or expiration within [***] following the effective date of termination or expiration and (b) all licenses under Section 2.1 from Biogen to Bluebird shall terminate.

13.5.2. Upon termination of this Agreement, Bluebird shall have the right to sell its remaining inventory of Licensed Products for a period of up to [***]

following the termination of this Agreement so long as Bluebird has fully paid, and continues to fully pay when due, any and all Fees owed to Biogen, and Bluebird otherwise is not in material breach of this Agreement.

13.5.3. A termination of this Agreement will not automatically terminate any sublicense granted by Bluebird pursuant to Section 2.2 with respect to a Third Party, ***provided that*** (a) such sublicensee is not then in breach of any provision of this Agreement or the applicable sublicense agreement; (b) Biogen will have the right to step into the role of Bluebird as sublicensor, with all the rights that Bluebird had under such sublicense prior to termination of this Agreement (including the right to receive any payments to Bluebird by such sublicensee that accrue from and after the date of the termination of this Agreement); and (c) Biogen will only have those obligations to such sublicensee as Biogen had to Bluebird hereunder. Bluebird shall include in any sublicense agreement a provision in which said sublicensee acknowledges its obligations to Biogen hereunder and the rights of Biogen to terminate this Agreement with respect to any sublicensee for material breaches of this Agreement by such sublicensee.

13.6. Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 5.1.7 (Late Payments), 5.2 (Payment Method), 5.3 (Taxes), 6 (Records; Audit Rights), 7.1 (Pre-Existing IP), 7.2 (Developed IP), 9 (Confidentiality), 11 (Indemnification), 12 (Limitation of Liability), 13.5 (Effect of Termination or Expiration), 14.1.2 (Public Statements), 15 (Bluebird Insurance), 16 (Dispute Resolution), 17.3 (Governing Law) and 17.8 (Notices) shall survive expiration or termination of this Agreement.

14. PUBLICITY, PUBLICATIONS AND RESTRICTED ACCESS

14.1. Publicity and Publications.

14.1.1. Use of Trademarks. Neither Party (nor any of its Affiliates or agents) shall use the Trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance.

14.1.2. Public Statements. Except as expressly set forth herein, each Party agrees not to issue any press release or other public statement or any information relating to this Agreement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement or the terms hereof without the prior written consent of the other Party; ***provided, however***, that neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or the rules of any recognized stock exchange, including disclosure of the terms of this Agreement, so long as the disclosing Party provides the other Party at least [***] prior written notice to the extent practicable and only discloses

information to the extent required by Applicable Laws or the rules of any recognized stock exchange.

14.1.3. Publications. Biogen acknowledges that Bluebird personnel may desire to publish or present data that is derived from the research, Development or Commercialization of the Licensed Products in the Field or related to the Licensed Patent Rights. No such publication by Bluebird will be submitted and no such presentation shall be made unless a written copy of such proposed publication or presentation is submitted to Biogen no later than [***] before submission for publication or presentation. Biogen shall provide its comments with respect to such publications and presentations within [***] after its receipt of such written copy from Bluebird. Bluebird shall consider in good faith all comments made by Biogen, including limitations on disclosure of Bluebird confidential information requested by Biogen consistent with what Bluebird would consider normal procedure for its own development products. Bluebird will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any such publication.

14.2. Restricted Disclosure and Internal Access. At any time after [***], Bluebird's obligation to submit details of Bluebird's research and Development activities with respect to the Licensed Products, including specific vector sequences used in the Licensed Products pursuant to clause (a) or (b) of Section 3.3 or proposed manuscripts pursuant to Section 14.1.3 (such information, the "**Restricted Information**") shall be limited to submitting such information solely to Biogen's intellectual property group, and Biogen shall restrict the access of any such Restricted Information to Biogen's intellectual property group; ***provided that***, notwithstanding the foregoing, (i) Biogen's intellectual property group may disclose to other employees and consultants of Biogen information derived from Restricted Information concerning whether or not Bluebird has complied with its payment obligations under Section 5.1.2 and Section 5.1.3 and (ii) the restrictions contained in this Section 14.2 shall not apply in the event of any dispute under this Agreement.

