

# ELEVEN BIOTHERAPEUTICS, INC.

## FORM 10-Q (Quarterly Report)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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(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, 2017

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 No. 001-36296

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**Eleven Biotherapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**26-2025616**

(I.R.S. Employer  
Identification No.)

**245 First Street, Suite 1800  
Cambridge, MA**

(Address of principal executive offices)

**02142**

(Zip code)

**Registrant's telephone number, including area code: (617) 444-8550**

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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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company)

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

Number of outstanding shares of Common Stock as of April 30, 2017 : 24,700,746

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## 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 strategy, future operations, future product research or development, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “goals,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our expected future loss and accumulated deficit levels;
- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues, capital requirements and needs for, and ability to obtain, additional financing;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operations;
- the success, cost and timing of our pre-clinical studies and clinical trials in the United States, Canada and in other foreign jurisdictions;
- the potential enrollment challenges to our Phase 3 clinical trial of Vicinium due to anticipated shortages of Bacillus Calmette-Guérin, or BCG;
- the potential that results of pre-clinical studies and clinical trials indicate our product candidates are unsafe or ineffective;
- our dependence on third parties, including contract research organizations, or CROs, in the conduct of our pre-clinical studies and clinical trials;
- the difficulties and expenses associated with obtaining and maintaining regulatory approval of our product candidates and companion diagnostics, if any, in the United States, Canada and in other foreign jurisdictions, and the labeling under any approval we may obtain;
- our plans and ability to develop and commercialize our product candidates;
- our ability to achieve certain future regulatory, development and commercialization milestones under our license agreement, which we refer to as the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche;
- market acceptance of our product candidates, the size and growth of the potential markets for our product candidates, and our ability to serve those markets;
- obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology;
- the successful development of our commercialization capabilities, including sales and marketing capabilities; and
- the success of competing therapies and products that are or become available.

Our product candidates are investigational biologics undergoing clinical development and have not been approved by the U.S. Food and Drug Administration, or FDA, Health Canada, or the European Commission, or submitted to the FDA, Health Canada or the European Medicines Agency, or EMA, as part of the approval process. Our product candidates have not been, nor may they ever be, approved by any regulatory agency or competent authorities nor marketed anywhere in the world.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and our stockholders should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements

**ELEVEN BIOTRAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	March 31, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 20,268	\$ 25,342
Prepaid expenses and other current assets	712	585
Total current assets	20,980	25,927
Property and equipment, net	714	796
Restricted cash	10	10
Intangible assets	60,500	60,500
Goodwill	16,864	16,864
Total assets	\$ 99,068	\$ 104,097
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,214	\$ 1,667
Accrued expenses	1,897	1,774
Deferred revenue	—	425
Due to related party	115	114
Total current liabilities	3,226	3,980
Warrant liability	2	5
Deferred tax liability	16,335	16,335
Contingent consideration	46,600	45,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at March 31, 2017 and December 31, 2016 and no shares issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock, \$0.001 par value per share; 200,000,000 shares authorized at March 31, 2017 and December 31, 2016 and 24,683,026 and 24,531,964 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	162,243	161,963
Accumulated deficit	(129,363)	(123,311)
Total stockholders' equity	32,905	38,677
Total liabilities and stockholders' equity	\$ 99,068	\$ 104,097

See accompanying notes.

**ELEVEN BIOTHERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(unaudited)**  
**(in thousands, except per share data)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2017</b>	<b>2016</b>
Revenue:		
Collaboration revenue	\$ —	\$ 229
License revenue	425	—
Total revenue	425	229
Operating expenses:		
Research and development	2,874	4,632
General and administrative	2,213	2,147
Loss from change in fair value of contingent consideration	1,500	—
Total operating expenses	6,587	6,779
Loss from operations	(6,162)	(6,550)
Other income (expense):		
Other income, net	101	138
Loss on extinguishment of debt	—	(915)
Interest expense	—	(247)
Total other income (expense), net	101	(1,024)
Net loss and comprehensive loss	\$ (6,061)	\$ (7,574)
Net loss per share — basic and diluted	\$ (0.25)	\$ (0.39)
Weighted-average number of common shares used in net loss per share — basic and diluted	24,610	19,639

