bluebird bio, Inc.
Form 10-Q
May 03, 2019
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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 March 31, 2019

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	02142

Cambridge, Massachusetts
(Address of Principal Executive Offices) (Zip Code)

(339) 499-9300

(Registrant's Telephone Number, Including Area Code)

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. (Check one):

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

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 Global Select Market LLC

As of April 26, 2019, there were 55,123,256 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," "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;
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- the timing or success of commercialization of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- 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 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; 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.

bluebird bio, Inc.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

bluebird bio, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except par value amounts)

	As of March 31, 2019	As of December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$221,738	$402,579
Marketable securities	1,100,079	982,725
Prepaid expenses	23,766	19,762
Receivables and other current assets	19,449	13,931
Total current assets	1,365,032	1,418,997
Marketable securities	408,949	506,123
Property, plant and equipment, net	114,030	246,622
Intangible assets, net	12,228	13,169
Goodwill	13,128	13,128
Operating lease right-of-use assets	184,618	—
Restricted cash and other non-current assets	40,630	44,805
Total assets	$2,138,615	$2,242,844
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$30,241	$17,831
Accrued expenses and other current liabilities	76,152	99,393
Operating lease liability, current portion	17,566	—
Deferred revenue, current portion	11,490	18,602
Collaboration research advancement, current portion	11,242	10,605
Total current liabilities	146,691	146,431
Deferred revenue, net of current portion	14,777	16,338
Collaboration research advancement, net of current portion	30,746	33,349
Contingent consideration	5,526	5,230
Operating lease liability, net of current portion	168,200	—
Financing lease obligation, net of current portion	—	153,319
Other non-current liabilities	576	3,107
Total liabilities	366,516	357,774
Commitments and contingencies (Note 8)		

Stockholders' Equity:		
Preferred stock, $0.01 par value, 5,000 shares authorized; 0 shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value, 125,000 shares authorized; 55,069 and 54,738 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	551	547
Additional paid-in capital	3,430,030	3,386,958
Accumulated other comprehensive loss	(1,792)	(3,627)
Accumulated deficit	(1,656,690)	(1,498,808)
Total stockholders' equity	1,772,099	1,885,070
Total liabilities and stockholders' equity	$2,138,615	$2,242,844

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 March 31,	
	2019	2018
Revenue:		
Collaboration revenue	$11,177	$15,608
License and royalty revenue	1,294	349
Total revenues	12,471	15,957
Operating expenses:		
Research and development	122,640	97,109
General and administrative	60,279	34,926
Cost of license and royalty revenue	430	17
Change in fair value of contingent consideration	296	534
Total operating expenses	183,645	132,586
Loss from operations	(171,174)	(116,629)
Interest income, net	10,102	1,388
Other (expense) income, net	(3,389)	115
Loss before income taxes	(164,461)	(115,126)
Income tax benefit	15	—
Net loss	$(164,446)	$(115,126)
Net loss per share - basic and diluted:	$(2.99)	$(2.31)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	54,957	49,923
Other comprehensive income (loss):		
Other comprehensive income (loss), net of tax expense of $0.4 million and $0.0 million for the three months ended March 31, 2019 and 2018, respectively	1,835	(844)
Total other comprehensive income (loss)	1,835	(844)
Comprehensive loss	$(162,611)	$(115,970)

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(unaudited)

(in thousands)

	Common stock Shares	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balances at December 31, 2018	54,738	$ 547	$3,386,958	$ (3,627)	$(1,498,808)	$ 1,885,070
Adjustment to beginning accumulated deficit from adoption of ASU 2016-02	—	—	—	—	6,564	6,564
Vesting of restricted stock units	131	2	(2)	—	—	—
Exercise of stock options	189	2	9,502	—	—	9,504
Purchase of common stock under ESPP	11	—	1,231	—	—	1,231
Stock-based compensation	—	—	32,341	—	—	32,341
Other comprehensive income	—	—	—	1,835	—	1,835
Net loss	—	—	—	—	(164,446)	(164,446)
Balances at March 31, 2019	55,069	$ 551	$3,430,030	$ (1,792)	$(1,656,690)	$ 1,772,099

	Common stock Shares	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balances at December 31, 2017	49,406	$ 494	$2,540,951	$ (4,205)	$(913,808)	$ 1,623,432
Adjustment to beginning accumulated deficit from adoption of ASU 2014-09	—	—	—	—	(29,375)	(29,375)
Vesting of restricted stock units	74	1	(1)	—	—	—
Issuance of common stock upon public offering, net of issuance costs of $2,563	277	3	48,698	—	—	48,701
Exercise of stock options	301	3	19,727	—	—	19,730
Purchase of common stock under ESPP	9	—	687	—	—	687
Stock-based compensation	—	—	22,995	—	—	22,995
Other comprehensive loss	—	—	—	(844)	—	(844)
Net loss	—	—	—	—	(115,126)	(115,126)
Balances at March 31, 2018	50,067	$ 501	$2,633,057	$ (5,049)	$(1,058,308)	$ 1,570,201

See accompanying notes to unaudited condensed consolidated financial statements.

bluebird bio, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	For the three months ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$(164,446)	$(115,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of contingent consideration	296	534
Depreciation and amortization	3,783	4,020
Stock-based compensation expense	32,341	22,995
Unrealized loss on equity securities	3,085	—
Other non-cash items	(3,456)	2,403
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(12,793)	(13,486)
Operating lease right-of-use assets	5,374	—
Accounts payable	10,590	(737)
Accrued expenses and other liabilities	(21,514)	4,541
Operating lease liabilities	3,224	—
Deferred revenue	(8,672)	(13,966)
Collaboration research advancement	(1,966)	—
Net cash used in operating activities	(154,154)	(108,822)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(19,321)	(7,452)
Purchases of marketable securities	(381,735)	(402,413)
Proceeds from maturities of marketable securities	364,143	145,140
Net cash used in investing activities	(36,913)	(264,725)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of issuance costs	—	48,701
Reimbursement of assets under financing lease obligation	—	3,098
Payments on financing lease obligation	—	(106)
Proceeds from exercise of stock options and ESPP contributions	10,223	19,984
Net cash provided by financing activities	10,223	71,677
Decrease in cash, cash equivalents and restricted cash	(180,844)	(301,870)
Cash, cash equivalents and restricted cash at beginning of period	417,099	772,268
Cash, cash equivalents and restricted cash at end of period	$236,255	$470,398
Supplemental cash flow disclosures from investing and financing activities:		
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$9,302	$2,817
Assets acquired under operating lease obligation	$5,500	$—

