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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, 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

Eleven Biotherapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	**26-2025616**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
245 First Street, Suite 1800 Cambridge, MA	**02142**
(Address of principal executive offices)	**(Zip code)**

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

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	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	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 November 15, 2017: 31,831,995

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ELEVEN BIOTHERAPEUTICS, INC.
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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 potential impairment of our goodwill and our indefinite-lived intangible assets;
- the effect of recent changes in our senior management team on our business;
- 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 or submitted for approval to the U.S. Food and Drug Administration, or FDA, Health Canada, or the European Commission. 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 BIOTHRAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share data)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 11,338	$ 25,342
Prepaid expenses and other current assets	770	585
Total current assets	12,108	25,927
Property and equipment, net	585	796
Restricted cash	10	10
Intangible assets	46,400	60,500
Goodwill	13,064	16,864
Other assets	101	—
Total assets	$ 72,268	$ 104,097
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,366	$ 1,667
Accrued expenses	2,915	1,774
Deferred revenue	—	425
Due to related party	123	114
Total current liabilities	4,404	3,980
Other liabilities	170	—
Warrant liability	—	5
Deferred tax liability	12,528	16,335
Contingent consideration	38,100	45,100
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at September 30, 2017 and December 31, 2016 and no shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at September 30, 2017 and December 31, 2016 and 24,698,135 and 24,531,964 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	162,825	161,963
Accumulated deficit	(145,784)	(123,311)
Total stockholders' equity	17,066	38,677
Total liabilities and stockholders' equity	$ 72,268	$ 104,097

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Collaboration revenue	$ —	$ —	$ —	$ 406
License revenue	—	28,650	425	28,750
Total revenue	—	28,650	425	29,156
Operating expenses:				
Research and development	3,619	2,754	9,402	10,684
General and administrative	1,631	6,366	6,085	11,984
Loss from change in fair value of contingent consideration	3,900	—	7,600	—
Total operating expenses	9,150	9,120	23,087	22,668
(Loss) income from operations	(9,150)	19,530	(22,662)	6,488
Other income (expense):				
Other income (expense), net	45	(43)	180	96
Loss on extinguishment of debt	—	—	—	(915)
Interest expense	—	—	—	(247)
Total other income (expense), net	45	(43)	180	(1,066)
Net (loss) income and comprehensive (loss) income	$ (9,105)	$ 19,487	$ (22,482)	$ 5,422
Net (loss) income per share — basic	$ (0.37)	$ 0.95	$ (0.91)	$ 0.27
Weighted-average number of common shares used in net (loss) income per share — basic	24,691	20,495	24,663	20,004
Net (loss) income per share — diluted	$ (0.37)	$ 0.91	$ (0.91)	$ 0.26
Weighted-average number of common shares used in net (loss) income per share — diluted	24,691	21,423	24,663	20,796

See accompanying notes.

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

	Nine Months Ended September 30,	
	2017	2016
Operating activities		
Net (loss) income	$ (22,482)	$ 5,422
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	221	111
Non-cash interest expense	—	26
Stock-based compensation expense	819	3,351
Change in fair value of warrant liability	(5)	(38)
Loss from change in fair value of contingent consideration	7,600	—
Loss on extinguishment of debt	—	221
Gain on sale of equipment	(94)	(14)
Changes in operating assets and liabilities, excluding impact of acquisition:		
Prepaid expenses and other assets	(285)	62
Restricted cash	—	(10)
Accounts payable	(301)	(648)
Accrued expenses and other liabilities	803	(1,189)
Deferred revenue	(425)	844
Due to related party	9	—
Net cash (used in) provided by operating activities	(14,140)	8,138
Investing activities		
Cash acquired in the acquisition	—	136
Sales of equipment	84	283
Net cash provided by investing activities	84	419
Financing activities		
Payments on notes payable	—	(14,124)
Proceeds from exercise of common stock options	40	204
Proceeds from sale of common stock pursuant to ESPP	12	—
Net cash provided by (used in) financing activities	52	(13,920)
Net decrease in cash and cash equivalents	(14,004)	(5,363)
Cash and cash equivalents at beginning of period	25,342	36,079
Cash and cash equivalents at end of period	$ 11,338	$ 30,716
Supplemental non-cash investing and financing activities		
Viventia Bio Inc. acquisition:		
Common stock issued in connection with the acquisition	$ —	$ 13,525
Fair value of assets acquired in the acquisition, excluding cash and cash equivalents	$ —	$ 48,568
Fair value of liabilities assumed in the acquisition	$ —	$ 13,279
Adjustment to fair value of assets acquired and liabilities assumed during provisional period (Note 4)	$ 14,600	$ —
Supplemental cash flow information		
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, 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 financial statements as of September 30, 2017 and for the three and nine months ended September 30, 2017 and 2016 and the related information contained within the notes to the condensed consolidated financial statements 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 September 30, 2017 and its results of operations for the three and nine months ended September 30, 2017 and 2016 and its cash flows for the nine months ended September 30, 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 and nine-month periods are also unaudited. The results of operations for the three and nine months ended September 30, 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.