*See accompanying notes.*

**ELEVEN BIOTHERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Operating activities</b>		
Net loss	\$ (6,061)	\$ (7,574)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	82	54
Non-cash interest expense	—	26
Stock-based compensation expense	244	586
Change in fair value of warrant liability	(3)	(115)
Loss from change in fair value of contingent consideration	1,500	—
Loss on extinguishment of debt	—	221
Gain on sale of equipment	(76)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(127)	(162)
Restricted cash	—	(80)
Accounts payable	(453)	342
Accrued expenses and other liabilities	123	(1,645)
Deferred revenue	(425)	(203)
Due to related party	1	—
Net cash used in operating activities	(5,195)	(8,550)
<b>Investing activities</b>		
Sales of property and equipment	76	—
Net cash provided by investing activities	76	—
<b>Financing activities</b>		
Payments on notes payable	—	(14,124)
Proceeds from exercise of common stock options	40	14
Proceeds from sale of common stock pursuant to ESPP	5	—
Net cash provided by (used in) financing activities	45	(14,110)
Net decrease in cash and cash equivalents	(5,074)	(22,660)
Cash and cash equivalents at beginning of period	25,342	36,079
Cash and cash equivalents at end of period	\$ 20,268	\$ 13,419
<b>Supplemental cash flow information</b>		
Cash paid for interest	\$ —	\$ 663

*See accompanying notes.*

**ELEVEN BIOTHERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**1. Organization and Basis of Presentation**

Eleven Biotherapeutics, Inc. (the "Company"), a Delaware corporation formed on February 25, 2008, is a biologics oncology company focused primarily on designing, engineering and developing targeted protein therapeutics ("TPTs"). The Company's TPTs are single protein therapeutics composed of targeting moieties genetically fused via linker domains to cytotoxic protein payloads that are produced through the Company's proprietary one-step manufacturing process. The Company targets tumor cell surface antigens that allow for rapid internalization into the targeted cancer cell and have limited expression on normal cells. The Company has designed its TPTs to overcome the fundamental efficacy and safety challenges inherent in existing antibody drug conjugates ("ADCs"), where a payload is chemically attached to a targeting antibody.

***Basis of presentation***

The condensed consolidated balance sheet as of March 31, 2017, and the condensed consolidated statements of operations and comprehensive loss and cash flows for the three months ended March 31, 2017 and 2016, are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position as of March 31, 2017 and its results of operations and cash flows for the three months ended March 31, 2017 and 2016. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three -month periods are also unaudited. The results of operations for the three months ended March 31, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 or for any other future annual or interim period. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 that was filed with the Securities and Exchange Commission ("SEC") on March 24, 2017 (the "2016 Form 10-K").

The condensed consolidated financial statements include the accounts of Eleven Biotherapeutics, Inc., its wholly owned subsidiary, Viventia Bio Inc. ("Viventia"), and its indirect subsidiaries, Viventia Bio USA Inc. and Viventia Biotech (EU) Limited. All inter-company transactions and balances have been eliminated in consolidation. The condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles.

The functional currency of Viventia Bio Inc., Viventia Bio USA Inc. and Viventia Biotech (EU) Limited is the U.S. dollar. Consolidated balance sheet accounts of the Company's subsidiaries are translated into U.S. dollars using the exchange rate in effect at the consolidated balance sheet date while expenses are translated using the average exchange rate in effect during the period. Gains and losses arising from translation of the wholly owned subsidiaries' financial statements are included in the determination of net income (loss).

***Liquidity***

The Company has financed its operations to date primarily through debt and equity offerings and collaboration and licensing arrangements. As of March 31, 2017, the Company had cash and cash equivalents totaling \$ 20.3 million, net working capital of \$ 17.8 million and an accumulated deficit of \$ 129.4 million.

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The successful discovery and development of product candidates requires substantial working capital which may not be available to the Company on favorable terms.

To date, the Company has no revenue from product sales and management expects continuing operating losses in the future. As of March 31, 2017, the Company had available cash and cash equivalents of \$ 20.3 million, which it believes is not sufficient to fund the Company's current operating plan through May 4, 2018. Management expects to seek additional funds through equity or debt financings or through additional collaboration or licensing transactions. The Company may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions and, if necessary, the Company will be required to implement cost reduction strategies. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed

consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

## 2. Significant Accounting Policies and Recent Accounting Pronouncements

### *Recently adopted accounting standards*

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 requires companies to classify all deferred tax assets and liabilities as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The Company adopted, prospectively, ASU 2015-07 as of January 1, 2017. The adoption of ASU 2015-17 did not have an impact on the Company's financial statements as the deferred tax liability was classified as noncurrent on the balance sheet as of December 31, 2016.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company adopted ASU 2016-09 as of January 1, 2017 and elected an accounting policy to record forfeitures as they occur. The impact of this change in accounting policy has been recorded as an \$9,000 cumulative effect adjustment to accumulated deficit, as of January 1, 2017. ASU 2016-09 also provides that companies no longer record excess tax benefits or certain tax deficiencies in additional paid-in capital. Instead, all excess tax benefits and tax deficiencies are recorded as income tax expense or benefit in the statement of operations and comprehensive loss. There was no financial statement impact of adopting this provision of ASU 2016-09 as the Company is currently in a net operating loss position and the excess tax benefits that existed from options previously exercised had a full valuation allowance. The effects of adopting the remaining provisions in ASU 2016-09 affecting the classification of awards as either equity or liabilities when an entity partially settles the award in cash in excess of the employer's minimum statutory withholding requirements and classification in the statement of cash flows did not have a significant impact on the Company's financial position, results of operations or cash flows.