15. BLUEBIRD INSURANCE

15.1. Insurance Requirements. Bluebird shall maintain during the Term and until the later of: (a) [***] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Licensed Products have expired, commercial general liability insurance from a minimum "A-" AM Bests rated insurance company or insurer reasonably acceptable to Biogen, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than [***]. Bluebird has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on Bluebird's liability hereunder. Such policies shall name Biogen and its Affiliates as additional insured and provide a waiver of subrogation in favor of Biogen and its Affiliates. Such insurance policies shall be primary and non-

contributing with respect to any other similar insurance policies available to Biogen or its Affiliates. Any deductibles for such insurance shall be assumed by Bluebird.

15.2. **Policy Notification**. Bluebird shall provide Biogen with original certificates of insurance (which may be done through the submission of an electronic copy of such certificate) evidencing such insurance: (a) promptly following execution by both Parties of this Agreement; and (b) prior to expiration of any one coverage. Biogen shall be given at least thirty (30) days written notice prior to cancellation, termination or any change to restrict the coverage or reduce the limits afforded.

16. DISPUTE RESOLUTION

16.1. **General**. Promptly after the written request of either Party, each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute that arises under this Agreement. If the designated representatives do not resolve the dispute within [***] of such request, then a senior executive of each Party shall meet in person or by telephone to review and attempt to resolve the dispute in good faith. The senior executives shall have [***] days to attempt to resolve the dispute. If the senior executives cannot resolve such dispute within such period of time, then the Parties shall each be free to pursue any avenue available to them under law or equity to resolve the dispute. If a Party's legal rights would be adversely affected as a result of the passage of time that would occur by participating in the dispute resolution mechanism set forth above, including the effect of applicable statutes of limitations or time-based defenses (such as estoppels or laches), such Party may commence legal proceedings prior to or during the course of such dispute resolution mechanism.

16.2. **Injunctive Relief**. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 16.1.

17. GENERAL PROVISIONS

17.1. **Assignment**. [***]

17.2. **Severability**. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

17.3. **Governing Law.** This Agreement shall be governed by and construed under the laws in effect in the Commonwealth of Massachusetts, U.S., without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result.

17.4. **Force Majeure**. Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a "**Force Majeure Event**"), ***provided that*** the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for [***] or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

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

17.6. **Relationship of the Parties**. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Biogen and Bluebird, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

17.7. **Successors and Assigns**. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

17.8. **Notices**. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt); (b) sent by fax (with written confirmation of receipt), ***provided that*** a copy is sent by an internationally recognized overnight delivery service (receipt requested); or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to Biogen:

Biogen Idec
225 Binney Street
Cambridge, MA 02142
Attn: Executive Vice President and General Counsel

Facsimile: (866) 546-2758

with a copy to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600 U.S.A.
Attn: Marc A. Rubenstein, Esq.
Facsimile: (617) 235-0706

If to Bluebird:

bluebird bio, Inc.
150 2nd Street
Cambridge, MA 02141
Attn: General Counsel

with a copy to:

Goodwin Procter LLP
53 State Street
Boston, MA 02109-2802
Attn: Michael Bison

17.9. Further Assurances. Bluebird and Biogen hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

17.10. No Third Party Beneficiary Rights. Except as expressly provided in this Agreement, this Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except in the case of Section 11, Biogen Indemnitees and Bluebird Indemnitees, as applicable.

17.11. Entire Agreement; Confidentiality Agreement. This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, without limitation, that certain mutual confidentiality agreement by and between Bluebird and Biogen Idec Inc., dated February 14, 2014 (the "**CDA**"). The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information (as defined in the CDA) disclosed by Biogen or its Affiliates pursuant to the CDA shall be considered Biogen's Confidential Information and subject to the terms set forth in this Agreement. In the event of any conflict between a material provision of this Agreement and any Schedule hereto, this Agreement shall control.

17.12. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. An executed signature page of this Agreement delivered by electronic or facsimile transmission shall be as effective as an original executed signature page.

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

17.14. Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

17.15. Headings. The captions to the several sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

17.16. Construction. Except where the context otherwise requires, the use of any gender herein shall be deemed to be or include the other genders, the use of the singular shall be deemed to include the plural (and vice versa) and the word "or" is used in the inclusive sense commonly associated with the term "and/or". The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (b) any reference herein to any Person shall be construed to include the Person's successors and assigns, (c) the words "herein", "herewith", "hereof" and "hereunder", and words of similar import, shall, unless otherwise stated, be construed to refer to this Agreement in its entirety and not to any particular provision hereof and (d) all references to "Section" and "Schedule", unless otherwise specified, are intended to refer to a Section or Schedule of or to this Agreement.