Liquidity

The Company has financed its operations to date primarily through debt and equity offerings and collaboration and licensing arrangements. As of September 30, 2017, the Company had cash and cash equivalents totaling $11.3 million, net working capital of $7.7 million and an accumulated deficit of $145.8 million. In November 2017, the Company issued and sold 5,525,000 shares of its common stock, pre-funded warrants to purchase an aggregate of 4,475,000 shares of common stock and common warrants to purchase up to an aggregate of 10,000,000 shares of common stock for net proceeds of approximately $7.0 million, excluding any proceeds from the potential exercise of the pre-funded warrants and common warrants.

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 or not at all.

To date, the Company has no revenue from product sales and management expects continuing operating losses in the future. As of September 30, 2017, the Company had available cash and cash equivalents of $11.3 million, which it believes, together with the proceeds received in November 2017, is not sufficient to fund the Company's current operating plan for twelve months from the date of issuance of these financial statements. Management expects to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. 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 a $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.

Recently issued accounting standards

In May 2014, the FASB issued ASU No. 2014-09, codified as Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective on January 1, 2018 and earlier application is permitted only for annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. ASC 606 allows for either a full retrospective adoption, in which the standard is applied to all of the periods presented, or a modified retrospective application, in which the standard is applied to the most current period presented in the financial statements. The Company expects to adopt this standard using the modified retrospective approach. All of the revenue generated in the nine months ended September 30, 2017 is from the Company's license arrangement with Roche. It is expected that the evaluation of variable consideration, and in particular, milestone payments due from Roche will require further judgment to assess the timing of when to include them in the transaction price, which may result in earlier revenue recognition under ASC 606 compared to the current guidance. The Company is continuing to assess the potential impact that ASC 606 may have on its financial position and results of operations as it relates to this arrangement but based on its preliminary assessment does not expect the adoption of ASC 606 to have a material impact on its financial position and results of operations.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). This update clarifies the changes to terms or conditions of a share-based payment award that require an entity to apply modification accounting. ASU 2017-09 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. Early application is permitted and prospective application is required. The Company does not expect that the adoption of this guidance will 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 September 30, 2017 (in thousands):

Description	September 30, 2017	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 11,338	$ 11,338	$ —	$ —
Restricted cash	10	10	—	—
Total assets	$ 11,348	$ 11,348	$ —	$ —
Liabilities:				
Warrant liability	$ —	$ —	$ —	$ —
Contingent consideration	38,100	—	—	38,100
Total liabilities	$ 38,100	$ —	$ —	$ 38,100

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)
Assets:				
Cash and cash equivalents	$ 25,342	$ 25,342	$ —	$ —
Restricted cash	10	10	—	—
Total assets	$ 25,352	$ 25,352	$ —	$ —
Liabilities:				
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:

	September 30, 2017	December 31, 2016
Risk-free interest rate	0.96%	0.85%
Expected dividend yield	—%	—%
Expected term (in years)	0.17	0.92
Expected volatility	60.04%	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		(5)
Ending balance, September 30, 2017	$	—

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 $0 and $64,000 for the three months ended September 30, 2017 and 2016, respectively, and $(5,000) and $(38,000) for the nine months ended September 30, 2017 and 2016, respectively, was recorded as other income (expense) in the accompanying condensed consolidated statements of operations and comprehensive income (loss). As of September 30, 2017, none of the common stock warrants had been exercised.

Contingent consideration

In connection with the acquisition of Viventia (the "Acquisition"), 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 condensed consolidated statements of operations and comprehensive income (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
Provisional purchase price accounting adjustment (Note 4)		(14,600)
Loss from change in fair value of contingent consideration		7,600
Ending balance, September 30, 2017	$	38,100

The 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 2020 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 8.6% to 10.3% as of September 30, 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 and nine months ended September 30, 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 and nine months ended September 30, 2017.

4. Business Combination

The Company finalized its purchase accounting for the Acquisition during the third quarter of 2017. The Company has valued the acquired assets and liabilities based on their estimated fair values as of September 20, 2016 (the "Acquisition Date"). The fair values included in the condensed consolidated balance sheet as of September 30, 2017 are based on the best estimates of the Company.

