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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 March 31, 2015

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.)**
215 First Street, Suite 400 Cambridge, MA	**02142**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (781) 461-1000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): ☐ Yes ☒ No

Number of outstanding shares of Common Stock as of April 17, 2015:19,371,411

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 plans to research and develop our product candidates;
- the initiation and conduct of clinical trials, including the timing, cost, conduct and outcome of our clinical trials of EBI-005 for the treatment of dry eye disease and allergic conjunctivitis and EBI-031 for the treatment of diabetic macular edema, including statements regarding the timing of the availability of, and the costs to obtain, top-line data from such trials, the timing of completion of and outcomes of such trials, and the timing of regulatory filings;
- our ability to successfully develop our product candidates and complete our planned clinical programs;
- interim results from a clinical trial and whether they will be predictive of the final results of the trial or results of early clinical studies and whether they will be indicative of the results of future studies;
- expectations regarding regulatory approvals, including the requirements for marketing approval of EBI-005, the nature and timing of our future interactions with regulatory authorities and our ability to design, implement and complete registration trials acceptable to such regulatory authorities and sufficient to support applications for regulatory approvals;
- the timing of and our ability to obtain marketing approval of EBI-005 and our other product candidates, and the ability of EBI-005 and our other product candidates to meet existing or future regulatory standards;
- the potential advantages of EBI-005;
- our estimates regarding the potential market opportunity for EBI-005 and our other product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of EBI-005 and our other product candidates;
- our ability to maintain our collaboration with ThromboGenics N.V., enter into and successfully complete other collaborations or in-license or acquire rights to other products, product candidates or technologies for the treatment of eye diseases;
- our ability to obtain, maintain and protect our intellectual property for our technology and products;
- the rate and degree of market acceptance and clinical utility of our products;
- our estimates regarding expenses, future revenues, capital requirements and need for additional financing;
- the impact of governmental laws and regulations; and
- our competitive position.

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 BALANCE SHEETS
(unaudited)
(in thousands, except share and per share data)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 45,549	$ 54,059
Restricted cash	94	—
Prepaid expenses and other current assets	495	342
Total current assets	46,138	54,401
Property and equipment, net	422	486
Restricted cash	—	94
Other assets	18	19
Total assets	$ 46,578	$ 55,000
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,043	$ 2,458
Accrued expenses	1,327	1,987
Notes payable, current portion	1,010	251
Deferred revenue	262	506
Total current liabilities	4,642	5,202
Other liabilities	65	4
Notes payable, net of current portion	8,990	9,749
Warrant liability	1,915	3,219
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at March 31, 2015 and December 31, 2014 and no shares issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at March 31, 2015 and December 31, 2014 and 18,015,423 and 17,933,260 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	18	18
Additional paid-in capital	129,222	128,558
Accumulated deficit	(98,274)	(91,750)
Total stockholders' equity	30,966	36.826
Total liabilities and stockholders' equity	$ 46,578	$ 55,000

See accompanying notes.

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

	Three Months Ended March 31,	
	2015	2014
Collaboration revenue	$ 244	$ 568
Operating expenses:		
Research and development	5,238	5,819
General and administrative	2,603	1,938
Total operating expenses	7,841	7,757
Loss from operations	(7,597)	(7,189)
Other income (expense):		
Other income, net	1,308	51
Interest expense	(235)	(84)
Total other income (expense), net	1,073	(33)
Net loss and comprehensive loss	$ (6,524)	$ (7,222)
Cumulative preferred stock dividends	—	(519)
Net loss applicable to common stockholders	$ (6,524)	$ (7,741)
Net loss per share applicable to common stockholders—basic and diluted	$ (0.36)	$ (0.80)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	17,971	9,635

See accompanying notes.