Tenant improvements included in receivables and other current assets	$8,009	$14
Restricted cash included in receivables and other current assets	$100	$100
Restricted cash included in restricted cash and other non-current assets	$14,417	$13,763

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 researches, develops, manufactures and plans to commercialize gene therapies for the treatment of 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 general and administrative support for these operations.

The Company's programs in severe genetic diseases include ZYNTEGLO™ (autologous CD34+ cells encoding A-T87Q-globin gene) as a treatment for transfusion-dependent -thalassemia, or TDT; its LentiGlobin® product candidate as a treatment for sickle cell disease, or SCD; and its Lenti-D™ product candidate as a treatment for cerebral adrenoleukodystrophy, or CALD. In the second half of 2018, the Company filed a marketing authorization application with the European Medicines Agency, or EMA, for ZYNTEGLO (formerly referred to as LentiGlobin for TDT) for the treatment of patients 12 years and older with TDT who do not have a 0/0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte-matched related HSC donor is not available. In March 2019, the Committee for Medicinal Products for Human Use of the EMA adopted a positive opinion recommending conditional marketing authorization for ZYNTEGLO in Europe. Assuming that the application is conditionally approved, the Company expects to begin commercializing and generating product revenues in the second half of 2019. The Company's programs in oncology are focused on developing novel T cell-based immunotherapies, including chimeric antigen receptor (CAR) and T cell receptor (TCR) T cell therapies. Idecabtagene vicleucel, or ide-cel (bb2121), and bb21217, which are product candidates in oncology under the Company's collaboration arrangement with Celgene Corporation ("Celgene"), are CAR T cell product candidates for the treatment of multiple myeloma. Please refer to Note 9, "Collaborative arrangements" for further discussion of the Company's collaboration with Celgene.

As of March 31, 2019, the Company had cash, cash equivalents and marketable securities of $1.73 billion. Although the Company has incurred recurring losses and expects to continue to incur losses for the foreseeable future, the Company expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund current planned operations for at least the next twelve months.

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 Update ("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 interim 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 March 31, 2019 and 2018.

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 interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2018, 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 21, 2019.

Certain items in the prior year's condensed consolidated financial statements have been reclassified to conform to the current presentation. As a result, no subtotals in the prior year condensed consolidated financial statements were impacted.

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

Principles of consolidation

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 months ended March 31, 2019 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2018 Annual Report on Form 10-K, except as noted below with respect to the Company's lease accounting policies and as noted within the "Recent accounting pronouncements – Recently adopted" section below.

Leases

Effective January 1, 2019, the Company adopted ASU 2016-02, Leases (Topic 842), ("ASU 2016-02" or "ASC 842"), using the required modified retrospective approach and utilizing the effective date as its date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840, Leases ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company does not have material financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate its incremental borrowing rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

ASC 842 transition practical expedients and application of transition provisions to leases at the transition date

The Company elected the following practical expedients, which must be elected as a package and applied consistently to all of its leases at the transition date (including those for which the entity is a lessee or a lessor): i) the Company did not reassess whether any expired or existing contracts are or contain leases; ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and iii) the Company did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

Application of ASC 842 policy elections to leases post adoption

The Company has made certain policy elections to apply to its leases executed post adoption, or subsequent to January 1, 2019, as further described below.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

ASC 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the bright line thresholds referenced in ASC 842-10-55-2 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to the Company’s entire portfolio of leases.

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: subsequent fair value estimates used to assess potential impairment of long-lived assets, including goodwill and intangible assets, right-of-use assets and lease liabilities, contingent consideration, stock-based compensation expense, accrued expenses, revenue and income taxes.

Recent accounting pronouncements

Recently adopted

ASU No. 2016-02, Leases (Topic 842), ASU No. 2018-10 Codification Improvements to Topic 842, Leases, ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, and ASU No. 2019-01 Leases (Topic 842): Codification Improvements

In February 2016, the FASB issued ASU 2016-02, as amended, which superseded the lease accounting requirements in ASC 840 and created ASC 842. ASC 842 requires a lessee to recognize assets and liabilities on the balance sheet for most leases and changes many key definitions, including the definition of a lease. The new standard includes a short-term lease exception for leases with a term of 12 months or less, as part of which a lessee can make an accounting policy election not to recognize lease assets and lease liabilities. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases using classification criteria that are substantially similar to the previous guidance.

Effective January 1, 2019, the Company adopted ASU 2016-02, using the required modified retrospective approach and utilizing the effective date as its date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840.

The adoption of this standard resulted in the recognition of operating lease right-of-use assets and operating lease liabilities of $184.4 million and $177.0 million, respectively, on the Company's condensed consolidated balance sheet relating to its leases for its corporate headquarters at 60 Binney Street in Cambridge, Massachusetts (the "60 Binney Street Lease"), its office and laboratory space in Seattle, Washington, its office space in Zug, Switzerland, and its embedded leases associated with certain of the Company's contract manufacturing agreements. The application of the standard's transition guidance required the de-recognition of the 60 Binney Street Lease building asset, financing lease obligation, current portion, and financing lease obligation, net of current portion in the amounts of $149.3 million, $1.4 million, and $153.3 million, respectively, as well as certain other adjustments to related account balances. In adopting ASU 2016-02, the Company recorded a total one-time adjustment of $6.6 million to the opening balance of accumulated deficit in the first quarter of 2019 primarily relating to the de-recognition of the 60 Binney Street Lease building asset finance lease obligation.