The consideration for the Acquisition and the final allocation of the purchase consideration presented has been updated from the amounts previously disclosed to reflect new information related to facts and circumstances which existed as of the Acquisition Date. The changes in assumptions were primarily due to additional information gathered regarding the potential market for Vicinium outside of the U.S., which resulted in adjustments to the fair value of contingent consideration as of the acquisition date and the in-process research and development assets for Vicinium in the European Union ("E.U.") and the rest of world. The assumptions related to the U.S. market were not updated as sufficient information had previously been gathered to support this estimate. The update of these assumptions also had an effect on the discount rate and certain other valuation assumptions used to value the acquired assets due to an adjustment in the Company specific risk factors, which effected the in-process research and development assets for Vicinium in the U.S., E.U., and the rest of world. As a result of these changes, the Company updated (1) the fair value of the in-process research and development assets for Vicinium, which resulted in a reduction in the fair value of the in-process research and development asset for Vicinium in the rest of the world to a di minimus amount, (2) the fair value of the contingent consideration, and (3) the related deferred tax liability and goodwill.

The preliminary estimate of the purchase price and the final purchase price as of the Acquisition Date are reflected in the following table (in thousands):

	Preliminary Fair Value of Consideration*	Adjustment	Final Fair Value of Consideration
Shares Issued	$ 13,525	$ —	$ 13,525
Contingent Consideration	46,200	(14,600)	31,600
	$ 59,725	$ (14,600)	$ 45,125

*As presented in the Company's Form 10-K as of and for the year ended December 31, 2016.

The preliminary allocation of the purchase consideration and the final allocation of the purchase consideration as of the Acquisition Date are reflected in the following table (in thousands):

	Preliminary Allocation*	Adjustment	Final Allocation
Cash and cash equivalents	$ 136	$ —	$ 136
Prepaid expenses and other assets	1,162	—	1,162
Property and equipment	867	—	867
In-process research and development assets (all markets)	60,500	(14,100)	46,400
Goodwill	16,864	(3,800)	13,064
Accounts payable	(1,163)	—	(1,163)
Accrued expenses	(1,494)	(507)	(2,001)
Other liabilities	(812)	—	(812)
Deferred tax liability	(16,335)	3,807	(12,528)
	$ 59,725	$ (14,600)	$ 45,125

*As presented in the Company's Form 10-K as of and for the year ended December 31, 2016.

The revised fair values of indefinite-lived intangible assets, deferred tax liability and goodwill noted above did not have an impact on the Company's condensed consolidated statement of operations and comprehensive income (loss), as the effected assets are not amortized. The Company is required to revalue its contingent consideration at each balance sheet date. As such, changes in the fair value of contingent consideration since the Acquisition Date due to updated assumptions and estimates are recognized within the condensed consolidated statements of operations and comprehensive income (loss) (Note 3).

5. 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 September 30, 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 nine months ended September 30, 2017 allocated to the transfer of pre-clinical inventory. No revenue was recognized during the three months ended September 30, 2017.

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.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Development costs	$ 2,156	$ 852
Employee compensation (including reduction in workforce)	453	352
Professional fees	244	413
Other	62	157
	$ 2,915	$ 1,774

7. 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 September 30, 2017, the total number of shares of common stock available for issuance under the 2014 Plan was 1,989,329.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock options	$ 201	$ 1,932	$ 656	$ 2,825
Restricted stock	50	50	152	155
Restricted stock units	—	156	3	354
Employee stock purchase plan	2	6	8	17
	$ 253	$ 2,144	$ 819	$ 3,351

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research and development expense	$ 56	$ 971	$ 179	$ 1,417
General and administrative expense	197	1,173	$ 640	1,934
	$ 253	$ 2,144	$ 819	$ 3,351

At September 30, 2017, there was $1.6 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 2.59 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	248,025	1.85
Exercised	(140,400)	0.28
Cancelled or forfeited	(166,887)	9.85
Outstanding at September 30, 2017	1,965,206	$ 3.92
Exercisable at September 30, 2017	1,161,259	$ 4.51
Vested and expected to vest at September 30, 2017[1]	1,965,206	$ 3.92

[1] 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	(13,290)	11.43
Unvested at September 30, 2017	8,860	$ 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 September 30, 2017	—	$ —

Employee Stock Purchase Plan

On September 14, 2017, the Company issued and sold 6,249 shares of its common stock pursuant to the 2014 ESPP at a purchase price of $1.19 per share. 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.

8. Net (Loss) Income Per Share

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net (loss) income 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) income 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, using the treasury-stock method, were included in the calculation of diluted net (loss) income per share for the periods indicated.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock options	—	891,341	—	776,580
Unvested restricted stock	—	—	—	—
Restricted stock units	—	37,063	—	15,156
Common stock warrants	—	—	—	—
	—	928,404	—	791,736

The following common stock equivalents were excluded from the calculation of diluted net (loss) income 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Stock options	1,965,206	1,732,954	1,965,206	1,829,193
Unvested restricted stock	8,860	26,580	8,860	26,580
Common stock warrants	926,840	926,840	926,840	926,840
	2,900,906	2,686,374	2,900,906	2,782,613

9. Reduction in Workforce

On August 15, 2017, the Board approved a strategic restructuring of the Company to eliminate a portion of the Company's workforce in order to preserve the Company's resources. As of September 30, 2017, the Company estimated total restructuring costs of approximately $0.2 million, which included severance and benefits in accordance with the Company's severance benefit plan, all of which was recorded in the three months ended September 30, 2017.