There have been no other material changes to the significant accounting policies and recent accounting pronouncements previously disclosed in the 2016 Form 10-K.

## 3. Fair Value of Financial Instruments

The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The following table presents information about the Company's financial assets and liabilities that have been measured at fair value, and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value. The Company determines the fair value of the common stock warrants and contingent consideration using Level 3 inputs.

The following table summarizes the assets and liabilities measured at fair value on a recurring basis at March 31, 2017 (in thousands):

Description	March 31, 2017	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash and cash equivalents	\$ 20,268	\$ 20,268	\$ —	\$ —
Restricted cash	10	10	—	—
Total assets	\$ 20,278	\$ 20,278	\$ —	\$ —
<b>Liabilities:</b>				
Warrant liability	\$ 2	\$ —	\$ —	\$ 2
Contingent consideration	46,600	—	—	46,600
Total liabilities	\$ 46,602	\$ —	\$ —	\$ 46,602

The following table summarizes the assets and liabilities measured at fair value on a recurring basis at December 31, 2016 (in thousands):

Description	December 31, 2016	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash and cash equivalents	\$ 25,342	\$ 25,342	\$ —	\$ —
Restricted cash	10	10	—	—
Total assets	\$ 25,352	\$ 25,352	\$ —	\$ —
<b>Liabilities:</b>				
Warrant liability	\$ 5	\$ —	\$ —	\$ 5
Contingent consideration	45,100	—	—	45,100
Total liabilities	\$ 45,105	\$ —	\$ —	\$ 45,105

### Warrant Liability

The Company measures the fair value of the warrants classified as a liability at each reporting date using the Black-Scholes option pricing model using the following assumptions:

	March 31, 2017	December 31, 2016
Risk-free interest rate	0.95%	0.85%
Expected dividend yield	—%	—%
Expected term (in years)	0.67	0.92
Expected volatility	81.42%	83.39%

The following table sets forth a summary of changes in the fair value of the Company's common stock warrant liability, which represented a recurring measurement classified within Level 3 of the fair value hierarchy, wherein fair value was estimated using significant unobservable inputs (in thousands):

Beginning balance, January 1, 2017	\$ 5
Change in fair value	(3)
Ending balance, March 31, 2017	\$ 2

The change in the fair value of the warrant liability is influenced primarily by the price of the underlying common stock. The change in fair value of \$ (3,000) and \$ (115,000) was recorded as other income in the accompanying condensed statements of operations and comprehensive loss for the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, none of the common stock warrants had been exercised.

### **Contingent consideration**

In connection with the acquisition of Viventia, the Company recorded contingent consideration pertaining to the amounts potentially payable to Viventia's shareholders pursuant to the terms of the share purchase agreement. 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 consolidated statements of operations and comprehensive loss.

Contingent consideration may change significantly as development progresses and additional data are obtained, impacting the Company's assumptions regarding probabilities of successful achievement of related milestones used to estimate the fair value of the liability and the timing in which they are expected to be achieved. In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques could result in materially different fair value estimates. The following table sets forth a summary of changes in the fair value of the Company's contingent consideration liability, which represented a recurring measurement classified within Level 3 of the fair value hierarchy, wherein fair value was estimated using significant unobservable inputs (in thousands):

Beginning balance, January 1, 2017	\$	45,100
Loss from change in fair value of contingent consideration		1,500
Ending balance, March 31, 2017	\$	46,600

The preliminary fair value of the Company's contingent consideration was determined using probabilities of successful achievement of regulatory milestones and commercial sales, the period in which these milestones and sales are expected to be achieved ranging from 2019 to 2033, the level of commercial sales of Vicinium, and discount rates ranging from 9.3% to 11.5% as of December 31, 2016 and 9.2% to 10.4% as of March 31, 2017. Significant changes in any of these assumptions would result in a significantly higher or lower fair value measurement.

There have been no changes to the valuation methods utilized during the three months ended March 31, 2017. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three months ended March 31, 2017.