As a result of adopting ASU 2016-02, the Company recorded an increase to deferred tax assets and deferred tax liabilities of $5.3 million and $7.1 million, respectively. The $1.8 million net increase to deferred tax liabilities and an offsetting valuation allowance adjustment was recorded through the accumulated deficit, such that there was no tax impact on the Company's condensed consolidated financial statements as a result of adoption.

ASU No. 2017-08, Receivables – Nonrefundable Fees and Other Costs (Topic 310-20): Premium Amortization on Purchased Callable Debt Securities

In April 2017, the FASB issued ASU 2017-08, Receivables – Nonrefundable Fees and Other Costs (Topic 310-20): Premium Amortization on Purchased Callable Debt Securities ("Subtopic 310-20"). The new standard amends the amortization period for certain purchased callable debt securities held at a premium by shortening the amortization period for the premium to the earliest call date. Subtopic 310-20 calls for a modified retrospective application under which a cumulative-effect adjustment will be made to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The Company adopted this standard on January 1, 2019 and it did not have a material impact on the Company's financial position or results of operations upon adoption.

ASU No. 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

In February 2018, the FASB issued ASU 2018-02, Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. The new standard allows for a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. The Company adopted this standard on January 1, 2019 and it did not have a material impact on the Company's financial position and results of operations upon adoption.

Not yet adopted

ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The new standard will be effective beginning January 1, 2020 and early adoption is permitted with measurement dates on or after January 1, 2019. The adoption of this standard is not expected to have a material impact on the Company's financial position or results of operations upon adoption.

ASU No. 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. To address concerns over the cost and complexity of the two-step goodwill impairment test, the amendments in this ASU remove the second step of the test. An entity will instead apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The new guidance does not amend the optional qualitative assessment of goodwill impairment. The new standard will be effective beginning January 1, 2020 and early adoption is permitted with measurement dates on or after January 1, 2017. The adoption of this standard is not expected to have a material impact on the Company's financial position or results of operations

upon adoption.

ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, ("ASU 2018-13"). The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the potential impact ASU 2018-13 may have on its disclosures upon adoption.

ASU No. 2018-15, Intangibles-Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract

In August 2018, the FASB issued ASU 2018-15, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, ("ASU 2018-15"). The amendments in this update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the potential impact ASU 2018-15 may have on its financial position and results of operations upon adoption.

ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606, ("ASU 2018-18"). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the potential impact ASU 2018-18 may have on its financial position and results of operations upon adoption.

3. Marketable securities

The following table summarizes the marketable securities held at March 31, 2019 and December 31, 2018 (in thousands):

Description	Amortized cost / Cost	Unrealized gains	Unrealized losses	Fair value
March 31, 2019				
U.S. government agency securities and treasuries	$1,357,641	$ 1,604	$ (1,400)	$1,357,845
Certificates of deposit	5,960	—	—	5,960
Corporate bonds	83,536	81	(19)	83,598
Commercial paper	42,542	—	—	42,542
Equity securities	20,017	—	(934)	19,083
Total	$1,509,696	$ 1,685	$ (2,353)	$1,509,028
December 31, 2018				
U.S. government agency securities and treasuries	$1,459,649	$ 963	$ (3,011)	$1,457,601

Certificates of deposit	9,080	—	—	9,080
Equity securities	20,017	2,150	—	22,167
Total	$1,488,746	$ 3,113	$ (3,011)	$1,488,848

No available-for-sale debt securities held as of March 31, 2019 or December 31, 2018 had remaining maturities greater than three 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 March 31, 2019 and December 31, 2018 (in thousands):

Description	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2019				
Assets:				
Cash and cash equivalents	$221,738	$214,346	$7,392	$ —
Marketable securities:				
U.S. government agency securities and treasuries	1,357,845	—	1,357,845	—
Certificates of deposit	5,960	—	5,960	—
Commercial paper	42,542	—	42,542	—
Corporate bonds	83,598	—	83,598	—
Equity securities	19,083	19,083	—	—
Total assets	$1,730,766	$233,429	$1,497,337	$ —
Liabilities:				
Contingent consideration	$5,526	$—	$—	$ 5,526
Total liabilities	$5,526	$—	$—	$ 5,526
December 31, 2018				
Assets:				
Cash and cash equivalents	$402,579	$348,638	$53,941	$ —
Marketable securities:				
U.S. government agency securities and treasuries	1,457,601	—	1,457,601	—
Certificates of deposit	9,080	—	9,080	—
Equity securities	22,167	22,167	—	—
Total assets	$1,891,427	$370,805	$1,520,622	$ —
Liabilities:				
Contingent consideration	$5,230	$—	$—	$ 5,230
Total liabilities	$5,230	$—	$—	$ 5,230

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 March 31, 2019, cash and cash equivalents comprise funds in cash, money market accounts, and commercial paper. As of December 31, 2018, cash and cash equivalents comprise funds in cash, U.S. treasury securities, U.S. government agency securities, and money market accounts.

Marketable securities

Marketable securities classified as Level 2 within the valuation hierarchy generally consist of certificates of deposit, U.S. treasury securities and government agency securities, 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 earliest call date for premiums or to maturity for discounts. At March 31, 2019 and December 31, 2018, the balance in the Company's accumulated other comprehensive loss was composed primarily of 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 securities during the three months ended March 31, 2019 or 2018, and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive loss for the same periods.

