Edgar Filing: bluebird bio, Inc. - Form 10-Q

bluebird bio, Inc. Form 10-Q May 03, 2019 !		
UNITED STATES		
SECURITIES AND EXCHANGE CO	MMISSION	
Washington, DC 20549		
FORM 10-Q		
(Mark One)		
QUARTERLY REPORT PURSUANT 1934 For the quarterly period ended March		(d) OF THE SECURITIES EXCHANGE ACT OF
OR		
TRANSITION REPORT PURSUANT 1934 For the transition period from	to	(d) OF THE SECURITIES EXCHANGE ACT OF
Commission File Number: 001-35966		
bluebird bio, Inc.		
(Exact Name of Registrant as Specifie	d in Its Charter)	
Dela (Stat	ware e or Other Jurisdiction of	13-3680878 (IRS Employer
Inco	rporation or Organization)	Identification No.)

02142

60 Binney Street

Edgar Filing: bluebird bio, Inc. - Form 10-Q

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

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.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	2
Item 1.	Financial Statements (unaudited)	2
	Condensed Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018	2
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months	
	Ended March 31, 2019 and 2018	3
	Condensed Consolidated Statements of Stockholders' Equity for the Three Months Ended March 31,	
	2019 and 2018	4
	Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2019 and	
	<u>2018</u>	5
	Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Item 3.	Quantitative and Qualitative Disclosures About Market Risks	35
Item 4.	Controls and Procedures	35
PART II.	OTHER INFORMATION	36
Item 1.	<u>Legal Proceedings</u>	36
Item 1A.	Risk Factors	36
Item 2.	<u>Unregistered Sales of Equity Securities and Uses of Proceeds</u>	65
Item 3.	<u>Defaults Upon Senior Securities</u>	65
Item 4.	Mine Safety Disclosures	65
Item 5.	Other Information	65
Item 6.	<u>Exhibits</u>	65
SIGNAT	<u>URES</u>	69

CERTIFICATIONS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

bluebird bio, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except par value amounts)

	As of	As of
	March 31,	December 31,
	2019	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)		

Edgar Filing: bluebird bio, Inc. - Form 10-Q

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,			
θ θ θ			
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.

2

bluebird bio, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(in thousands, except per share data)

	For the three ended	ee months
	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 Shares	n stock Amount	Additional paid-in capital	Accumulat other comprehen loss	ed sive 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		<u>—</u>	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
	Commo Shares	Amount	Additional paid-in t capital	Accumula other compreher loss	ted nsiveAccumulated deficit	Total stockholders' equity
Balances at December 31, 2017	Shares		paid-in	other compreher	nsiveAccumulated deficit	stockholders'
Adjustment to beginning accumulated deficit from	Shares	Amount	paid-in t capital	other compreher loss	nsive Accumulated deficit) \$ (913,808	stockholders' equity \$1,623,432
Adjustment to beginning accumulated deficit from adoption of ASU 2014-09	Shares 49,406	Amount \$ 494	paid-in t capital \$2,540,951	other compreher loss \$ (4,205	nsiveAccumulated deficit	stockholders' equity
Adjustment to beginning accumulated deficit from	Shares	Amount	paid-in t capital	other compreher loss	nsive Accumulated deficit) \$ (913,808	stockholders' equity \$1,623,432
Adjustment to beginning accumulated deficit from adoption of ASU 2014-09 Vesting of restricted stock units Issuance of common stock upon public offering, net	Shares 49,406	Amount \$ 494	paid-in t capital \$2,540,951	other compreher loss \$ (4,205	nsive Accumulated deficit) \$ (913,808	stockholders' equity \$1,623,432
Adjustment to beginning accumulated deficit from adoption of ASU 2014-09 Vesting of restricted stock units Issuance of common stock upon public	Shares 49,406 — 74	Amount \$ 494	paid-in t capital \$2,540,951	other compreher loss \$ (4,205	nsive Accumulated deficit) \$ (913,808	stockholders' equity) \$ 1,623,432
Adjustment to beginning accumulated deficit from adoption of ASU 2014-09 Vesting of restricted stock units Issuance of common stock upon public offering, net of issuance costs of \$2,563	Shares 49,406 74	Amount \$ 494	paid-in t capital \$2,540,951 — (1	other compreher loss \$ (4,205	nsive Accumulated deficit) \$ (913,808	stockholders' equity \$ 1,623,432 (29,375) 48,701