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

	Three Months Ended March 31,	
	2015	2014
Operating activities		
Net loss	$ (6,524)	$ (7,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	96	101
Non-cash interest expense	2	8
Stock-based compensation expense	664	636
Change in fair value of warrant liability	(1,304)	(50)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(155)	(64)
Accounts payable	(415)	1,885
Accrued expenses and other liabilities	(598)	(215)
Deferred revenue	(244)	(113)
Net cash used in operating activities	(8,478)	(5,034)
Investing activities		
Purchases of property and equipment	(32)	(50)
Net cash used in investing activities	(32)	(50)
Financing activities		
Proceeds from issuance of common stock and common stock warrants, net of offering costs	(46)	51,507
Payments on notes payable	—	(416)
Proceeds from exercise of common stock options and warrants	46	15
Net cash provided by financing activities	—	51,106
Net (decrease) increase in cash and cash equivalents	(8,510)	46,022
Cash and cash equivalents at beginning of period	54,059	7,942
Cash and cash equivalents at end of period	$45,549	$53,964
Supplemental non-cash financing activities		
Conversion of preferred stock into common stock	$ —	$56,678
Conversion of preferred stock warrants into common stock warrants	$ —	$ 247
Supplemental cash flow information		
Cash paid for interest	$ 175	$ 64

See accompanying notes.

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

1. Organization and Basis of Presentation

Eleven Biotherapeutics, Inc. (the "Company"), formerly known as Denovo Therapeutics, Inc. and Newco LS14, Inc., a Delaware corporation formed on February 25, 2008, is a biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. The Company's most advanced product candidate is EBI-005, which it designed, engineered and generated using its AMP-Rx platform and is developing as a topical treatment for dry eye disease and allergic conjunctivitis. In 2013, the Company completed a Phase 1b/2a clinical trial of EBI-005 in patients with moderate to severe dry eye disease. In 2014, the Company initiated a pivotal Phase 3 clinical program evaluating EBI-005 for the treatment of moderate to severe dry eye disease. The Company also initiated and completed a Phase 2 clinical trial to evaluate the use of EBI-005 in patients with allergic conjunctivitis in 2014.

On May 28, 2013, the Company entered into a collaboration and license agreement with ThromboGenics N.V ("ThromboGenics"). Under the agreement, the Company and ThromboGenics are collaborating to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease (Note 4).

These financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP").

Liquidity

The Company has generated an accumulated deficit at March 31, 2015 of $98.3 million since inception and will require substantial additional capital to fund operations. 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 drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. On February 11, 2014, the Company completed its initial public offering ("IPO") whereby the Company sold 5,750,000 shares of its common stock for aggregate net proceeds of approximately $50.2 million. In November 2014, the Company amended its Loan and Security Agreement with Silicon Valley Bank ("SVB") to increase the amount it may borrow up to $15.0 million. The Company borrowed $10.0 million in 2014. On December 2, 2014, the Company issued and sold 1,743,680 shares of its common stock and warrants to purchase 871,840 shares of common stock for net proceeds of approximately $18.2 million. On April 17, 2015, the Company issued and sold 1,251,784 shares of its common stock for net proceeds of approximately $12.5 million after deducting underwriter's discount but before deducting expenses payable by the Company. The Company believes that its unrestricted cash and cash equivalents at March 31, 2015, together with the proceeds from the sale of common stock in April 2015, will be sufficient to fund the Company's current operating plan through at least the next twelve months.

2. Significant Accounting Policies

Unaudited interim financial information

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the "2014 10-K").

The unaudited condensed financial statements as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 and the related information contained within the notes to the financial statements are unaudited. The unaudited financial statements have been prepared on the same basis as the annual audited financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial position as of March 31, 2015, and the statements of operations and comprehensive loss and cash flows for the three months ended March 31, 2015 and 2014. The results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for the year ending December 31, 2015, or any other future annual or interim periods.

Net loss per share

Basic net loss per share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share was the same for all periods presented.

The following common stock equivalents were excluded from the calculation of diluted net loss per share applicable to common stockholders 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.

	As of March 31,	
	2015	2014
Stock options	1,933,158	1,414,355
Unvested restricted stock	98,535	203,753
Common stock warrants	899,340	—
	2,931,033	1,618,108

There have been no material changes to the significant accounting policies previously disclosed in the 2014 10-K.

Recent Accounting Pronouncements

In the second quarter of 2014, the Financial Accounting Standards Board (FASB) issued amended guidance applicable to revenue recognition that will be effective for the Company for the year ending December 31, 2017. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Early adoption is not permitted. The new guidance applies a more principles-based approach to recognizing revenue. The Company is evaluating the new guidance and the expected effect on the Company's financial statements.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Going Concern (Subtopic 205-40)* ("ASU 2014-15"). ASU 2014-15 requires management of all entities to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). The guidance is effective for fiscal years beginning after December 15, 2016 and for interim periods within that fiscal year. The Company does not expect the adoption of this guidance to have a material effect on the Company's financial statements, but may require additional disclosure once adopted.