The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of March 31, 2019 and December 31, 2018 was $189.2 million and $787.5 million, respectively. As of March 31, 2019 and December 31, 2018, there were $411.6 million and $315.3 million in securities held by the Company in an unrealized loss position for more than twelve months, respectively. The aggregate unrealized loss on securities held by the Company for less than twelve months as of March 31, 2019 and December 31, 2018 was $0.1 million and $0.9 million, respectively. The aggregate unrealized loss on securities held by the Company for more than twelve months as of March 31, 2019 and December 31, 2018 was $1.3 million and $2.1 million, respectively. The Company has the intent and ability to hold such securities until recovery. The Company determined that there was no material change in the credit risk of the above investments. As a result, the Company determined it did not hold any investments with any other-than-temporary impairment as of March 31, 2019 and December 31, 2018.

The Company holds equity securities with an aggregate fair value of $19.1 million and $22.2 million as of March 31, 2019 and December 31, 2018, respectively, within short-term marketable securities on its condensed consolidated balance sheet. The Company has recorded a $3.1 million unrealized loss during the three months ended March 31, 2019 related to its equity securities, which is 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.

The significant unobservable inputs used in the measurement of fair value of the Company's contingent consideration are probabilities of successful achievement of clinical and commercial milestones, the period in which these milestones are expected to be achieved ranging from 2021 to 2028 and discount rates ranging from 14.3% to 15.2%. Significant increases or decreases in any of the probabilities of success would result in a significantly higher or lower fair value measurement, respectively. Significant increases or decreases in the other inputs would result in a significantly lower or higher fair value measurement, respectively.

The table below provides a roll-forward of fair value of the Company's contingent consideration obligations, which include Level 3 inputs (in thousands):

For the

	three months ended March 31, 2019
Beginning balance	$ 5,230
Additions	—
Changes in fair value	296
Payments	—
Ending balance	$ 5,526

Please refer to Note 8, “Commitments and contingencies” for further information.

5. Property, plant and equipment, net

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

	As of March 31, 2019	As of December 31, 2018
Land	$1,210	$ 1,210
Building	14,913	180,094
Computer equipment and software	6,474	6,365
Office equipment	5,788	5,584
Laboratory equipment	39,442	35,693
Leasehold improvements	12,325	183
Construction-in-progress	60,766	46,669
Total property, plant and equipment	140,918	275,798
Less accumulated depreciation and amortization	(26,888)	(29,176)
Property, plant and equipment, net	$114,030	$ 246,622

North Carolina manufacturing facility

In November 2017, the Company acquired a manufacturing facility, which is in the process of construction, in Durham, North Carolina for the future manufacture of lentiviral vector for the Company's gene therapies. Construction-in-progress as of March 31, 2019 and December 31, 2018 includes $47.1 million and $40.4 million, respectively, related to the North Carolina manufacturing facility. During the three months ended March 31, 2019, the Company placed an additional $2.7 million of the North Carolina manufacturing facility into service and began to depreciate the assets. Total building assets placed into service related to the North Carolina manufacturing facility as of March 31, 2019 and December 31, 2018 were $14.9 million and $12.2 million, respectively.

60 Binney Street Lease

As a result of the adoption of ASU 2016-02, the Company de-recognized $156.0 million of the building asset and $6.7 million of accumulated depreciation related to its corporate headquarters at 60 Binney Street. Prior to the adoption of ASU 2016-02, the Company classified leasehold improvements associated with the 60 Binney Street building as building. Subsequent to the adoption of ASU 2016-02, the leasehold improvements associated with the 60 Binney Street building are classified as leasehold improvements. Please refer to Note 2, "Basis of presentation, principles of consolidation and significant accounting policies" and Note 7, "Leases" for further information.

6. Accrued expenses and other current liabilities

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

	As of March 31, 2019	As of December 31, 2018
Employee compensation	$ 16,404	$ 28,567
Accrued manufacturing costs	12,125	21,618
Accrued clinical and contract research organization costs	14,724	11,891
Accrued license and milestone fees	323	7,739
Accrued professional fees	1,906	1,830
Financing lease obligation, current portion	—	1,424
Other	30,670	26,324
Total accrued expenses and other current liabilities	$ 76,152	$ 99,393

7. Leases

The Company leases certain office and laboratory space. Additionally, the Company has embedded leases at contract manufacturing organizations.

Embedded operating leases

On June 3, 2016, the Company entered into a manufacturing agreement for the future commercial production of the Company's ZYNTEGLO, LentiGlobin, and Lenti-D drug products with a contract manufacturing organization. Under this 12-year agreement, the contract manufacturing organization will complete the design, construction, validation and process validation of the leased suites prior to anticipated commercial launch of the product candidates. During construction, the Company paid $12.0 million upon the achievement of certain contractual milestones, and may pay up to $8.0 million in additional contractual milestones if the Company elects its option to lease additional suites. Construction was completed in March 2018 and beginning in April 2018 the Company pays $5.1 million per year in fixed suite fees as well as certain fixed labor, raw materials, testing and shipping costs for manufacturing services, and may pay additional suite fees if it elects its option to reserve or lease additional suites.

The Company may terminate this agreement at any time upon payment of a one-time termination fee and up to 24 months of fixed suite and labor fees. The Company concluded in prior periods that this agreement contained an embedded lease under ASC 840 as the suites are designated for the Company's exclusive use during the term of the agreement. The Company concluded that it was not the deemed owner during construction nor was it a capital lease under ASC 840. As a result, in prior periods the Company accounted for the agreement as an operating lease under ASC 840 and recognized straight-line rent expense over the non-cancellable term of the embedded lease. As part of its adoption of ASC 842, effective January 1, 2019, the Company carried forward its existing lease classification under ASC 840. Additionally, the Company recorded a right-of-use asset and lease liability for this operating lease on the effective date and is recognizing rent expense on a straight-line basis throughout the remaining term of the embedded lease.

The Company's other embedded leases are not material to the condensed consolidated financial statements.