#### **4. License Agreement with Roche**

The Company has determined that the License Agreement with Roche contains four units of accounting. The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in Accounting Standards Codification ("ASC") Topic 605-25, *Revenue Recognition-Multiple-Element Arrangements* ("ASC 605-25") are satisfied for that particular unit of accounting. As of March 31, 2017, the basic revenue recognition criteria has been met for all units of accounting. Accordingly, the Company recognized \$0.4 million in revenue related to the License Agreement for the three months ended March 31, 2017 allocated to the transfer of pre-clinical inventory.

The Company determined that the milestone payments under the License Agreement were not subject to ASC Topic 605-28 because the achievement of the milestone event depends solely on Roche's performance. The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

#### **5. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<b>March 31, 2017</b>	<b>December 31, 2016</b>
Development costs	\$ 1,308	\$ 852
Employee compensation	318	352
Professional fees	178	413
Other	93	157
	<u>1,897</u>	<u>\$ 1,774</u>

## 6. Share-Based Payments

Pursuant to the terms of the Company's 2014 Stock Incentive Plan (the "2014 Plan"), the number of shares authorized for issuance automatically increases on the first day of each fiscal year. On January 1, 2017, the number of shares reserved for issuance under the 2014 Plan increased by 982,164 shares. As of March 31, 2017, the total number of shares of common stock available for issuance under the 2014 Plan was 2,237,354.

The Company also maintains the Eleven Biotherapeutics, Inc. 2009 Stock Incentive Plan, as amended and restated.

### *Stock-Based Compensation Expense*

Stock-based compensation expense by award type was as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Stock options	\$ 187	\$ 435
Restricted stock	51	54
Restricted stock units	3	92
Employee stock purchase plan	3	5
	<u>\$ 244</u>	<u>\$ 586</u>

The Company allocated stock-based compensation expense as follows in the consolidated statements of operations and comprehensive loss (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Research and development expense	\$ 40	\$ 221
General and administrative expense	204	365
	<u>\$ 244</u>	<u>\$ 586</u>

At March 31, 2017, there was \$1.8 million of total unrecognized compensation expense related to unvested stock options, unvested restricted stock, and shares issued pursuant to the Company's 2014 Employee Stock Purchase Plan (the "2014 ESPP"). This unrecognized compensation expense is expected to be recognized over a weighted-average period of 2.88 years.

### *Stock Options*

A summary of the stock option activity is presented below:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2016	2,024,468	\$ 4.41
Granted	—	—
Exercised	(140,400)	0.28
Cancelled or forfeited	(166,887)	9.85
Outstanding at March 31, 2017	<u>1,717,181</u>	\$ 4.22
Exercisable at March 31, 2017	<u>863,767</u>	\$ 4.93
Vested and expected to vest at March 31, 2017 <sup>(1)</sup>	<u>1,717,181</u>	\$ 4.22

<sup>(1)</sup>Represents the number of vested options, plus the number of unvested options expected to vest. The Company adopted ASU 2016-09 as of January 1, 2017 and elected an accounting policy to record forfeitures as they occur.

### **Restricted Stock**

From time to time, upon approval by the Board, certain employees, directors and advisors have been granted restricted shares of common stock. A summary of the restricted stock is presented below:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2016	22,150	\$ 11.43
Vested	(4,430)	11.43
Unvested at March 31, 2017	<u>17,720</u>	\$ 11.43

### **Restricted Stock Units**

From time to time, upon approval by the Board, certain employees have been granted restricted stock units. A summary of the restricted stock units is presented below:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2016	3,333	\$ 4.09
Vested	(3,333)	4.09
Unvested at March 31, 2017	<u>—</u>	\$ —

### **Employee Stock Purchase Plan**

On March 14, 2017, the Company issued and sold 2,899 shares of its common stock pursuant to the 2014 ESPP at a purchase price of \$1.71 per share. The Company has estimated the number of shares to be issued at the end of the current offering period and recognizes expense over the requisite service period.

## **7. Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock, restricted stock units and common stock warrants are considered to be common stock equivalents.

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect or the exercise prices were greater than the average market price of the common shares.

	Three Months Ended March 31,	
	2017	2016
Stock options	1,717,181	2,420,804
Unvested restricted stock	17,720	35,440
Restricted stock units	—	147,598
Common stock warrants	926,840	926,840
	<u>2,661,741</u>	<u>3,530,682</u>

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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2016 included in our Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K which are incorporated herein by reference, our actual results could differ materially from the results described in or implied by the forward-looking statements.*

### Overview

We are a biologics oncology company primarily focused on designing, engineering and developing targeted protein therapeutics, or TPT's. Our TPT's are single-protein therapeutics composed of targeting moieties genetically fused via linker domains to cytotoxic protein payloads that are produced through our proprietary one-step manufacturing process. We target tumor cell surface antigens that allow for rapid internalization into the targeted cancer cell and have limited expression on normal cells. We have designed our TPTs to overcome the fundamental efficacy and safety challenges inherent in existing antibody drug conjugates, or ADCs, where a payload is chemically attached to a targeting antibody.