In April 2015, the FASB issued Accounting Standard Update No. 2015-03, *"Interest – Imputation of Interest (Subtopic 835-30)* ("ASU 2015-03")*."* ASU 2015-03 requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts. The recognition and measurement

guidance for debt issuance costs are not affected by the new amendment. The new guidance will be applied on a retrospective basis to each prior reporting period presented. Upon transition, the Company is required to comply with applicable disclosures for a change in accounting principle. The amendment is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2015-03 on the Company's financial statements.

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 using Level 3 inputs.

The following table summarizes the assets measured at fair value on a recurring basis at March 31, 2015 (in thousands):

Description	March 31, 2015	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 45,549	$45,549	$ —	$ —
Total	$ 45,549	$45,549	$ —	$ —

Description	March 31, 2015	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ 1,915	$ —	$ —	$ 1,915
Total	$ 1,915	$ —	$ —	$ 1,915

The following table summarizes the assets and liabilities measured at fair value on a recurring basis at December 31, 2014 (in thousands):

Description	December 31, 2014	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 54,059	$54,059	$ —	$ —
Total	$ 54,059	$54,059	$ —	$ —

Description	December 31, 2014	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ 3,219	$ —	$ —	$ 3,219
Total	$ 3,219	$ —	$ —	$ 3,219

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

	March 31, 2015	December 31, 2014
Risk-free interest rate	0.89%	1.10%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	2.67	2.92
Expected volatility	62.19%	56.79%

The following table sets forth a summary of changes in the fair value of the Company's preferred 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, 2015	$ 3,219
Change in fair value	(1,304)
Ending balance, March 31, 2015	$ 1,915

The carrying amounts reflected in the balance sheets for restricted cash, prepaid expenses and other current assets, other assets, accounts payable and accrued expenses approximate their fair values at March 31, 2015 and December 31, 2014, due to their short-term nature. At March 31, 2015, the carrying value of the notes payable approximates fair value, which was determined using Level 3 inputs, including a quoted rate.

There have been no changes to the valuation methods during the three months ended March 31, 2015. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three months ended March 31, 2015.

4. Collaboration Agreement

On May 28, 2013, the Company entered into the collaboration and license agreement with ThromboGenics. Under this agreement, the Company and ThromboGenics are collaborating to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. The Company and ThromboGenics jointly own any know-how made by or on behalf of either party in the course of the research and any patent rights claiming such know-how. The Company has granted ThromboGenics an exclusive, sublicenseable, royalty-bearing license under the Company's rights in these patent rights and know-how, as well as under any other patent rights and know-how that the Company controls during the research term that are necessary for ThromboGenics to perform its obligations to research, develop, manufacture and commercialize collaboration products.

ThromboGenics will fund certain research and development services performed by the Company during the research term, which is initially thirty (30) months and automatically extends to the extent that the parties mutually agree in writing. The activities under the agreement are governed by a Joint Research Committee ("JRC"). The JRC is responsible for overseeing the research activities under the agreement. The JRC will disband at the end of the research term.

The Company received a $1.75 million upfront payment and will receive a set rate per annual full time equivalent personnel working on the collaboration, which will be paid quarterly in advance. The Company is also eligible to receive up to an aggregate of $25.0 million in milestone payments and may also receive low single-digit royalties on sales of any commercialized products resulting from the collaboration. There are no commercialization or sales-based milestones under the agreement.

The agreement expires when all of ThromboGenics' payment obligations expire. The agreement provides that either party may terminate the agreement in the event of the other party's insolvency, bankruptcy or comparable proceedings, or if the other party materially breaches the agreement and does not cure such breach during a specified cure period. The Company may terminate the agreement if ThromboGenics or any of its affiliates or licensees challenges the patent rights licensed to ThromboGenics. ThromboGenics may terminate the agreement for convenience by providing the Company with notice following the end of the research term. There are no refund provisions in this agreement.

The Company accounts for this agreement pursuant to ASC Topic 605-25, *Revenue Recognition – Multiple Element Arrangements*, or ASC 605-25. The Company identified the following deliverables in this agreement:

- an exclusive license to the Company's intellectual property that is necessary for ThromboGenics to perform its obligations during the research term. ("Research License Deliverable");
- the Company's obligation to provide research services ("Research Services Deliverable"); and
- the Company's participation on the JRC ("JRC Deliverable").

