

REGENXBIO Inc.  
Form 10-Q  
November 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

Commission File Number 001-37553

REGENXBIO Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	47-1851754
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)

9600 Blackwell Road, Suite 210

Rockville, MD	20850
(Address of principal executive offices)	(Zip Code)

(240) 552-8181

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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 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 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.

Large accelerated filer

Accelerated filer

Non-accelerated filer (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

As of November 4, 2016, there were 26,475,379 outstanding shares of the registrant's common stock, \$0.0001 par value per share.

REGENXBIO INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2016

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## INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek” the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, assumptions and other important factors, including those described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 3, 2016. In light of these risks, uncertainties, assumptions and other factors, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q or our Annual Report on Form 10-K may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Forward-looking statements include, but are not limited to, statements about:

- the timing of enrollment, commencement and completion of our clinical trials;
- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the scope, progress, expansion and costs of developing and commercializing our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates and technology;
- our anticipated growth strategies;
- our expectations regarding competition;
- the anticipated trends and challenges in our business and the market in which we operate;
- our ability to attract or retain key personnel;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- the rate and degree of market acceptance of any of our product candidates;
- our ability to establish and maintain development partnerships;
- our expectations regarding our expenses and revenue;
- our expectations regarding regulatory developments in the United States and foreign countries; and
- the use or sufficiency of our cash and cash equivalents and needs for additional financing.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. All of our development timelines could be subject to adjustment depending on recruitment rates, regulatory agency review, and other factors that could delay the initiation and completion of our clinical trials. Any forward-looking statement made by us in this Quarterly Report on Form 10-Q speaks only as of the date of this report. Except as required by law, we disclaim any duty to update any of these forward-looking statements after the date such statements are made, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

We encourage you to read the discussion and analysis of our financial condition and our financial statements contained in this Quarterly Report on Form 10-Q. We also encourage you to read Item 1A of Part II this Quarterly Report on Form 10-Q, entitled “Risk Factors,” which contains a more complete discussion of the risks and uncertainties

associated with our business. In addition to the risks described above and in Item 1A of Part II of this Quarterly Report on Form 10-Q, other unknown or unpredictable factors also could affect our results. There can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Therefore no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements.

## REGENXBIO INC.

## BALANCE SHEETS

(unaudited)

(in thousands, except per share data)

	September 30, 2016	December 31, 2015
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 28,108	\$ 54,116
Marketable securities	63,662	60,025
Accounts receivable	679	2,136
Prepaid expenses	2,171	1,020
Other current assets	2,000	851
Total current assets	96,620	118,148
Marketable securities	93,087	102,226
Property and equipment, net	5,804	538
Cost method investments	—	300
Restricted cash	225	—
Other assets	239	168
Total assets	\$ 195,975	\$ 221,380
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 5,376	\$ 1,014
Accrued expenses and other current liabilities	9,006	3,198
Advance payments	—	127
Total current liabilities	14,382	4,339
Deferred rent, net of current portion	1,367	233
Total liabilities	15,749	4,572
<b>Commitments and contingencies (Note 6)</b>		
<b>Stockholders' equity</b>		
Preferred stock; \$0.0001 par value; 10,000 shares authorized, and no shares issued		
and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock; \$0.0001 par value; 100,000 shares authorized at September 30, 2016		
and December 31, 2015; 26,475 and 26,313 shares issued and outstanding at		
September 30, 2016 and December 31, 2015, respectively	3	3
Additional paid-in capital	274,349	269,144
Accumulated other comprehensive income (loss)	853	(719 )
Accumulated deficit	(94,979 )	(51,620 )

Total stockholders' equity	180,226	216,808
Total liabilities and stockholders' equity	\$ 195,975	\$ 221,380

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

REGENXBIO INC.

## STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except per share data)

	Three Months		Nine Months Ended	
	Ended September 30, 2016	2015	September 30, 2016	2015
<b>Revenues</b>				
License revenue	\$65	\$65	\$2,638	\$635
License revenue from related party	—	1,000	—	2,000
Reagent sales	47	61	213	200
Grant revenue	13	14	42	305
Total revenues	125	1,140	2,893	3,140
<b>Expenses</b>				
<b>Costs of revenues</b>				
Licensing costs (including amounts to related parties)	13	213	528	527
Costs of reagent sales (including amounts to related parties)	22	44	101	94
Research and development (including amounts to related parties)	12,560	5,664	29,423	12,471
General and administrative (including amounts to related parties)	6,200	2,567	17,848	7,671
Other operating expenses (income)	(2 )	(1 )	(136 )	15
Total operating expenses	18,793	8,487	47,764	20,778
Loss from operations	(18,668)	(7,347)	(44,871)	(17,638)
<b>Other Income (Expense)</b>				
Investment income	514	15	1,512	23
Interest expense	—	—	—	(20 )
Total other income (expense)	514	15	1,512	3
Net loss	\$(18,154)	\$(7,332)	\$(43,359)	\$(17,635)
<b>Other Comprehensive Income (Loss)</b>				
Unrealized gain (loss) on available-for-sale securities	332	(26 )	1,572	(26 )
Total other comprehensive income (loss)	332	(26 )	1,572	(26 )
Comprehensive loss	\$(17,822)	\$(7,358)	\$(41,787)	\$(17,661)
<b>Reconciliation of net loss to net loss applicable to common stockholders</b>				
Net loss	\$(18,154)	\$(7,332)	\$(43,359)	\$(17,635)
Net accretion and dividends on convertible preferred stock	—	—	—	(1,747 )
Net gain on extinguishment of convertible preferred stock	—	—	—	759
Net loss applicable to common stockholders	\$(18,154)	\$(7,332)	\$(43,359)	\$(18,623)
Basic and diluted net loss per common share	\$(0.69 )	\$(1.52 )	\$(1.64 )	\$(5.48 )
Weighted-average basic and diluted common shares	26,469	4,809	26,386	3,397



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

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REGENXBIO INC.

## STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	\$(43,359)	\$(17,635)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	5,031	2,059
Net amortization of premiums and accretion of discounts on marketable debt securities	1,502	1
Depreciation and amortization	264	43
Realized gains on sales of marketable securities	(20 )	—
Unrealized foreign currency transaction gains	(2 )	(4 )
Imputed interest on related party promissory notes	—	13
Changes in operating assets and liabilities		
Accounts receivable	1,459	1,277
Prepaid expenses	(1,151 )	(1,372 )
Other current assets	(1,149 )	(127 )
Other assets	(71 )	(128 )
Accounts payable	3,595	317
Accrued expenses and other current liabilities	4,591	758
Due to related party under services agreement	—	(34 )
Other related party payables	—	(3,412 )
Advance payments	(127 )	(26 )
Deferred rent	1,302	198
Net cash used in operating activities	(28,135)	(18,072)
Cash flows from investing activities		
Restricted cash	(225 )	—
Purchases of marketable securities	(32,262)	(19,065)
Maturities of marketable securities	38,131	—
Sales of marketable securities	23	—
Purchases of property and equipment	(3,714 )	(394 )
Net cash provided by (used in) investing activities	1,953	(19,459)
Cash flows from financing activities		
Proceeds from exercise of stock options	174	100