The table below provides a roll-forward of the reduction in workforce liability (in thousands):

Balance as of January 1, 2017	$	31
Charges		188
Payments		(28)
Balance as of September 30, 2017	$	191

On September 22, 2017, the Company announced that it has completed the manufacturing of all Vicinium necessary for its ongoing Phase 3 registration trial in patients with non-muscle invasive bladder cancer ("NMIBC"), and for its Cooperative Research and Development Agreement with the National Cancer Institute. In conjunction with this achievement, the Company is ending its large-scale manufacturing activities and redirecting resources toward completing its Phase 3 trial and preparing for discussions with the U.S. Food and Drug Administration regarding, as appropriate, the submission of a Biologics License Application for Vicinium in patients with NMIBC. This change included the reduction in workforce discussed above.

10. Subsequent Event

On October 4, 2017, the Company granted 1,055,000 options at an exercise price of $1.59.

On November 1, 2017, the Company raised approximately $7.0 million of net proceeds from the sale of 5,525,000 units (each unit consisting of one share of common stock and one common warrant to purchase one share of common stock) and 4,475,000 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase one share of common stock) at a purchase price of $0.80 per unit and $0.79 per pre-funded unit. Each common warrant contained in a unit or a pre-funded unit has an exercise price of $0.80 per share and is exercisable

immediately and will expire five years from the date of issuance. Each pre-funded warrant contained in a pre-funded unit is exercisable for one share of common stock and the exercise price is $0.01 per share. The Company granted the underwriter an option to purchase up to 1,500,000 additional shares of common stock at a purchase price of $0.79 per share and/or common warrants to purchase up to an aggregate of 1,500,000 shares of common stock at a purchase price of $0.01 per common warrant with an exercise price of $0.80 per share, less underwriting discount and commissions. If the underwriters exercise this option in full, the Company will receive approximately $1.1 million of additional net proceeds. The underwriter can exercise this option at any time on or before December 1, 2017.

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 II, Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q and in Part I, Item IA, "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 focused primarily on designing, engineering and developing targeted protein therapeutics, or TPTs. Our TPTs 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 a completed Phase 2 clinical trial, of the 45 evaluable subjects treated with Vicinium, 40% achieved a complete response or no evidence of disease at three months while 16% remained disease-free for at least 18 months. In the third quarter of 2015, we, through our subsidiary, Viventia Bio Inc., or 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. We anticipate complete enrollment in this clinical trial in the first quarter of 2018 with topline three-month data in mid-2018 and topline twelve-month data in the second quarter of 2019. In June 2017, we entered into a Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute, or NCI, for the development of Vicinium in combination with AstraZeneca's immune checkpoint inhibitor, durvalumab, for the treatment of NMIBC. Under the terms of the CRADA, the NCI will conduct a Phase 1 clinical trial in subjects with high-grade NMIBC to evaluate the safety, efficacy and biological correlates of Vicinium in combination with durvalumab.

Our second most advanced product candidate is Proxinium™, a locally-administered TPT intended for the treatment of squamous cell carcinoma of the head and neck, or SCCHN. In our two Phase 1 clinical trials, 53% of evaluable subjects treated with Proxinium demonstrated antitumor activity with epithelial cell adhesion molecule, or EpCAM-expressing tumors as assessed by investigator's clinical measurements, the investigator's overall assessment including qualitative changes, and assessment of available radiologic data. In addition, three out of the four subjects with complete responses of injected tumors had regression or complete resolution of adjacent non injected lesions. In a Phase 2 clinical trial, we observed tumor shrinkage in 10 of the 14 evaluable subjects (71.4%). We intend to initiate a Phase 1/2a clinical trial that will explore the potential of Proxinium in combination with a checkpoint inhibitor for the treatment of SCCHN and is actively seeking partners for a combination program. In addition to our locally-administered TPTs, our pipeline also includes systemically-administered TPTs in development. Our systemically-administered TPTs are built around our proprietary de-immunized variant of the plant-derived cytotoxin bouganin, or deBouganin. Our lead systemically-administered product candidate, VB6-845d, is being developed for the treatment of multiple types of EpCAM-positive solid tumors. VB6-845d is administered by intravenous infusion. A Phase 1 clinical trial conducted with VB6-845, the prior version of VB6-845d, revealed no clinically relevant immune response to the deBouganin payload. We plan on submitting an Investigational New Drug application, or IND, with VB6-845d, once funding or a partner is secured for this program.

We have deferred further development of Proxinium and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium. We are also exploring collaboration agreements for Vicinium, Proxinium and VB6-845d.