The Company determined that the licenses to future collaboration product candidates are contingent upon the identification of future product candidates as a result of the Research Services, and as such, have not been identified as a separate deliverable at the inception of the arrangement.

The Company determined that the Research License Deliverable did not have standalone value from the Research Services Deliverable because the License is not sold separately and could not be resold on a standalone basis. While the intellectual property rights granted to ThromboGenics under this agreement are sublicensable, the Company determined that the Research License Deliverable does not have value without the Research Services Deliverable as the Company's intellectual property could not be sold separately or utilized to develop product candidates without the expertise of the Company that is provided through the Research Services Deliverable. The Company concluded that ThromboGenics does not have the expertise to perform the specialized research activities and such expertise is not readily available in the marketplace. As such, the Company has accounted for the Research License Deliverable and the Research Services Deliverable as a combined unit of accounting. The Company determined that the JRC Deliverable has standalone value from the Research License Deliverable and the Research Services Deliverable (the combined unit of account). The Company has determined that the best estimate of selling price of the JRC Deliverable is de minimis, and thus the non-contingent arrangement consideration has been allocated to the combined unit of accounting.

The Company is recognizing the arrangement consideration using the proportional performance method, by which the amounts are recognized in proportion to the costs incurred based on full time equivalent personnel efforts. The Company recorded revenue of $244,000 for the three months ended March 31, 2015. The costs incurred by the Company related to the research activities are recorded as research and development expense in the statement of operations and comprehensive loss.

The potential milestone payments under this agreement are comprised of (i) up to an aggregate of $10.0 million of milestone payments due upon the achievement of specified preclinical and clinical development milestone events, and (ii) up to an aggregate of $15.0 million in milestone payments due upon the achievement of specified regulatory milestone events. The Company believes that certain of the preclinical and clinical development milestone payments are consistent with the definition of substantive milestones, and, accordingly, the Company will recognize these payments upon the achievement of such milestones, if any, in the period that such milestone is achieved. The remaining clinical development and regulatory milestone payments were not considered substantive and will be recognized upon achievement of the revenue recognition criteria of ASC 605. Factors considered in the evaluation of whether the milestones are substantive included the degree of risk associated with performance of the milestone, the level of effort and investment required, whether the milestone consideration was reasonable relative to the deliverables and whether the milestone was earned at least in part based on the Company's performance.

As of March 31, 2015, the Company had not received any milestone or royalty payments.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Development costs	$ 588	$ 834
Employee compensation	384	874
Professional fees	192	195
Interest	81	84
Other	82	—
	$ 1,327	$ 1,987

6. Share-Based Payments

2009 Stock Incentive Plan

The Company maintains the Eleven Biotherapeutics, Inc. 2009 Stock Incentive Plan (the "2009 Plan"), as amended and restated, for employees, directors, consultants, and advisors to the Company. Upon the closing of the Company's IPO in February 2014, the Company ceased granting stock incentive awards under the 2009 Plan. The 2009 Plan provides for the grant of incentive and non-qualified stock options and restricted stock grants as determined by the Board of Directors. Under the 2009 Plan, stock options may not be granted at less than fair value on the date of the grant. Furthermore, the exercise price of incentive stock options granted to an employee, who, at the time of grant, is a 10% shareholder, may not be less than 110% of the fair value on the date of grant.

Terms of stock option agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2009 Plan. Options and restricted stock awards granted by the Company generally vest ratably over four years, with a one-year cliff for new employee awards, and are exercisable from the date of grant for a period of ten years. Restricted stock issuances and early exercises of stock options are subject to the Company's right of repurchase at the original issuance price, which right lapses over the vesting period of the stock. For options and restricted stock awards granted to date, the exercise price equaled the estimated fair value of the common stock as determined by the Board of Directors on the date of grant.