[*Signatures on next page*]

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

Biogen Idec MA Inc.

By: /s/ Steven Holtzmann

Name: Steven Holtzmann

Title: EVP, Corporate Development

bluebird bio, Inc.

By: /s/ Jason F. Cole

Name: Jason F. Cole

Title: SVP, General Counsel

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SCHEDULE A

COM IP

[***]

SCHEDULE B

MOT IP

[***]

EXHIBIT 10.23

THE NATIONAL INSTITUTES OF HEALTH

PATENT LICENSE AGREEMENT – *EXCLUSIVE*

COVER PAGE

For the **NIH** internal use only:

License Number: L-224-2015/0

License Application Number: A-107-2014

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

[***]

Licensee: bluebird bio, Inc.

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): n/a

Additional Remarks: none

Public Benefit(s):

Autologous cell therapy has shown the potential to result in a significant and durable clinical benefit to patients with advanced tumors; the newest iteration of this approach uses engineered chimeric antigen receptors (CAR) to activate T cell response to the tumor. B cell maturation antigen (BCMA) is an attractive target for application of CAR technology due to its expression in different tumor types (especially hematological cancers) and lack of expression in non-transformed tissues; therefore, development of BCMA CAR products by the **Licensee**, in partnership with the **NIH**, has the potential to generate new, efficacious, and safe therapies for patients that have not responded to all other therapies.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**"), an agency within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as the "**Licensee**".

The **NIH** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **NIH** or the **FDA** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **NIH** or **FDA** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIH** or the **FDA**.

1.3 The Secretary of **HHS** has delegated to the **NIH** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 The **NIH** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.3 "**Combination Product**" means a product that contains a **Licensed Product(s)** and at least one other active therapeutic component or device other than a **Licensed Product(s)** that is not claimed or covered by the **Licensed Patent Rights**.

2.4 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.5 "**CRADA"** means a Cooperative Research and Development Agreement.

2.6 "**FDA**" means the Food and Drug Administration.

2.7 "**First Commercial Sale**" means the initial transfer by or on behalf of the **Licensee**, its A**ffiliates** or sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee**, its **Affiliates**, or sublicensees in a country or other jurisdiction, in each case, after all applicable marketing and pricing approvals (if any) have been granted by the applicable governing regulatory authority in such country or other jurisdiction, in exchange for cash or some equivalent consideration to which value can be assigned for the purpose of determining **Net Sales**.

2.8 "**Government**" means the Government of the United States of America.

2.9 "**Licensed Fields of Use**" means the fields of use identified in Appendix B

2.10 "**Licensed Patent Rights**" shall mean, subject to Paragraph 6.6:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these

applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.10(a):

(i) continuations-in-part of 2.10(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.10(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.10(a): all counterpart foreign and U.S. patent applications and patents to2.10(a) and 2.10(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include claims included in patents or applications identified in 2.10(b) or 2.10(c) to the extent that such claims are directed to new matter which is not the subject matter disclosed in 2.10(a).

2.11 "**Licensed Processes**" means processes which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights**.

2.12 "**Licensed Products**" means tangible materials which, in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights**.

2.13 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.14 (a) "**Net Sales**" means [***]

2.15 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.16 "**Research License**" means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research and not for purposes of commercial manufacture, sale, or distribution in lieu of purchase.

2.17 [***].

2.18 "**Licensee's Development Partner**" means Celgene Corporation, which was identified in **Licensee's** commercial development plan included with its license application as **Licensee's** partner for developing and commercializing the **Licensed Patent Rights**.

2.19 "**Notice**" means a legal notification by **Licensee** to **NIH** that is delivered in a written format to **NIH's** official mailing address for **Agreement** notices and reports.

2.20 "**Collaboration and Option Agreement**" means the amended and restated master collaboration agreement between **Licensee** and **Licensee's Development Partner**, dated as of June 3, 2015, focused on anti-BCMA product candidates, and as may be amended from time to time.

3. GRANT OF RIGHTS

3.1 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Field of Use I** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Field of Use I**.

3.2 The **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Field of Use II** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Field of Use II**. [***]

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **NIH** and which shall not be unreasonably withheld, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**. With respect to any proposed sublicense agreement, if the **NIH** does not provide the **Licensee** with a written objection thereof within [***] after the date the **NIH** receives **Notice** of **Licensee's** intent to sublicense and a copy of the proposed sublicense from the **Licensee**, the **NIH** shall be deemed to have given its approval of such sublicense agreement and the **Licensee** shall have the right to enter into such sublicense agreement.