We maintain global development, marketing and commercialization rights for all of our TPT-based product candidates. Upon regulatory approval for our product candidates, we will explore various commercialization strategies to market our products. If we obtain regulatory approval for Vicinium in high-grade NMIBC, we may build a North American specialty urology sales force to market the product or seek commercialization partners. If we obtain regulatory approval for our other product candidates, including Proxinium, we may seek partners with oncology expertise in order to maximize the commercial value of each asset or a portfolio of assets. We also own or exclusively license worldwide intellectual property rights for all of our TPT-based product candidates, covering our key patents with protection ranging from 2018 to 2036.

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 and Other Product Candidates

On June 10, 2016, we entered into a License Agreement, which we refer to as the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche, pursuant to which we licensed our monoclonal antibody EBI-031 and all other IL-6 antagonist antibody technology owned by us. Under the License Agreement, Roche is required to continue developing EBI-031 at its cost. At the time of the License Agreement, EBI-031, which was derived using our previous AMP-Rx platform, was in pre-clinical development as an intravitreal injection for diabetic macular edema and uveitis. We have received $30.0 million in payments from Roche pursuant to the License Agreement, including a $7.5 million upfront payment and a $22.5 million milestone payment as a result of the IND application for EBI-031 becoming effective. We are also entitled to receive up to an additional $240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as royalties based on net sales of potential future products containing EBI-031 or any other potential future products containing other IL-6 compounds.

We also previously invested a significant portion of our efforts and financial resources in the development of our product candidate isunakinra (EBI-005) for the treatment of subjects with dry eye disease and allergic conjunctivitis. Based on negative results from our completed Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, we do not plan to pursue further development of isunakinra.

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 $22.5 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of $145.8 million.

On November 1, 2017, we raised approximately $7.0 million of net proceeds from the sale of 5,525,000 units (each unit consisting of one share of common stock and one common warrant to purchase one share of common stock) and 4,475,000 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase one share of common stock) at a purchase price of $0.80 per unit and $0.79 per pre-funded unit, which we refer to as the November 2017 Financing. Each common warrant contained in a unit or pre-funded unit has an exercise price of $0.80 per share and is exercisable immediately and will expire five years from the date of issuance. Each pre-funded warrant contained in a pre-funded unit is exercisable for one share of common stock and the exercise price is $0.01 per share. These proceeds exclude any amounts that will be received from the exercise of pre-funded or common warrants, if any.

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 further 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 $11.3 million as of September 30, 2017, together with the $7.0 million of net proceeds received in November 2017, will be sufficient to fund our current operating plan into mid 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., or ThromboGenics. 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. We are also entitled to receive up to an additional $240.0 million upon the achievement of other specified regulatory, development and commercial milestones, as well as royalties based on net sales of potential future products containing EBI-031 or any other potential future products containing other IL-6 compounds. The next licensing milestone payment expected from Roche, if any, will be triggered upon commencement of a Phase 2 clinical trial.

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;
- 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, Proxinium, VB6-845d, 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 are no longer developing isunakinra. We have deferred further development of Proxinium and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium. Since the acquisition of Viventia, our research and development expenses have been related primarily to the development of Vicinium. We expect our research and development expenses for Vicinium will continue to 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 September 30,		Nine Months Ended September 30,	
	2017	2016*	2017	2016*
	(in thousands)			
Programs:				
Vicinium (1)	$ 2,133	$ 164	$ 5,252	$ 164
Proxinium (2)	—	—	27	—
VB6-845d (2)	—	—	88	—
EBI-031 (3)	—	230	—	2,982
Isunakinra/EBI-005 (4)	—	34	—	1,564
Total direct program expenses	2,133	428	5,367	4,710
Personnel and other expenses:				
Employee and contractor-related expenses	1,005	2,085	2,821	4,985
Platform-related lab expenses	111	45	402	284
Facility expenses	103	170	297	480
Other expenses	267	26	515	225
Total personnel and other expenses	1,486	2,326	4,035	5,974
Total research and development expenses	$ 3,619	$ 2,754	$ 9,402	$ 10,684

(1) We expect our development activities for Vicinium will increase significantly during subsequent periods.
(2) We have deferred further development of Proxinium and VB6-845d in order to focus our efforts and our resources on our ongoing development of Vicinium.
(3) Beginning August 16, 2016, Roche is responsible for all development costs for EBI-031.
(4) Our development activities for isunakinra are no longer ongoing.
* Includes Viventia related expenses since September 20, 2016.

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.

Changes in Fair Value of 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. The fair value of contingent consideration is assessed at each balance sheet date and changes, if any, to the fair value are recognized within the condensed consolidated statements of operations and comprehensive income (loss).

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.

Recently adopted accounting standards

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 a $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.