2014 Stock Incentive Plan

In December 2013, the Company's 2014 Stock Incentive Plan (the "2014 Plan") was adopted by the Board of Directors and was approved by the Company's stockholders in January 2014. The 2014 Plan became effective immediately prior to the closing of the Company's IPO in February 2014. The 2014 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The number of shares of the Company's common stock reserved for issuance under the 2014 Plan is the sum of (1) 708,661 shares, plus (2) the number of shares (up to 1,347,821 shares) equal to (x) 1,586 shares (representing the number of shares reserved for issuance under the 2009 Plan that remained available for future issuance as of the effectiveness of the 2014 Plan) and (y) the number of shares of the Company's common stock subject to outstanding awards under the Company's 2009 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued, plus (3) an annual increase, to be added on the first day of each fiscal year, equal to the lowest of 1,102,362 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year and an amount determined by the Company's board of directors. On January 1, 2015, the Company increased the number of shares reserved for issuance under the 2014 Plan by 722,331 shares.

The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2014 Plan. However, incentive stock options may only be granted to the Company's employees.

A summary of the Company's stock option activity and related information follows:

	Shares	Weighted-Average Exercise Price	Remaining Contractual Life (in years)
Outstanding at December 31, 2014	1,438,528	$ 4.93	7.86
Granted	566,556	10.78	
Exercised	(54,371)	0.82	
Cancelled or forfeited	(17,555)	6.83	
Outstanding at March 31, 2015	1,933,158	$ 6.74	8.27
Exercisable at March 31, 2015	645,757	$ 3.91	7.35
Vested and expected to vest at March 31, 2015(1)	1,593,293	$ 7.19	8.45

(1) Represents the number of vested options, plus the number of unvested options expected to vest.

The total intrinsic value of options vested and expected to vest as of March 31, 2015 was $4.6 million. The total intrinsic value of options exercised for the three months ended March 31, 2015 and 2014 was $584,000 and $120,000, respectively. The total fair value of employee and director options vested for the three months ended March 31, 2015 and 2014 was $215,000 and $186,000, respectively.

Restricted Stock

From time to time, upon approval by the Board of Directors, certain employees, directors and advisors have been granted restricted shares of common stock. Certain of these shares of restricted stock are subject to repurchase rights. Accordingly, the Company has recorded the proceeds from the issuance of restricted stock as a liability in the balance sheets. The restricted stock liability is reclassified into stockholders' equity (deficit) as the restricted stock vests. A summary of the status of unvested restricted stock is presented below:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2014	125,027	$ 5.39
Granted	1,300	10.08
Vested	(27,792)	2.37
Unvested at March 31, 2015	98,535	$ 6.31

The Company issued 1,300 shares of restricted stock to non-employees during the three months ended March 31, 2015. The Company did not issue any restricted stock to non-employees during the three months ended March 31, 2014. The non-employee restricted stock is revalued as it vests. There were 1,083 shares of non-employee unvested restricted stock outstanding at March 31, 2015. There were no shares of non-employee unvested restricted stock outstanding at March 31, 2014. The expense related to the restricted stock granted to non-employees for the three months ended March 31, 2015 and 2014 was $27,000 and $48,000, respectively.

Performance-Based Stock Options

The Company has granted stock options to the founders of the Company, which contain both performance-based and service-based vesting criteria. Milestone events are specific to the Company's corporate goals, including but not limited to certain preclinical and clinical development milestones related to the Company's product candidates. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance condition is considered probable of achievement using management's best estimates. There was no expense recorded for milestone based vesting awards during the three months ended March 31, 2015. During the three months ended March 31, 2014, management determined that a performance-based milestone was achieved and recorded stock-based compensation expense of $17,000. The remaining milestones were not deemed to be probable of achievement as of March 31, 2015. As of March 31, 2015, unrecognized compensation expense related to performance based awards was $1.7 million.

Stock-Based Compensation Expense

The fair value of each stock option granted to employees and directors was estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions noted in the following table:

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	1.42–1.76%	1.80-2.02%
Expected dividend yield	—	—
Expected term (in years)	5.75-6	5.75-6
Expected volatility	73.07–74.11%	69.37-69.58%

The expense related to the options granted to employees and directors for the three months ended March 31, 2015 and 2014 was $554,000 and $288,000, respectively.

The Company did not grant any stock options to non-employees during the three months ended March 31, 2015 and 2014. The expense related to the options granted to non-employees for the three months ended March 31, 2015 and 2014 was $83,000 and $300,000, respectively.

During the three months ended March 31, 2015 and 2014, the Company recorded stock-based compensation expense for employee and non-employee stock options and restricted stock, which was allocated as follows in the statements of operations (in thousands):

	Three Months Ended March 31,	
	2015	2014
Research and development expense	$ 280	$ 355
General and administrative expense	384	281
	$ 664	$ 636

At March 31, 2015, there was $5.9 million of total unrecognized compensation cost related to non-vested stock options and unvested restricted stock with service-based vesting provisions, which is expected to be recognized over a weighted-average period of 3.03 years.