60 Binney Street Lease

On September 21, 2015, the Company entered into a lease agreement for office and laboratory space located in a building (the "Building") at 60 Binney Street, Cambridge, Massachusetts (the "60 Binney Street Lease"), which is now the Company's corporate headquarters. Under the terms of the 60 Binney Street Lease, starting on October 1, 2016, the Company leases approximately 253,108 square feet of office and laboratory space at $72.50 per square foot per year, or $18.4 million per year in base rent, which is subject to scheduled annual rent increases of 1.75% plus certain

operating expenses and taxes. The Company currently maintains a $13.8 million collateralized letter of credit and, subject to the terms of the lease and certain reduction requirements specified therein, including market capitalization requirements, this amount may decrease to $9.2 million over time. Pursuant to a work letter entered into in connection with the 60 Binney Street Lease, the landlord contributed an aggregate of $42.4 million toward the cost of construction and tenant improvements for the Building.

The Company has occupied the Building beginning on March 27, 2017 and the 60 Binney Street Lease will continue until March 31, 2027. The Company has the option to extend the 60 Binney Street Lease for two successive five-year terms. The Company is accounting for this lease under ASC 842 using its initial 10-year term through March 31, 2027 and will reassess the lease term on a quarterly basis.

Due to the Company’s involvement in the construction project, including having responsibility to pay for a portion of the costs of finish work and mechanical, electrical, and plumbing elements of the Building, among other items, the Company was deemed for accounting purposes to be the owner of the Building during the construction period, per ASC 840. Accordingly, under ASC 840, construction costs that were incurred by the landlord directly or indirectly through reimbursement to the Company as part of its tenant improvement allowance were recorded as an asset in Property, plant and equipment, net on the Company’s consolidated balance sheets.

The Company evaluated the 60 Binney Street Lease upon occupancy on March 27, 2017 and determined that the 60 Binney Street Lease did not meet the criteria for “sale-leaseback” treatment under ASC 840. This determination was based on, among other things, the Company's continuing involvement with the property in the form of non-recourse financing to the lessor. Accordingly, upon occupancy, the Company commenced depreciating the portion of the building in service over a useful life of 40 years and incurred interest expense related to the financing obligation.

As part of its adoption of ASC 842, the Company de-recognized the building asset and corresponding financing obligation recorded on the Company's consolidated balance sheets as of December 31, 2018, in accordance with the ASC 842 transition guidance. In applying the ASC 842 transition guidance, the Company classified this lease as an operating lease and recorded a right-of-use asset of $127.3 million and lease liability of $125.8 million on the effective date. The Company is recognizing rent expense on a straight-line basis throughout the remaining term of the lease.

Summary of all lease costs recognized under ASC 842

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the three months ended March 31, 2019:

Operating leases (in thousands)	For the three months ended March 31, 2019
Lease cost (1)	
Operating lease cost	$ 8,483
Total lease cost	$ 8,483
Other information	
Operating cash flows used for operating leases	$ 7,946
Weighted average remaining lease term	7.7 years
Weighted average discount rate	6.64 %

(1) Short-term lease costs and variable lease costs incurred by the Company for the three months ended March 31, 2019 were immaterial.

As of March 31, 2019, future minimum commitments under ASC 842 under the Company's operating leases were as follows:

Maturity of lease liabilities (in thousands)	As of March 31, 2019
2019 (excluding the three months ended March 31, 2019)	$21,286

2020	32,093
2021	32,480
2022	27,632
2023	28,033
2024 and thereafter	98,151
Total lease payments	239,675
Less: imputed interest	(53,909)
Total operating lease liabilities	$185,766

The above table excludes $18.0 million of legally binding minimum lease payments for leases executed but not yet commenced as of March 31, 2019. Please refer to Note 14, “Subsequent events” for discussion of a sublease agreement which was executed in April 2019.

8. Commitments and contingencies

Contingent consideration related to business combinations

On June 30, 2014, the Company acquired Pregenen. The Company may be required to make up to $120.0 million in remaining future contingent cash payments to the former equityholders of Pregenen upon the achievement of certain clinical and commercial milestones related to the Pregenen technology, of which $20.1 million relates to clinical milestones and $99.9 million relates to commercial milestones. In accordance with accounting guidance for business combinations, contingent consideration liabilities are required to be recognized on the 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. Please refer to Note 4, “Fair value measurements” for additional information.

Other funding commitments

The Company is party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met at March 31, 2019 and December 31, 2018 or royalties on future sales of specified products, which includes the collaboration agreement entered into with Regeneron Pharmaceuticals, Inc. (“Regeneron”) in August 2018. 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. Please refer to Note 9, “Collaborative arrangements,” for further information on the collaboration agreement with Regeneron.

We may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with our 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, such contingencies are recorded in the Company’s financial statements.

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. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

9. Collaborative arrangements

To date, the Company’s collaboration revenue has been exclusively generated from its collaboration arrangements with Celgene Corporation and Regeneron, each as further described below.

Celgene

Celgene Original Collaboration Agreement

On March 19, 2013, the Company entered into a Master Collaboration Agreement (the "Celgene Collaboration Agreement") with Celgene to discover, develop and commercialize potentially disease-altering gene therapies in oncology. The collaboration is focused on applying gene therapy technology to genetically modify a patient's own T cells, known as chimeric antigen receptor, or CAR T cells, to target and destroy cancer cells. Additionally, on March 19, 2013, the Company entered into a Platform Technology Sublicense Agreement (the "Sublicense Agreement") with Celgene pursuant to which the Company obtained a sublicense to certain intellectual property from Celgene, originating under Celgene's license from Baylor College of Medicine, for use in the collaboration.

Under the terms of the Celgene Collaboration Agreement, the Company received a $75.0 million up-front, non-refundable cash payment. The Company was responsible for conducting discovery, research and development activities through completion of phase 1 clinical studies, if any, during the initial term of the Celgene Collaboration Agreement, or three years. The collaboration is governed by a joint steering committee ("JSC") formed by an equal number of representatives from the Company and Celgene. The JSC, among other activities, reviews the collaboration program, reviews and evaluates product candidates and approves regulatory plans. In addition to the JSC, the Celgene Collaboration Agreement provides that the Company and Celgene each appoint representatives to a patent committee, which is responsible for managing the intellectual property developed and used during the collaboration.