Recently issued accounting standards

In May 2014, the FASB issued ASU No. 2014-09, codified as Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("ASC 606"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The new standard will be effective on January 1, 2018 and earlier application is permitted only for annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. ASC 606 allows for either a full retrospective adoption, in which the standard is applied to all of the periods presented, or a modified retrospective application, in which the standard is applied to the most current period presented in the financial statements. We expect to adopt this standard using the modified retrospective approach. All of the revenue generated in the nine months ended September 30, 2017 is from our license arrangement with Roche. It is expected that the evaluation of variable consideration, and in particular, milestone payments due from Roche will require further judgment to assess the timing of when to include them in the transaction price, which may result in earlier revenue recognition under ASC 606 compared to the current guidance. We are continuing to assess the potential impact that ASC 606 may have on financial position and results of operations as it relates to this arrangement but based on our preliminary assessment we do not expect the adoption of ASC 606 to have a material impact on our financial position and results of operations.

In May 2017, the FASB issued ASU No. 2017-09, *Scope of Modification Accounting (Topic 718),* or ASU 2017-09, which amends the scope of modification accounting for share-based payment arrangements. ASU 2017-09 provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The new standard is effective for annual periods beginning after December 15, 2017 and interim periods within those years. Early adoption is permitted. We are currently evaluating the impact this update will have on our financial statements.

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 September 30, 2017 and 2016

	Three Months Ended September 30,		
	2017	2016	Change
	(in thousands)		
Revenue:			
License revenue	$ —	$ 28,650	$ (28,650)
Total revenue	—	28,650	(28,650)
Operating expenses:			
Research and development	3,619	2,754	865
General and administrative	1,631	6,366	(4,735)
Loss from change in fair value of contingent consideration	3,900	—	3,900
Total operating expenses	9,150	9,120	30
(Loss) income from operations	(9,150)	19,530	(28,680)
Other income (expense), net	45	(43)	88
Net (loss) income and comprehensive (loss) income	$ (9,105)	$ 19,487	$ (28,592)

Revenue. There was no revenue for the three months ended September 30, 2017 compared to $28.7 million for the three months ended September 30, 2016. In August 2016, we recognized the upfront license fee and the development milestone payment under the License Agreement with Roche, relating to the execution of the License Agreement and the successful submission of the IND application for EBI-031.

Research and development expenses. Research and development expenses were $3.6 million for the three months ended September 30, 2017 compared to $2.8 million for the three months ended September 30, 2016. The increase of $0.9 million was due primarily to increases in Vicinium-related development expenses of $2.0 million, which was acquired in connection with our acquisition of Viventia in September 2016. This increase was partially offset by a decrease in EBI-031 related development expenses of $0.2 million due to the License Agreement with Roche in which Roche is responsible for all on-going development expenses. In addition, total personnel and other expenses were $1.5 million for the three months ended September 30, 2017 compared to $2.3 million for the three months ended September 30, 2016.

General and administrative expenses. General and administrative expenses were $1.6 million for the three months ended September 30, 2017 compared to $6.4 million for the three months ended September 30, 2016. The decrease of $4.7 million was due primarily to a reduction in professional fees as well as salaries and related costs for personnel, including stock-based compensation. For the three months ended September 30, 2016, we had higher professional fees related to the License Agreement with Roche, our 2016 review of strategic alternatives and our acquisition of Viventia. In addition, for the three months ended September 30, 2016, we had higher severance costs related to our acquisition of Viventia.

Loss from change in fair value of contingent consideration. The change in fair value of contingent consideration was $3.9 million for the three months ended September 30, 2017 compared to $0 million for the three months ended September 30, 2016 was primarily due to updates in the projected revenue assumptions related to Vicinium.

Other income (expense), net. Other income, net was $45,000 for the three months ended September 30, 2017 compared to other expense, net of $43,000 for the three months ended September 30, 2016. The change of $88,000 was due to an increase in interest income in addition to a change in the fair value of the warrant liability.

Comparison of the Nine Months Ended September 30, 2017 and 2016

	Nine Months Ended September 30,		
	2017	2016	Change
	(in thousands)		
Revenue:			
Collaboration revenue	$ —	$ 406	$ (406)
License revenue	425	28,750	(28,325)
Total revenue	425	29,156	(28,731)
Operating expenses:			
Research and development	9,402	10,684	(1,282)
General and administrative	6,085	11,984	(5,899)
Loss from change in fair value of contingent consideration	7,600	—	7,600
Total operating expenses	23,087	22,668	419
(Loss) income from operations	(22,662)	6,488	(29,150)
Other income (expense), net	180	(1,066)	1,246
Net (loss) income and comprehensive (loss) income	$ (22,482)	$ 5,422	$ (27,904)

Revenue. Revenue was $0.4 million for the nine months ended September 30, 2017 compared to $29.2 million for the nine months ended September 30, 2016. The decrease was due primarily to a decrease in license revenue as we recognized the upfront license fee and development milestone payment under the License Agreement with Roche, relating to the execution of the License Agreement and the successful submission of the IND application for EBI-031, as well as a decrease in collaboration revenue from our terminated collaboration with ThromboGenics. This decrease was partially offset by revenue recognized under the License Agreement with Roche in 2017 relating to the transfer of pre-clinical inventory to Roche.