Our most advanced product candidate is Vicinium™, which is a locally-administered TPT. In the third quarter of 2015, we, through our recently acquired subsidiary Viventia, commenced in the United States and Canada a Phase 3 clinical trial of Vicinium for the treatment of subjects with high-grade non-muscle invasive bladder cancer, or NMIBC. Our second most advanced product candidate is Proxinium™, a locally-administered TPT intended for the treatment of EpCAM positive squamous cell carcinoma of the head and neck, or SCCHN. A Phase 1/2a clinical trial will explore the potential of Proxinium in combination with a checkpoint inhibitor for the treatment of SCCHN and is planned to commence enrollment in the second half of 2017. We are also developing cancer therapies for systemic administration utilizing our TPT platform and our proprietary de-immunized variant of the plant-derived cytotoxin bouganin, or deBouganin. We may explore additional therapeutic indications for Vicinium and Proxinium.

Our locally-administered TPTs contain a targeting moiety that is designed to bind to epithelial cell adhesion molecule, or EpCAM, which is a protein over expressed in many cancers. This targeting moiety is genetically fused to a truncated form of exotoxin A, or ETA, which is an immunogenic cytotoxic protein payload that is produced by the bacterial species, Pseudomonas. These product candidates are designed to bind to EpCAM on the surface of cancer cells. The TPT-EpCAM complex is subsequently internalized into the cell and, once inside the cell, the TPT is cleaved by a cellular enzyme to release the cytotoxic protein payload, thus enabling cancer cell-killing. We believe that our TPTs designed for local administration may not only directly kill cancer cells through a targeted delivery of a cytotoxic protein payload, but also potentiate an anti-cancer therapeutic immune response in cancer cells near the site of administration. This immune response is believed to be triggered by both the immunogenic cell death of the cancer cells due to our payloads' mechanism of action and the subsequent release of tumor antigens and the immunologically active setting created by the nature of the cytotoxic protein payloads. Our early pipeline product candidate, VB6-845d, is being developed for systemic administration as a treatment for multiple types of EpCAM-positive solid tumors. VB6-845d is a TPT consisting of an EpCAM targeting fragment antigen binding domains genetically linked to deBouganin, a novel plant derived cytotoxic payload that we have optimized for minimal immunogenic potential.

We were incorporated and commenced active operations in early 2008, and our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking pre-clinical studies and conducting clinical trials. To date, we have financed our operations primarily through debt and equity offerings and collaboration and licensing arrangements. We have devoted substantially all of our financial resources and efforts to research and development activities. We have not completed development of any of our product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

#### ***License Agreement with Roche***

On June 10, 2016, we entered into the License Agreement with Roche. Under the License Agreement, we granted Roche an exclusive, worldwide license to develop and commercialize, at its cost, our monoclonal antibody EBI-031 and all other IL-6 antagonist antibody technology owned by us.

Roche paid an upfront license fee of \$7.5 million and a development milestone payment of \$22.5 million as a result of the investigational new drug, or IND, application for EBI-031 becoming effective. Roche has also agreed to pay up to an additional \$240.0 million upon the achievement of specified regulatory, development and commercial milestones. In addition, we are entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

#### ***Liquidity***

Since inception, we have incurred significant operating losses and expect to continue to incur operating losses for the foreseeable future. We had a net loss of \$6.1 million for the three months ended March 31, 2017. As of March 31, 2017, we had an accumulated deficit of \$129.4 million.

We do not know when, or if, we will generate any revenue from the sale of our product candidates as we seek regulatory approval for, and potentially begin to commercialize, any of our product candidates. We anticipate that we will continue to incur losses for the next several years and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks common to the development of new products and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Until we can generate substantial revenue from commercial sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing shareholders will be diluted and the terms may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds when needed we may be required to delay, limit, reduce or terminate our development or commercialization efforts or grant rights to develop and market our technologies that we would otherwise prefer to develop and market ourselves.

Our future capital requirements will depend on many factors, including:

- the scope, initiation, progress, timing, costs and results of pre-clinical development and laboratory testing and clinical trials for our product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third party licensors under our licensing agreements;

- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, to require that we perform more studies or clinical trials than those that we currently expect;
- our ability to achieve certain future regulatory, development and commercialization milestones under the License Agreement with Roche;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval.