The **NIH** hereby provides written approval for the **Collaboration and Option Agreement** with the following stipulations:

[***]

4.2 The **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to the **NIH** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, 13.6-13.8 of this **Agreement** shall be explicitly binding to sublicensee as if it were a party to this **Agreement**.

4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **NIH**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **NIH** approval, which will not be unreasonably withheld, and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 The **Licensee** agrees to forward to the **NIH** a complete copy of each fully executed sublicense agreement postmarked within [***] of the execution of the agreement. To the extent permitted by law, the **NIH** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 (a) the **NIH** reserves on behalf of the **Government** an irrevocable, non-exclusive, non-transferable, royalty-free license for the practice of all inventions licensed under the **Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory; and

(b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, to the extent set forth in 15 U.S.C. §3710a(b)(1)(A), a non-exclusive, non-transferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.

5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIH**, which written waiver will not be unreasonably withheld or denied.

5.3 The **Licensee** acknowledges that the **NIH** may enter into future **CRADA**s under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **NIH** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) in addition to the reserved license of Paragraph 5.1, the **NIH** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **NIH** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, to the extent set forth in 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by the **Licensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by the **Licensee**; or

(iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

(d) The **NIH** acknowledges and agrees that a **Research License** or other right granted pursuant to this Paragraph 5.4 shall only pertain to the **Licensed Patent Rights** and shall not include a right or license to any patent or other intellectual property right solely owned or solely controlled by the **Licensee** or its **Affiliates** other than the **Licensed Patent Rights**. Without limiting the foregoing, except as expressly provided herein, nothing contained in this **Agreement** shall be construed as granting, by implication, estoppel or otherwise, any licenses or rights under any patents or other intellectual property rights other than the **Licensed Patent Rights**.

5.5 Notwithstanding anything to the contrary set forth in this **Agreement**, the **NIH** shall not grant to any third party any rights under the **Licensed Patent Rights** within the **Licensed Field of Use I** and shall not provide any **Licensed Products** or materials made through the **Licensed Processes** to any third party for any commercial purpose within the **Licensed Field of Use I**.

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **NIH** a non-creditable, non-refundable license issue royalty as set forth in Appendix C.

6.2 The **Licensee** agrees to pay the **NIH** a non-refundable, fully creditable (against earned royalties due for sales made in that specific year under Paragraph 6.3 below) minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **NIH** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **NIH** benchmark royalties as set forth in Appendix C.

6.5 The **Licensee** agrees to pay the **NIH** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application, in any given country or other jurisdiction, licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments on the earliest of the dates that, in such country or other jurisdiction:

(a) the application has lapsed or been rejected, revoked or abandoned and not continued;

(b) the patent expires or irrevocably lapses, or

(c) the patent has been held to be revoked, invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

(d) one or more claims have been pending before the United States Patent and Trademark Office for more than [***] as of the date of **Licensee's** signature found at the Signature Page of this **Agreement**, except that such [***] period shall be extended by a period equal to the time the examination of the claim(s) has been interrupted by (i) a derivation proceeding under 35 U.S.C. Section 135 or (ii) the claim(s) are the subject of an appeal filed by the **NIH** of a decision of an patent examiner pursuant to 37 C.F.R Part 1; provided, however, that if the claim(s) issue in a form substantially similar to the form in which they were originally filed, the claim(s) shall be deemed to fall within the scope of the **Licensed Patent Rights** on which royalties on **Net Sales** are due.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of the **Licensed Products** by the **Licensee** to its **Affiliates** or sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** prior to the effective date of this **Agreement**, an amount equal to [***], the **Licensee** shall pay the **NIH**, as an additional royalty, within sixty (60) days of the **NIH's** submission of a statement and request for payment to the **Licensee** an amount equivalent to these unreimbursed expenses previously paid by the **NIH**, or a *pro rata* share thereof if there are multiple commercial licensees of the **Licensed Patent Rights** prior to the end of the sixty (60) day period for such payment by **Licensee**.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIH** on or after the effective date of this **Agreement** and during the term of this **Agreement**, the **NIH**, at its sole option, may require the **Licensee**:

[***]