Research and development expenses. Research and development expenses were $9.4 million for the nine months ended September 30, 2017 compared to $10.7 million for the nine months ended September 30, 2016. The decrease of $1.3 million was due primarily to a decrease in EBI-031 related development expenses of $3.0 million due to the License Agreement with Roche in which Roche is responsible for all on-going development expenses, as well as a decrease of $1.6 million of isunakinra-related development expenses, which development activities are no longer ongoing. These decreases were partially offset by increases in Vicinium-related development expenses of $5.1 million, which was acquired in connection with our acquisition of Viventia in September 2016. In addition, total personnel and other expenses were $4.0 million for the nine months ended September 30, 2017 compared to $6.0 million for the nine months ended September 30, 2016.

General and administrative expenses. General and administrative expenses were $6.1 million for the nine months ended September 30, 2017 compared to $12.0 million for the nine months ended September 30, 2016. The decrease of $5.9 million was primarily due to a reduction of professional fees as well as salaries and related costs for personnel, including stock-based compensation. For the nine months ended September 30, 2016, we had higher professional fees related to the License Agreement with Roche, our 2016 review of strategic alternatives and the acquisition of Viventia. In addition, for the nine months ended September 30, 2016, we had higher severance costs related to the acquisition of Viventia.

Loss from change in fair value of contingent consideration. The change in fair value of contingent consideration was $7.6 million for the nine months ended September 30, 2017 compared to $0 million for the nine months ended September 30, 2016 was primarily due to updates in projected revenue assumptions related to Vicinium.

Other income (expense), net. Other income, net was $0.2 million for the nine months ended September 30, 2017 compared to other expense, net of $1.1 million for the nine months ended September 30, 2016. The change of $1.2 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.

On November 1, 2017, we raised approximately $7.0 million of net proceeds from the sale of 5,525,000 units (each unit consisting of one share of common stock and one common warrant to purchase one share of common stock) and 4,475,000 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase one share of common stock) at a purchase price of $0.80 per unit and $0.79 per pre-funded unit. Each common warrant contained in a unit or a pre-funded unit has an exercise price of $0.80 per share and is exercisable immediately and will expire five years from the date of issuance. Each pre-funded warrant contained in a pre-funded unit is exercisable for one share of common stock and the exercise price is $0.01 per share. We granted the underwriter an option to purchase up to 1,500,000 additional shares of common stock at a purchase price of $0.79 per share and/or common warrants to purchase up to an aggregate of 1,500,000 shares of common stock at a purchase price of $0.01 per common warrant with an exercise price of $0.80 per share, less underwriting discount and commissions. If the underwriters exercise this option in full, we will receive approximately $1.1 million of additional net proceeds. The underwriter can exercise this option at any time on or after December 1, 2017.

Cash Flows

As of September 30, 2017, we had cash and cash equivalents of $11.3 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:

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Net cash (used in) provided by :		
Operating activities	$ (14,140)	$ 8,138
Investing activities	84	419
Financing activities	52	(13,920)
Net decrease in cash and cash equivalents	$ (14,004)	$ (5,363)

Operating activities. Net cash used in operating activities was $14.1 million for the nine months ended September 30, 2017 and consisted primarily of net loss of $22.5 million, adjusted for non-cash items, including stock-based compensation expense of $0.8 million, depreciation expense and impairment of fixed asset expense of $0.2 million, change in fair value of contingent consideration of $7.6 million, gain on sale of equipment of $0.1 million and a net change in operating assets and liabilities of $(0.2) million.

Net cash provided by operating activities was $8.1 million for the nine months ended September 30, 2016, and consisted primarily of net income of $5.4 million resulting from the License Agreement with Roche, adjusted for non-cash items, including stock-based compensation expense of $3.4 million, depreciation expense of $0.1 million, $0.2 million loss on extinguishment of debt and a net change in operating assets and liabilities of $(0.9) million.

Investing activities. Net cash provided by investing activities consisted of sales of equipment. For the nine months ended September 30, 2017, we had cash proceeds from the sale of equipment of $0.1 million. For the nine months ended September 30, 2016, we sold $0.3 million of property and equipment. In addition, we also acquired $0.1 million of cash from the acquisition of Viventia.

Financing activities. Net cash provided by financing activities for the nine months ended September 30, 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 nine months ended September 30, 2016 was $13.9 million and consisted primarily of the repayment of outstanding debt obligations. On March 1, 2016, we prepaid all outstanding amounts owed to Silicon Valley Bank and terminated the loan agreement. This was partially offset by proceeds from the exercise of stock options of $0.2 million.