Accordingly, until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

We believe that our cash and cash equivalents of \$20.3 million as of March 31, 2017 will be sufficient to fund our current operating plan into early 2018; however, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

## **Financial Operations Overview**

### ***Revenue***

To date, we have not generated any revenue from the sale of products. Substantially all of our revenue to date has been derived from the License Agreement with Roche and, to a lesser extent, from our former collaboration with ThromboGenics N.V. We do not expect to generate significant product revenue unless and until we obtain marketing approval for and commercialize our product candidates.

Under the terms of the License Agreement with Roche, Roche paid an upfront license fee of \$7.5 million and a development milestone payment of \$22.5 million as a result of the IND application for EBI-031 becoming effective.

### ***Research and Development Expenses***

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

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies; and
- expenses associated with pre-clinical and regulatory activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

The successful development and commercialization of any product candidate is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;

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- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our product candidates;
- the cost and timing of the implementation of commercial-scale manufacturing of our product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation; and
- the timing, receipt and terms of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of any product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently contemplate will be required for the completion of clinical development of any product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and costs related to manufacturing or purchasing clinical trial materials, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for our Vicinium, EBI-031 and isunakinra product programs and other expenses by category. Based on negative results for our completed Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, we do not plan to pursue further development of isunakinra. Following the acquisition of Viventia, our research and development expenses for Vicinium, Proxinium and VB6-845d will materially increase during subsequent periods. We did not allocate research and development expenses to any other specific product program during the periods presented:

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Programs:		
Vicinium (1)	\$ 1,519	\$ —
Proxinium (1)	27	—
VB6-845d (1)	72	—
EBI-031 (2)	—	1,739
Isunakinra/EBI-005 (3)	—	1,322
Total direct program expenses	1,618	3,061
Personnel and other expenses:		
Employee and contractor-related expenses	855	1,184
Platform-related lab expenses	127	137
Facility expenses	91	147
Other expenses	183	103
Total personnel and other expenses	1,256	1,571
Total research and development expenses	\$ 2,874	\$ 4,632

(1) Our development activities for Vicinium, Proxinium and VB6-845d will increase significantly during subsequent periods.

(2) Beginning August 16, 2016, Roche is responsible for all development costs for EBI-031.

(3) Our development activities for isunakinra are no longer ongoing.

### General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation, in executive, operational, finance, business development and human resource functions. Other general and administrative expenses include facility-related costs and professional fees for legal, patent, consulting and accounting services.

### **Other Income (Expense), Net**

Other income (expense), net consists primarily of interest income earned on cash and cash equivalents, interest expense on outstanding debt, the gain or loss associated with the change in the fair value of our common stock warrant liability that is carried at fair value and the loss on extinguishment of debt.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our condensed consolidated financial statements. Management has determined that our most critical accounting policies are those relating to revenue recognition, accrued research and development expenses, stock-based compensation, fair value of warrants to purchase common stock, fair value of intangible assets and goodwill, income taxes including the valuation allowance for deferred tax assets, contingent consideration and going concern considerations.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. We adopted ASU 2016-09 as of January 1, 2017 and elected an accounting policy to record forfeitures as they occur. The impact of this change in accounting policy has been recorded as an \$9,000 cumulative effect adjustment to accumulated deficit, as of January 1, 2017. ASU 2016-09 also provides that companies no longer record excess tax benefits or certain tax deficiencies in additional paid-in capital. Instead, all excess tax benefits and tax deficiencies are recorded as income tax expense or benefit in the statement of operations and comprehensive loss. There was no financial statement impact of adopting this provision of ASU 2016-09 as we are currently in a net operating loss position and the excess tax benefits that existed from options previously exercised had a full valuation allowance. The effects of adopting the remaining provisions in ASU 2016-09 affecting the classification of awards as either equity or liabilities when an entity partially settles the award in cash in excess of the employer's minimum statutory withholding requirements and classification in the statement of cash flows did not have a significant impact on our financial position, results of operations or cash flows.

There have been no other significant changes to our critical accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2016, which we refer to as our 2016 Form 10-K.

### **Results of Operations**

#### **Comparison of the Three Months Ended March 31, 2017 and 2016**

	<b>Three Months Ended March 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>Change</b>
	<b>(in thousands)</b>		
<b>Revenue:</b>			
Collaboration revenue	\$ —	\$ 229	\$ (229)
License revenue	425	—	\$ 425
Total revenue	425	229	196
<b>Operating expenses:</b>			
Research and development	2,874	4,632	(1,758)
General and administrative	2,213	2,147	66
Loss from change in fair value of contingent consideration	1,500	—	1,500
Total operating expenses	6,587	6,779	(192)
Loss from operations	(6,162)	(6,550)	388
Other income (expense), net	101	(1,024)	1,125
Net loss and comprehensive loss	\$ (6,061)	\$ (7,574)	\$ 1,513

**Revenue** . Revenue was \$0.4 million for the three months ended March 31, 2017 compared to \$0.2 million for the three months ended March 31, 2016 . The increase was due to revenue recognized under the License Agreement with Roche partially offset by the reduction in collaboration revenue due to the termination of our collaboration with ThromboGenics.