Celgene Amended Collaboration Agreement

On June 3, 2015, the Company and Celgene amended and restated the Celgene Collaboration Agreement (the "Amended Celgene Collaboration Agreement"). Under the Amended Celgene Collaboration Agreement, the parties narrowed the focus of the collaboration to exclusively work on anti- B-cell maturation antigen ("BCMA") product candidates for a new three-year term that ended in June 2018. In connection with the Amended Celgene Collaboration Agreement, the Company received an up-front, one-time, non-refundable, non-creditable payment of $25.0 million to fund research and development under the collaboration. The collaboration is governed by the JSC. Under the terms of the Amended Celgene Collaboration Agreement, for up to two product candidates selected for development under the collaboration, the Company was responsible for conducting and funding all research and development activities performed up through completion of the initial phase 1 clinical study of such product candidates.

On a product candidate-by-product candidate basis, up through a specified period following enrollment of the first patient in an initial phase 1 clinical study for such product candidate (the "Option Period"), the Company had granted Celgene an option to obtain an exclusive worldwide license to develop and commercialize such product. Following Celgene's license of each product candidate, the Company is entitled to elect to co-develop and co-promote each product candidate in the U.S.

Celgene Ide-cel License Agreement

On February 10, 2016, Celgene exercised its option to obtain an exclusive worldwide license to develop and commercialize ide-cel, the first product candidate under the Amended Celgene Collaboration Agreement, pursuant to an executed license agreement ("Ide-cel License Agreement") entered into by the parties on February 16, 2016 and paid to the Company the associated $10.0 million option fee. Pursuant to the Ide-cel License Agreement, Celgene was responsible for development and related funding of ide-cel after the substantial completion of the phase 1 clinical trial. The Company was responsible for the manufacture of vector and associated payload throughout development and upon Celgene's request, throughout commercialization, the costs of which were reimbursable by Celgene in accordance with the terms of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement, as further described below. Celgene was responsible for the manufacture of drug product throughout development and commercialization.

Celgene Ide-cel Co-Development, Co-Promote and Profit Share Agreement

On March 28, 2018, the Company elected to co-develop and co-promote ide-cel within the U.S. pursuant to the execution of the Amended and Restated Co-Development, Co-Promote and Profit Share Agreement ("Ide-cel CCPS"), which replaced the Ide-cel License Agreement. The responsibilities of the parties remain unchanged from those under the Ide-cel License Agreement, however, the Company will share equally in all profits and losses relating to developing, commercializing and manufacturing ide-cel within the U.S. and has the right to participate in the development and promotion of ide-cel in the U.S. Celgene is responsible for the costs incurred to manufacture vector and associated payload for use outside of the U.S., plus a markup. Under the Ide-cel CCPS, the Company may receive up to $70.0 million in development milestone payments for the first indication to be addressed by ide-cel, with the ability to obtain additional milestone payments for a second indication and modified licensed products. In addition, to the extent ide-cel is commercialized, the Company is entitled to receive tiered royalty payments ranging from the mid-single digits to low-teens based on a percentage of net sales generated outside of the U.S., subject to certain reductions.

Celgene bb21217 License Agreement

On September 22, 2017, Celgene exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, the second product candidate under the Amended Celgene Collaboration Agreement, pursuant to an executed license agreement ("bb21217 License Agreement") entered into by the parties on September 28, 2017 and paid the Company an option fee of $15.0 million. Pursuant to the bb21217 License Agreement, Celgene is responsible for development and related funding of bb21217 after the substantial completion of the on-going phase 1 clinical trial. The Company is responsible for the manufacture of vector and associated payload throughout development and upon Celgene's request, throughout commercialization. Expenses incurred by the Company associated with these activities are fully reimbursable by Celgene at cost plus a mark-up. Throughout both development and commercialization, Celgene is responsible for the manufacture of drug product.

The Company currently expects it will exercise its option to co-develop and co-promote bb21217 within the U.S. The Company's election to co-develop and co-promote bb21217 must be made by the substantial completion of 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 U.S. and to have the right to participate in the development and promotion of bb21217 in the U.S. Celgene would be responsible for the costs incurred to manufacture vector and associated payload for use outside of the U.S., plus a markup. Under this scenario, the Company expects to receive, per product, up to $70.0 million in development milestone payments for the first indication to be addressed by the bb21217 product candidate, with the ability to obtain additional milestone payments for a second indication and modified licensed products. In addition, to the extent bb21217 is commercialized, the Company would be entitled to receive tiered royalty payments ranging from the mid-single digits to low-teens based on a percentage of net sales generated outside of the U.S., subject to certain reductions.

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 may be eligible to receive up to $10.0 million in clinical milestone payments, up to $117.0 million in regulatory milestone payments, and up to $78.0 million in commercial milestone payments. In addition, to the extent bb21217 is commercialized, the Company would be entitled to receive tiered royalty payments ranging from the mid-single digits to low-teens based on a percentage of net sales, subject to certain reductions.

Accounting Analysis – Ide-cel

ASC Topic 606, Revenue From Contracts With Customers ("Topic 606"), allows entities to reflect the aggregate effect of all contract modifications when identifying the satisfied and unsatisfied performance obligations for contracts that were modified prior to Topic 606 adoption. Celgene's option to in-license the first product candidate, ide-cel, under the arrangement was considered a material right at the time the Amended Celgene Collaboration Agreement was executed in June 2015 given the product candidate had been formally nominated by the JSC and that substantially all investigational new drug application, or IND, enabling activities had been completed by that time. In making this determination, the Company also considered the option price relative to the value of the underlying license. Celgene's exercise of this material right in February 2016 was determined to represent a contract modification and represents the last contract modification prior to the adoption of Topic 606. As a result, the Celgene Collaboration Agreement, Amended Celgene Collaboration Agreement, and Ide-cel CCPS are combined for accounting purposes and treated as a single arrangement. As of February 2016, Celgene's option to license an additional product candidate under the collaboration did not represent a material right due primarily to the significant uncertainty regarding whether any additional product candidates would be identified under the Amended Celgene Collaboration Agreement. Therefore, the license to the Company's second product candidate, bb21217, which was executed in September 2017, is accounted for as a separate contract. Refer below for discussion of the bb21217 accounting analysis.