6.11 The **NIH** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIH** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. The **Licensee** agrees that all information provided by the **NIH** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon thirty (30) days written notice to the **NIH** and owe no payment obligation under Paragraph 6.10 for patent-related expenses paid in that country after thirty (30) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 Except as otherwise provided in this Article 7, the **NIH** agrees to take responsibility for the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all relevant patent-related documents to the **Licensee**. **NIH** shall instruct the law firm prosecuting the **Licensed Patent Rights** to furnish, upon execution of this **Agreement** and on a continuous basis thereafter as long as the **Agreement** is in effect, copies of relevant patent-related documents to **Licensee**, including all drafts of patent applications filings, domestic and foreign, amendments thereto, related correspondence and other related documents, sufficiently in advance to allow **Licensee** to comment thereon prior to filing or submission. **NIH** shall, in good faith, take into consideration all reasonable comments provided by **Licensee** relating to the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**, provided however, that if **Licensee** has not commented prior to the relevant action deadline, **NIH** shall be free to act without consideration of **Licensee's** comments.

7.2 Upon the **NIH's** written request or upon any determination by the **NIH** not to proceed or continue with the preparation, filing, prosecution, or maintenance (or combination thereof) of any patent application or patent included in the **Licensed Patent Rights**, the **NIH** shall provide the **Licensee** with written notice of such determination at least sixty (60) days prior to the deadline for taking any action for such patent application or patent or the date on which the abandonment of any such patent or application would become effective, whichever is earlier, and the **Licensee** shall have the right but not the obligation to assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all relevant patent-related documents to the **NIH**. In this event, the **Licensee** shall select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee** and the **NIH**. The **NIH** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** and its attorneys or agents shall consult with the **NIH** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** and shall provide the **NIH** sufficient opportunity to comment on any document that the **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office. If **Licensee** notifies **NIH** that **Licensee** does not intend to pursue or pay (or both) the costs of an application, then **NIH** may file such application at its own expense and **Licensee's** rights derived from this **Agreement** to that application will terminate.

7.3 **NIH** may provide **Licensee** with written notice that **NIH** wishes to reassume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** only if **NIH** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with **Licensee's** request for a license and the **Licensee** cannot otherwise demonstrate to **NIH's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2; or

(c) is not fulfilling its obligations regarding diligent preparation, filing, prosecutions, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

7.4 In making the determination referenced in Paragraph 7.3, **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to resuming control under Paragraph 7.3, **NIH** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a [***] opportunity to respond to, **NIH's** concerns as to the items referenced in 7.3(a)-7.3(c). If **Licensee** fails to initiate corrective action to **NIH's** satisfaction, **NIH** may reassume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

7.5 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIH**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours, but not more than once per year, for inspection, at the expense of the **NIH**, by an accountant or other designated auditor selected by the **NIH** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only have the right to audit those records that have not previously been audited pursuant to this Paragraph 8.1, unless the **NIH** determines that there is just cause for an additional audit, and shall only disclose to the **NIH** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIH** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIH** provides to the **Licensee** notice of the payment due. The **Licensee** shall have the right to require that any accountant or auditor, prior to conducting an audit under this Paragraph 8.1, enter into an appropriate non-disclosure agreement with the **Licensee** regarding such financial information.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIH** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written summary annual reports on [***] for each of the **Licensed Fields of Use** within [***] These progress reports shall include, but not be limited to: [***]The **NIH** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. [***] the **Licensee** shall [***] In the annual report, the **Licensee** may [***] The **Licensee** agrees to provide any additional information reasonably required by the **NIH** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIH**, which approval shall not be unreasonably withheld. The **NIH** shall not unreasonably withhold approval of any request of the **Licensee** to [***]

9.3 The **Licensee** shall report to the **NIH** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within [***] of such occurrences.

9.4 Following **First Commercial Sale**, the **Licensee** shall submit to the **NIH**, within [***] after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **NIH** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** [***]. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

9.5 The **Licensee** agrees to forward semi-annually to the **NIH** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **NIH** by the **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. [***] The royalty report required by Paragraph 9.4 shall be mailed to the **NIH** at its address for **Agreement** Notices indicated on the Signature Page.

9.7 [***]

9.8 [***] may be assessed by the **NIH** on any payment that is more than ninety (90) days overdue, and not the subject of a good faith dispute, at the rate of [***]

9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **NIH** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIH** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include reasonable efforts to adhere to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D. The efforts of a sublicensee shall be considered the efforts of the **Licensee**.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make the **Licensed Products** and the **Licensed Processes** reasonably accessible to the United States public. The efforts of a sublicensee shall be considered the efforts of the **Licensee**.