**Research and development expenses** . Research and development expenses were \$2.9 million for the three months ended March 31, 2017 compared to \$4.6 million for the three months ended March 31, 2016 . The decrease of \$1.8 million was due primarily to a decrease of \$1.3 million of isunakinra-related development expenses, which development activities are no longer ongoing, as well as decreases in EBI-031 related development expenses of \$1.7 million due to the License Agreement with Roche. These decreases were partially offset by increases in Vicinium-related development expenses of \$1.5 million, which was acquired in connection with our acquisition of Viventia in September 2016. In addition, total personnel and other expenses were \$1.3 million for the three months ended March 31, 2017 compared to \$1.6 million for the three months ended March 31, 2016 .

**General and administrative expenses** . General and administrative expenses were \$2.2 million for the three months ended March 31, 2017 compared to \$2.1 million for the three months ended March 31, 2016 .

**Loss from change in fair value of contingent consideration** . The change in fair value of contingent consideration was \$1.5 million for the three months ended March 31, 2017 due to a decrease in the discount rate.

**Other income (expense), net** . Other income, net was \$0.1 million for the three months ended March 31, 2017 compared to other expense, net of \$1.0 million for the three months ended March 31, 2016 . The change of \$1.1 million was due primarily to the loss on extinguishment of debt recorded in 2016 associated with the prepayment of the loan with Silicon Valley Bank as well as the interest expense incurred until the loan was prepaid.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

Since inception, we have incurred significant operating losses and expect to continue to incur operating losses for the foreseeable future. To date, we have financed our operations primarily through debt and equity offerings and collaboration and licensing arrangements.

In June 2016, we entered into the License Agreement with Roche and received an up-front license fee of \$7.5 million and up to an additional \$262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to \$197.5 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of \$72.5 million in development milestones, \$50.0 million in regulatory milestones and \$75.0 million in commercialization milestones. We received the first development milestone payment of \$22.5 million as a result of the IND for EBI-031 becoming effective. In addition, we are entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and at up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

### **Cash Flows**

As of March 31, 2017 , we had cash and cash equivalents of \$20.3 million . Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

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

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (5,195)	\$ (8,550)
Investing activities	76	—
Financing activities	45	(14,110)
Net decrease in cash and cash equivalents	\$ (5,074)	\$ (22,660)

**Operating activities.** Net cash used in operating activities was \$5.2 million for the three months ended March 31, 2017 and consisted primarily of net loss of \$6.1 million , adjusted for non-cash items, including stock-based compensation expense of \$0.2 million , depreciation expense of \$0.1 million , change in fair value of contingent consideration of \$1.5 million , gain on sale of property and equipment of \$(0.1) million and a net change in operating assets and liabilities of \$(0.9) million .

Net cash used in operating activities was \$8.6 million for the three months ended March 31, 2016 , and consisted primarily of a net loss of \$7.6 million adjusted for non-cash items, including stock-based compensation expense of \$0.6 million , depreciation expense of \$0.1 million , a change of \$(0.1) million in the fair value of the warrant liability and a net change in operating assets and liabilities of \$(1.7) million .

**Investing activities** . Net cash provided by investing activities consisted of sales of property and equipment. For the three months ended March 31, 2017 , we had cash proceeds from the sale of property and equipment of \$0.1 million . There was no cash provided by investing activities for the three months ended March 31, 2016 .

**Financing activities** . Net cash provided by financing activities for the three months ended March 31, 2017 consisted of the proceeds from the exercise of stock options and the sale of common stock pursuant to our ESPP.

Net cash used in financing activities for the three months ended March 31, 2016 was \$14.1 million and consisted primarily of repayment of outstanding debt obligations. On March 1, 2016, we prepaid all outstanding amounts owed to Silicon Valley Bank and terminated the loan agreement.

### **Funding Requirements**

We will incur substantial expenses if and as we:

- continue our Phase 3 clinical trial for Vicinium and initiate our Phase 1/2a clinical trial for Proxinium;
- continue the research and pre-clinical and clinical development of our other product candidates;
- seek to discover and develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development;
- hire additional clinical, quality control, scientific and management personnel; and
- expand our operational, financial and management systems and personnel.