Funding Requirements

We will incur substantial expenses if and as we:

- continue our Phase 3 clinical trial for Vicinium;
- 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 $11.3 million as of September 30, 2017, together with the $7.0 million of net proceeds received from the November 2017 Financing, will be sufficient to fund our current operating plan into mid 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:

- 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, such as the financing we completed in November 2017, 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 and nine months ended September 30, 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 and nine months ended September 30, 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 September 30, 2017, we had cash and cash equivalents of $11.3 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 (1.0%) 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 September 30, 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 September 30, 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. Effective as of October 20, 2017, John McCabe resigned as our Chief Financial Officer and Richard Fitzgerald was appointed as our Interim Chief Financial Officer. In order to stabilize our remediation efforts in light of this transition, we also retained consultants to assist with the review of assumptions used and conclusions reached from the perspective of a typical market participant used in the acquisition valuation model for the final purchase price allocation. In connection with our remediation plan, we are continuing to evaluate steps to address the material weaknesses, which may include the addition of new personnel, including one or more employees to our financial and accounting group and the engagement of independent consultants to aid in the review of our financial reporting process.

Changes in Internal Control Over Financial Reporting

During the three and nine months ended September 30, 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 period covered by this Quarterly Report on Form 10-Q 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 and the risk factors included 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 and as set forth below, which could materially affect our business, financial condition or future results. The risks described in our 2016 Form 10-K and noted below 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.

Recent changes in our senior management team could harm our business.

Effective as of October 3, 2017, Arthur DeCillis resigned as our Chief Medical Officer. Effective as of October 20, 2017, John McCabe resigned as our Chief Financial Officer. As a result of these changes, we may experience disruption in our operations or have difficulty in maintaining or developing our business during this transition.

We may record impairment charges, which would adversely impact our financial position and results of operations.

We have recorded a material amount of goodwill and indefinite-lived intangible assets on our balance sheet in connection with our acquisition of Viventia. We review our goodwill and intangible assets for impairment at least annually, or whenever events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable, in accordance with Accounting Standards Codification 350, *Intangibles-Goodwill and Other*.

One potential indicator of goodwill impairment is whether our fair value, as measured by our market capitalization, is below our net book value. Whether our market capitalization triggers an impairment charge in any future period will depend on the underlying reasons for the decline in stock price, the significance of the decline, and the length of time the stock price has been trading at such prices.

In addition, the determination as to whether our indefinite-lived intangible assets related to Vicinium are impaired is heavily dependent on the results of our on-going clinical trial, as well as other factors, such as the potential market for Vicinium, if approved.

In the event that we determine in a future period that impairment exists for any reason, we would record an impairment charge, which could be material and which would reduce the underlying asset's value in the period such determination is made, which would adversely impact our financial position and results of operations.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of November 15, 2017, we had outstanding 31,831,995 shares of common stock. Of these shares, 9,302,744 shares are restricted securities under Rule 144 under the Securities Act of 1933, as amended, or Securities Act. Any of our remaining shares that are not restricted securities under Rule 144 under the Securities Act may be resold in the public market without restriction unless purchased by our affiliates.

Moreover, holders of an aggregate of 9,795,963 shares of our common stock, including 3,582,328 shares of common stock issued in connection with the acquisition of Viventia, have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have filed registration statements on April 9, 2014, March 12, 2015 and March 31, 2016 registering all shares of common stock that we may issue under our equity compensation plans.

As of November 15, 2017, we had outstanding options to purchase an aggregate of 2,815,796 shares of our common stock, of which options to purchase 1,219,301 shares were vested, and warrants to purchase 926,840 shares of common stock at a weighted average exercise price of $14.79 per share. In connection with the November 2017 Financing, we also have warrants to purchase an aggregate of 10,000,000 shares of common stock at an exercise price of $0.80 per share and pre-funded warrants to purchase an aggregate of 2,875,000 shares of our common stock at an exercise price of $0.01 per share, as of November 15, 2017. Shares issuable upon exercise of these options and warrants can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates.

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, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
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

* Filed herewith.

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/ Stephen A. Hurly

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

November 17, 2017

Exhibit 31.1

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

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

Dated: November 17, 2017

Exhibit 31.2

Rule 13a-14(a) CERTIFICATION

I, Richard F. Fitzgerald, 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) esigned 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/ Richard F. Fitzgerald

Richard F. Fitzgerald
Interim Chief Financial Officer
(Principal Financial Officer)

Dated: November 17, 2017

Exhibit 32.1

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 September 30, 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

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

Dated: November 17, 2017

/s/ Richard F. Fitzgerald

Richard F. Fitzgerald
Interim Chief Financial Officer
(Principal Financial Officer)

Dated: November 17, 2017