10.3 The **Licensee** agrees that, to the extent commercially reasonable or possible, after its **First Commercial Sale,** to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** available to patient assistance programs.

10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians reasonably detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 The **Licensee** agrees to supply to **NIH**, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, samples of of the marketing brochures for the **Licensed Products** or the **Licensed Processes** for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **NIH** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** may:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have the first right to take such actions; and

(d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **NIH** in writing. If the **NIH** does not notify the **Licensee** of its intent to pursue legal action within [***], the **Licensee** shall be free to initiate suit. The **NIH** shall have a continuing right to intervene in the suit at its own expense. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement; provided, however, that the **Government** will participate in the suit if required for legal standing purposes. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit brought by the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29 or other statutes, the **Licensee** may:

(a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights**;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, sue for damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights** provided, however, that the **NIH** and appropriate **Government** authorities shall have a continuing right to intervene in the suit at its own expense; and

(d) if the **NIH** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action brought by the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **NIH**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **NIH** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **NIH** and give careful consideration to the views of the **NIH** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 Except as otherwise set forth above, in any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by [***]

11.5 The **NIH** shall cooperate fully with [***] in connection with any action under Paragraphs 11.2 or 11.3. The **NIH** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by [***].

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **NIH** offers no other warranties than those specified in Article 1: (i) **HHS**, by assignment of rights from **NIH** employees, on behalf of the **Government**, owns all intellectual property rights claimed in the United States and foreign patent applications and patents in the **Licensed Patent**

Rights, (ii) **HHS** owns tangible embodiments of inventions actually reduced to practice, and (iii) **NIH** has the authority, by delegation from the Secretary of **HHS**, to enter into this **Agreement**.

12.2 The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **NIH** MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 The **NIH** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **NIH**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage to the extent arising out of any suit or proceeding brought by a third party for:

(a) the use by or on behalf of the **Licensee**, its sublicensees, their respective directors or employees, or third parties acting by the direction of **Licensee** of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or other materials, products or processes developed by or on behalf of the **Licensee** or its sublicensees in connection with or arising out of the **Licensed Patent Rights**.

12.6 **Licensee** shall have no obligation to indemnify hereunder with respect to any liability, demands, damages, expenses, and losses to the extent arising out of any negligence or willful misconduct of the **NIH** or its employees, students, fellows, agents or consultants, or any breach by the **NIH** of the warranty set forth in Section 12.1 above.

12.7 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13 TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within [***] after the date of notice in writing of the default, the **NIH** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify the **NIH** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any **Licensed Fields of Use** in any country or territory by giving the **NIH** [***] written notice to that effect.

13.5 The **NIH** shall specifically have the right to terminate or modify, at its option, this **Agreement** by written notice to the **Licensee**, if the **NIH** reasonably determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIH's** satisfaction that the

Licensee has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement** that has not been remedied within the [***] period set forth in Paragraph 13.2 above;

(e) is not keeping the **Licensed Products** or the **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs;

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the **NIH** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIH** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a [***] opportunity to respond to, the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIH's** concerns as to the items referenced in 13.5(a)-13.5(g) or within [***] following written notice from the **NIH** or otherwise fails to initiate corrective action to the **NIH's** satisfaction, the **NIH** may terminate this **Agreement** upon written notice to the **Licensee**.

13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a [***] opportunity to respond, the **NIH** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights**. The **NIH** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee**.

13.8 The **NIH** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** upon written notice to the **Licensee** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee** within [***] following written notice from the **NIH**.

13.9 Within [***] of receipt of written notice of the **NIH's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **NIH** official. The decision of the designated **NIH** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.10 Within [***] of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **NIH** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with the **NIH** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall have the right to offer for sale and sell any existing inventory of **Licensed Products** for a period of [***] following the effective termination date of this **Agreement**, subject to the royalty obligations as set forth in Appendix C. The **Licensee** may not be granted additional **NIH** licenses if the final reporting requirement is not fulfilled.

14 GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of a party to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by that party or excuse a similar subsequent failure to perform any of these terms or conditions by the other party.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

[***]

14.7 The **Licensee** agrees in its use of any **NIH**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the **NIH**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIH** of research involving human subjects or clinical trials outside of the United States shall be given no later than [***] prior to commencement of the research or trials.