As of the February 2016 contract modification date, the Company concluded the arrangement contained the following promised goods and services: (i) research and development services, (ii) a license to ide-cel, and (iii) manufacture of vectors and associated payload for incorporation into ide-cel through development. The Company determined that the manufacture of commercial vector represents an option to acquire additional goods and services that is not representative of a material right. In addition, at that time Celgene had not exercised its option to purchase any commercial vector. Accordingly, the manufacture of commercial vector is not considered to be a performance obligation at this time.

The Company concluded that the research and development services are distinct from the other promised goods and services under the arrangement given that Celgene can benefit from the research and development services on their own and such services are distinct within the context of the contract. Thus, such services are considered to be a separate performance obligation. The Company concluded that the license to ide-cel is not distinct from the vector manufacturing services because the manufacturing is essential to the use of the license. Accordingly, these two promised goods and services are considered a single combined performance obligation.

Ide-cel transaction price

The following tables summarize the total transaction price, the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of March 31, 2019:

(in thousands)

	Ide-cel transaction price as of March 31, 2019
Up-front non-refundable payment - Celgene Collaboration Agreement	$ 75,000
Up-front non-refundable payment - Amended Celgene Collaboration Agreement	25,000
Ide-cel license fee - Ide-cel License Agreement	10,000
Estimated variable consideration	84,664
	$ 194,664

(in thousands)	Allocation of transaction price to performance obligations	Transaction price unsatisfied as of March 31, 2019
Ide-cel research and development services	$ 38,438	$ —
Ide-cel license and manufacturing services	156,226	32,821
	$ 194,664	$ 32,821

The estimated variable consideration of $84.7 million relates to the estimated reimbursement from Celgene for the manufacture of vectors and associated payload through development. The total transaction price has been allocated to the performance obligations identified based on a relative standalone selling price ("SSP") basis. The Company estimated the SSP of the license after considering potential future cash flows under the license. The Company then discounted these probability-weighted cash flows to their present value. The Company estimated the SSP of each of the research and development services and manufacturing services to be provided based on the Company's estimated cost of providing the services plus an applicable profit margin commensurate with observable market data for similar services.

All of the clinical and regulatory milestones are fully constrained and are 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 clinical trials, the licensee's efforts, or the receipt of regulatory approval. Any consideration related to 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 Celgene and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur. The Company re-evaluates the transaction price, including its estimated variable consideration included in the transaction price and all constrained amounts, at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Ide-cel research and development services

The Company allocated $38.4 million of the transaction price to the research and development services. The Company satisfied this performance obligation as the research and development services were performed. The Company determined that the period of performance of the research and development services was three years through projected initial phase 1 clinical study substantial completion, or through May 2018. The Company recognized revenue related to research and development services performed using an input method by calculating costs incurred at each period end relative to total costs expected to be incurred. Although the Company fully satisfied this performance obligation during the second quarter of 2018, any changes to the total transaction price following the completion of this performance obligation in May 2018 will be allocated to the performance obligations under the arrangement based on a relative SSP basis and therefore the allocation of any changes to the total transaction price may impact the revenue recognized for this performance obligation in the period of change.

The following table summarizes the revenue recognized, or revenue adjustment recorded, related to the ide-cel research and development services for the three months ended March 31, 2019 and 2018:

	For the three months ended March 31,	
(in thousands)	2019	2018
Ide-cel research and development services revenue (revenue adjustment)	$(209)	$2,183
	$(209)	$2,183

Ide-cel license and manufacturing services

The Company allocated $156.2 million of the transaction price to the combined unit of accounting which consists of the license and manufacture of vectors and associated payload for incorporation into ide-cel.

The Company accounts for its vector manufacturing services for development in the U.S. and Celgene's U.S. development efforts 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 collaboration revenue for its U.S. manufacturing services by analogy to Topic 606. The portion of Celgene's U.S. development costs that the Company is responsible for are recognized as a reduction to its collaboration revenues, or, if in excess of such revenues in a given quarter, the excess is recorded as research and development expense.

Revenue recognition for the combined unit of accounting commenced during the first quarter of 2017. The Company recognizes revenue associated with the combined unit of accounting using the proportional performance method, as the Company will satisfy this performance obligation as the manufacturing services are performed through development. In using this method, the Company estimated its development plan for ide-cel, including expected demand from Celgene, and the costs associated with the manufacture of vectors and associated payload for incorporation into ide-cel. On a quarterly basis, the Company determines the proportion of effort incurred as a percentage of total effort it expects to expend. This ratio is applied to the transaction price, which includes variable consideration, allocated to the combined performance obligation consisting of the ide-cel license and manufacturing services. Management has applied significant judgment in the process of developing its budget estimates and any changes to these estimates will be recognized in the period in which they change as a cumulative catch up.

The following table summarizes the net collaboration revenue recognized or expense incurred related to the combined performance obligation for the license and vector manufacturing of ide-cel in the U.S. for the three months ended March 31, 2019, and 2018:

Ide-cel license and manufacturing services - U.S.	For the three months ended March 31,	
(in thousands)	2019	2018
ASC 808 ide-cel license and manufacturing revenue - U.S. (1)	$—	$3,761
ASC 808 ide-cel license and manufacturing research and development expense - U.S. (1)	$(3,244)	$—

(1) As noted above, the calculation of collaboration revenue or research and development expense to be recognized for the Company's combined performance obligation for its license and vector manufacturing of ide-cel in the U.S. 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.