We believe that our cash and cash equivalents of \$20.3 million as of March 31, 2017 will be sufficient to fund our current operating plan into early 2018; however, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

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- the scope, initiation, progress, timing, costs and results of pre-clinical development and laboratory testing of our pre-clinical product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of the implementation of commercial-scale manufacturing activities;
- the costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our obligation to make milestone, royalty and other payments to third party licensors under our licensing agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities, including Health Canada, to require that we perform more studies than those that we currently expect;
- our ability to achieve certain future regulatory, development and commercialization milestones under the License Agreement with Roche;
- the effect of competing technological and market developments; and
- the revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approval.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than the amounts payable under the License Agreement with Roche. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

### ***Contractual Obligations and Commitments***

The disclosure of our contractual obligations and commitments is set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations and Commitments" in our 2016 Form 10-K.

During the three months ended March 31, 2017, there were no material changes from the contractual commitments and obligations previously disclosed in our 2016 Form 10-K.

### ***License Agreements***

The disclosure of our obligations under our license agreements is set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — License Agreements" in our 2016 Form 10-K.

During the three months ended March 31, 2017, there were no material changes to our obligations under our license agreements previously disclosed in our 2016 Form 10-K.

### **Off-balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission, or SEC.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

**Interest Rate Risk**

We are exposed to market risk related to changes in interest rates. As of March 31, 2017, we had cash and cash equivalents of \$ 20.3 million, primarily money market mutual funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

**Foreign Currency Risk**

As our functional currency is in U.S. Dollars, we face foreign exchange rate risk as a result of entering into transactions denominated in Canadian dollars. As a result, our primary foreign currency exposure is to fluctuations in the Canadian dollar relative to the U.S. dollar. A hypothetical 10% change in average foreign currency exchange rates during any of the preceding periods presented would not have a material effect on our net loss. Foreign exchange rates will continue to be a factor in the future periods as we continue to expand and grow our business.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2017. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Previously Identified Material Weaknesses**

As previously disclosed in our 2016 Annual Report on Form 10-K, management concluded that, as of December 31, 2016, our internal control over financial reporting was not effective based on the criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. For a discussion of the material weaknesses in internal control over financial reporting, please see “Controls and Procedures” in Part II, Item 9A of our 2016 Annual Report on Form 10-K.

**Remediation Status**

As more fully discussed in our 2016 Annual Report on Form 10-K, to remediate the material weaknesses referenced above, we have implemented or have plans to implement the remediation initiatives described in Part II, Item 9A of our 2016 Annual Report on Form 10-K and will continue to evaluate the remediation and plan to implement additional measures in the future.

**Changes in Internal Control Over Financial Reporting**

During the three months ended March 31, 2017, management continued to implement certain remediation initiatives discussed in Part II, Item 9A of our 2016 Annual Report on Form 10-K. However, there were no material changes to our internal control over financial reporting during the first quarter of 2017 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II—OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not currently subject to any material legal proceedings.

**Item 1A. Risk Factors**

In addition to the other information contained elsewhere in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in “Item 1A. Risk Factors” in our 2016 Form 10-K, which could materially affect our business, financial condition or future results. The risks described in our 2016 Form 10-K are not the only risks we face. Additional risks that we do not presently know or that we currently believe are immaterial could also materially and adversely affect any of our business, financial condition or future results. The stock price and trading volume of our common stock may decline due to these risks.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

We did not sell or issue any equity securities that were not registered under the Securities Act during the period covered by this Quarterly Report on Form 10-Q.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits**

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index immediately preceding such exhibits, and are incorporated herein by reference.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELEVEN BIOTHERAPEUTICS, INC.

By:

/s/ John J. McCabe

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**John J. McCabe**

**Chief Financial Officer (Principal Financial and Accounting Officer)**

May 4, 2017

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
10.1+	Amendment to Retention Letter Agreement, dated March 5, 2017, by and between Eleven Biotherapeutics, Inc. and John J. McCabe. Incorporated herein by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 6, 2017 (File No. 001-36296).
31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

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\* Filed herewith.

+ This exhibit is a compensatory plan or arrangement in which our executive officers or directors participate.

**Rule 13a-14(a) CERTIFICATION**

I, Stephen A. Hurly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Stephen A. Hurly

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**Stephen A. Hurly**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Dated: May 4, 2017

**Rule 13a-14(a) CERTIFICATION**

I, John J. McCabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ John J. McCabe

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**John J. McCabe**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

Dated: May 4, 2017

**CERTIFICATION PURSUANT TO 18 U.S.C. §1350**

In connection with the Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc. (the "Company") for the fiscal quarter ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen A. Hurly

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**Stephen A. Hurly**  
**President and Chief Executive Officer**  
**(Principal Executive Officer)**

Dated: May 4, 2017

/s/ John J. McCabe

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**John J. McCabe**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

Dated: May 4, 2017