bluebird bio, Inc.

Form 10-Q November 12, 2014
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q
(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended September 30, 2014
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 (IRS Employer

Incorporation or Organization) Identification No.)

150 Second Street

Cambridge, Massachusetts 02141 (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 x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes x No "

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

Large accelerated filer "

Accelerated filer

Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company "Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

As of November 6, 2014, there were 28,822,524 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these 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 manufacturing and transduction capabilities;
- ·the timing or likelihood of regulatory filings and approvals;
- ·the 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;
- •the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- ·estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- ·our financial performance;
- ·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.

Form 10-Q

For the Three and Nine Months Ended September 30, 2014

TABLE OF CONTENTS

		Page
PART I. FINA	NCIAL INFORMATION	2
Item 1.	Financial Statements (unaudited)	2
	Condensed Consolidated Balance Sheets as of September 30, 2014 and December 31,	
	<u>2013</u>	2
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the three	
	and nine months ended September 30, 2014 and 2013	3
	Condensed Consolidated Statements of Cash Flows for the nine months ended September	
	30, 2014 and 2013	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	28
Item 4.	Controls and Procedures	29
PART II. OTH	IER INFORMATION	30
Item 1.	Legal Proceedings	30
Item 1A.	Risk Factors	30
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	57
Item 5.	Other Information	57
Item 6.	Exhibits	57

SIGNATURES

CERTIFICATIONS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

bluebird bio, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except par value amounts)

	September 30,	December 31,
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	\$89,603	\$206,279
Marketable securities	125,771	
Deferred tax assets	3,106	693
Prepaid expenses and other current assets	4,840	5,015
Total current assets	223,320	211,987
Marketable securities	48,446	_
Property and equipment, net	14,978	10,920
Intangible assets, net	29,159	_
Goodwill	13,128	
Restricted cash and other non-current assets	1,162	1,483
Total assets	\$330,193	\$224,390
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$3,641	\$4,359
Accrued expenses and other current liabilities	9,677	5,175
Deferred revenue, current portion	25,206	25,340
Total current liabilities	38,524	34,874
Deferred rent, net of current portion	8,724	6,740
Deferred revenue, net of current portion	11,458	30,208
Contingent consideration, net of current portion	6,166	_
Deferred tax liabilities	3,106	693
Other non-current liabilities	323	208
Total liabilities	68,301	72,723
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized;	_	_

0 shares issued and outstanding at September 30, 2014

and December 31, 2013

and December 31, 2013		
Common stock, \$0.01 par value, 125,000 shares authorized;		
28,702 and 23,940 shares issued and outstanding at September 30, 2014		
and December 31, 2013, respectively	287	239
Additional paid-in capital	389,519	250,103
Accumulated other comprehensive loss	(74)	_
Accumulated deficit	(127,840)	(98,675)
Total stockholders' equity	261,892	151,667
Total liabilities and stockholders' equity	\$330,193	\$224,390

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)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Revenue:				
Collaboration revenue	\$6,250	\$6,251	\$18,750	\$13,542
Research and license fees	115	134	285	304
Total revenue	6,365	6,385	19,035	13,846
Operating expenses:				
Research and development	16,649	8,706	42,043	21,237
General and administrative	6,648	3,836	17,924	9,441
Change in fair value of contingent consideration	78		78	
Total operating expenses	23,375	12,542	60,045	30,678
Loss from operations	(17,010)	(6,157)	(41,010)	(16,832)
Other income (expense), net	(20)	44		