Revenue related to the combined unit of accounting for the non-US license and vector manufacturing services is accounted for in accordance with Topic 606. The following table summarizes the revenue recognized related to the combined unit of accounting for the ide-cel non-US license and vector manufacturing services for the three months ended March 31, 2019, and 2018:

Ide-cel license and manufacturing services - outside of U.S.	For the three months ended March 31,	
(in thousands)	2019	2018
ASC 606 license and manufacturing revenue - outside of U.S.	$9,064	$8,942

As of March 31, 2019, the aggregate amount of the transaction price allocated to the combined performance obligation, which consists of the ide-cel license and manufacturing services, that is unsatisfied, or partially unsatisfied, is $32.8 million, which the Company expects to recognize as revenue as manufacturing services are provided through the remaining development period which is estimated to be through 2020. As of March 31, 2019 and December 31,

2018, the Company had $15.0 million and $23.0 million, respectively, of deferred revenue associated with the combined performance obligation consisting of the ide-cel license and manufacturing services.

Accounting Analysis – bb21217

On September 22, 2017, Celgene exercised its option to obtain an exclusive worldwide license to develop and commercialize bb21217, the second optioned product candidate, pursuant to the bb21217 License Agreement entered into by the parties on September 28, 2017. The bb21217 License Agreement is considered a separate contract for accounting purposes as the option to obtain an exclusive worldwide license to develop and commercialize bb21217, or any other product candidate, was not considered a material right to Celgene at the time the practical expedient was applied. The Company made this evaluation after considering the significant uncertainty at that time regarding whether any additional product candidates would be identified under the Amended Celgene Collaboration Agreement. In particular, the Company considered that bb21217 had not been formally nominated as a product candidate under the collaboration at that time, primarily due to a lack of pre-clinical data as well as uncertainty surrounding the ability to successfully complete various IND-enabling activities.

At contract inception, the Company concluded that the arrangement contained the following promised goods and services: (i) research and development services, (ii) a license to the second product candidate, bb21217, and (iii) manufacture of vectors and associated payload for incorporation into bb21217 through development. The Company determined that the manufacture of commercial vector represents an option to acquire additional goods and services that is not representative of a material right. In addition, at this time Celgene has not exercised its option to purchase any commercial vector. Accordingly, the manufacture of commercial vector is not considered to be a performance obligation at this time.

The Company concluded that the research and development services are distinct from the other promised goods and services under the arrangement given that Celgene can benefit from the research and development services on their own and such services are distinct within the context of the contract. Thus, such services are considered to be a separate performance obligation. Similar to ide-cel, the Company concluded that the license to bb21217 is not distinct from the vector manufacturing services because the manufacturing is essential to the use of the license. Accordingly, these two promised goods and services are considered a single combined performance obligation.

bb21217 transaction price

The following tables summarize the total transaction price, the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of March 31, 2019:

(in thousands)	bb21217 transaction price as of March 31, 2019
bb21217 license fee - bb21217 License Agreement	$ 15,000
Estimated variable consideration	26,687
	$ 41,687

(in thousands)	Allocation of transaction price to performance obligations	Transaction price unsatisfied as of March 31, 2019
bb21217 research and development services	$ 5,444	$ 1,118
bb21217 license and manufacturing services	36,243	36,243
	$ 41,687	$ 37,361

The estimated variable consideration of $26.7 million relates to reimbursement from Celgene for the manufacturing services during development. The total transaction price has been allocated to the performance obligations identified based on a relative SSP basis. The Company estimated the SSP of the license after considering potential future cash flows under the license. The Company then discounted these probability-weighted cash flows to their present value. The Company estimated the SSP of each of the research and development services and manufacturing services to be provided based on the Company's estimated cost of providing the services plus an applicable profit margin commensurate with observable market data for similar services.

All of the clinical and regulatory milestones are fully constrained and are 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 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 Celgene and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur. The Company re-evaluates the transaction price, including its 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.

bb21217 research and development services

The Company allocated $5.4 million of the transaction price to the research and development services. The Company will satisfy this performance obligation as the research and development services are performed. The Company determined that the period of performance of the research and development services was two years through projected initial phase 1 clinical study substantial completion, or through September 2019. The Company recognizes revenue related to research and development services performed using an input method by calculating costs incurred at each period end relative to total costs expected to be incurred.

The following table summarizes the revenue recognized related to the bb21217 research and development services for the three months ended March 31, 2019, and 2018:

	For the three months ended March 31,	
(in thousands)	2019	2018
bb21217 research and development services revenue	$721	$721
	$721	$721

As of March 31, 2019, and December 31, 2018, the aggregate amount of the transaction price allocated to the bb21217 research and development services performance obligation that are unsatisfied, or partially unsatisfied, and deferred is $1.1 million and $1.8 million, respectively, which the Company expects to recognize through September 2019 as research and development services are performed.

bb21217 license and manufacturing services

The Company will satisfy its performance obligation related to the manufacture of vectors and associated payload for incorporation into bb21217 through development as the bb21217 manufacturing services are performed. As of March 31, 2019, the manufacturing services for bb21217 had not yet commenced. Therefore, no amounts have been recognized for the combined performance obligation in the consolidate statement of operations for the three months ended March 31, 2019, and 2018.

The aggregate amount of the transaction price allocated to the combined performance obligation, which consists of the bb21217 license and manufacturing services, is $36.2 million. The Company does not expect that recognition will begin in the next twelve months and has therefore classified deferred revenue associated with the combined performance obligation as deferred revenue, net of current portion on its consolidated balance sheet. The Company had $9.8 million of remaining deferred revenue as of March 31, 2019 and December 31, 2018 associated with the combined performance obligation consisting of the bb21217 license and manufacturing services.

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 Celgene receivables and contract liabilities during the three months ended March 31, 2019:

(in thousands)	Balance at beginning of period	Additions	Deductions