14.8 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **NIH** neither represents that a license is or is not required or that, if required, it shall be issued.

14.9 The **Licensee** agrees to mark the **Licensed Products** or their packaging or containers in accordance with the applicable patent marking laws.

14.10 By entering into this **Agreement**, the **NIH** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the

Government, the **NIH**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIH**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature in connection with this **Agreement** or the **Licensed Patent Rights** without the prior written approval of the **NIH**.

14.11 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIH** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available. Notwithstanding anything to the contrary in this **Agreement**, the **Licensee** shall have the right, without waiving any right or remedy available under this **Agreement** or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of the **Licensee**, pending any such settlement or the determination of any such appeal.

14.12 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.13 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **NIH**.

14.14 Paragraphs 4.3, 8.1, 9.5-9.9, 12.1-12.5, 13.9, 13.10, 14.11 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.

14.15 The terms and conditions of this **Agreement** shall, at the **NIH's** sole option, be considered by the **NIH** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIH** within sixty (60) days from the date of the **NIH's** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

For the **NIH**:

/s/ Richard U. Rodriguez — 8/21/2015

Richard U. Rodriguez — Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

by:

/s/ Jason F. Cole — 8/31/2015

Signature of Authorized Official — Date

Jason F. Cole
Printed Name

SVP, General Counsel
Title

I. Official and Mailing Address for **Agreement** notices:

Jason Cole
Name

SVP, General Counsel
Title

Mailing Address

bluebird bio, Inc.
150 Second Street, Third Floor
Cambridge, MA 02141

Email Address: jcole@bluebirdbio.com
Phone:
Fax:

II. Official and Mailing Address for Financial notices (the **Licensee**'**s** contact person for royalty payments)

Amber Casares
Name

Title

Mailing Address:

Accounts Payable
bluebirdbio, Inc.
150 Second Street, Third Floor
Cambridge, MA 02141

Email Address: invoices@bluebirdbio.com
Phone:
Fax:

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

[***]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I: Licensed Field of Use I:

Exclusivity to the **Licensed Patent Rights** to make and have made, to sell, to offer for sale, to import, and to use in humans, human autologous peripheral blood T-cells modified by recombinant human immunodeficiency virus ("HIV")-based lentiviral vectors or murine leukemia virus ("MLV")-based gamma-retroviral vectors to express chimeric antigen receptors that recognize B-cell Maturation Antigen ("BCMA") for the treatment or prevention of cancer and autoimmune disease [***].

II: Licensed Field of Use II:

[***]

I. **Licensed Territory:** Worldwide

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to the **NIH** a non-creditable, non-refundable license issue royalty in the amount of [***] within sixty (60) days from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **NIH** a non-refundable minimum annual royalty as follows:

[***]

III. (a) The **Licensee** agrees to pay the **NIH** [***] on **Net Sales** by or on behalf of the **Licensee** and its sublicensees, as follows:

[***]

IV. The **Licensee** agrees to pay the **NIH Benchmark** royalties for certain preclinical, clinical and commercial milestones within sixty (60) days of achieving each milestone:

[***]

V. The **Licensee** agrees to pay the **NIH** the following sublicensing royalties for granting each sublicense within sixty (60) days of the execution of each sublicense:

[***]

APPENDIX D – BENCHMARKS AND PERFORMANCE

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **NIH** that the **Benchmark** has been achieved.

[***]

Certain information indicated with [***] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

[***]

APPENDIX F – EXAMPLE ROYALTY REPORT

[***]

APPENDIX G – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

[***]

Exhibit 31.1

CERTIFICATIONS

I, Nick Leschly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of bluebird bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2021

By: /s/ Nick Leschly

Nick Leschly
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Chip Baird, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of bluebird bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2021

By: /s/ Chip Baird

Chip Baird
Chief Financial Officer
(Principal Financial Officer, Principal Accounting Officer and Duly Authorized Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of bluebird bio, Inc. (the "Company") for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his or her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2021

By: /s/ Nick Leschly

Nick Leschly
President, Chief Executive Officer and Director
(Principal Executive Officer and Duly Authorized Officer)

Date: August 9, 2021

By: /s/ Chip Baird

Chip Baird
Chief Financial Officer
(Principal Financial Officer, Principal Accounting Officer and Duly Authorized Officer)