7. Subsequent Events

On April 17, 2015, the Company issued and sold 1,251,784 shares of its common stock for net proceeds of approximately $12.5 million after deducting underwriter's discount but before deducting expenses payable by the Company.

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 financial statements and the notes to those financial statements appearing in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2014 (the "2014 10-K"). This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item IA, "Risk Factors" of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that we apply to the discovery and development of protein therapeutics to treat diseases of the eye. Our therapeutic approach is based on the role of cytokines in diseases of the eye, our understanding of the structural biology of cytokines and our ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. Our most advanced product candidate is EBI-005, which we designed, engineered and generated using our AMP-Rx platform and are developing as a topical treatment for dry eye disease and allergic conjunctivitis. In 2013, we completed a Phase 1b/2a clinical trial of EBI-005 in patients with moderate to severe dry eye disease. In early 2014, we initiated a pivotal Phase 3 clinical program evaluating EBI-005 for the treatment of moderate to severe dry eye disease. We also initiated and completed a Phase 2 clinical trial to evaluate the use of EBI-005 in patients with allergic conjunctivitis in 2014. We hold worldwide commercialization rights to EBI-005.

Our most advanced preclinical product candidate is EBI-031 for the treatment of diabetic macular edema, or DME. We are undertaking the necessary CMC development work and nonclinical safety studies to support the submission of an investigational new drug application, or IND, to the FDA.

We were incorporated and commenced active operations in early 2008, and our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and, beginning in 2012, conducting clinical trials. To date, we have financed our operations primarily through private placements of our common stock, preferred stock and convertible bridge notes, venture debt borrowings, the initial public offering of our common stock, or IPO, and, to a lesser extent, from a collaboration. All of our revenue to date has been collaboration revenue, which we first began to generate in 2013. Since inception, we have incurred significant operating losses. As of March 31, 2015, we had an accumulated deficit of $98.3 million. We anticipate that our expenses will increase substantially as compared to prior periods in connection with conducting our pivotal Phase 3 clinical program, consisting of two Phase 3 clinical trials evaluating the safety and efficacy of EBI-005, our most advanced product candidate, for the treatment of moderate to severe dry eye disease and a separate clinical trial evaluating the safety of treatment with EBI-005 for one year, and if successful, seeking marketing approval for EBI-005 for this indication in the United States.

We also expect our expenses to increase as we conduct additional clinical trials of EBI-005 for the treatment of allergic conjunctivitis or additional indications or for use in other patient populations, as we seek, if clinical trials are successful, marketing approval of EBI-005 for the treatment of allergic conjunctivitis or other indications or for use in other patient populations, and as we continue research and development and initiate additional clinical trials of, and seek, if clinical trials are successful, marketing approval for, our other product candidates. In addition, if we obtain marketing approval for EBI-005 or any other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, since the closing of our IPO, we have incurred additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from the sale of products. All of our revenue to date has been derived from a collaboration. We do not expect to generate significant product revenue unless and until we obtain marketing approval for, and commercialize, EBI-005, which we do not expect will occur before 2017, if ever.

We have generated collaboration revenue exclusively from our collaboration and license agreement with ThromboGenics N.V., or Thrombogenics, which we entered into in May 2013. Under the agreement, we and ThromboGenics are collaborating to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. We call the therapeutics that are identified, and whose modulation of one of the targets is confirmed, in the course of the research collaboration, collaboration products. The initial research term extends for 30 months from the date we entered into the agreement, but may be extended on mutual agreement. The agreement expires when all of ThromboGenics' payment obligations expire. We are responsible for specified non-clinical activities during the research term. ThromboGenics is responsible for all development, manufacturing and commercialization activities with respect to the collaboration products. We granted ThromboGenics an exclusive, sublicensable, worldwide royalty-bearing license under our rights in any intellectual property made in the course of this collaboration, as well as under any other intellectual property we control during the research term that is necessary for ThromboGenics to perform its obligations to research, develop, manufacture and commercialize collaboration products. During the term of the agreement, neither we nor ThromboGenics, nor our respective affiliates other than any entities which become affiliates as a result of an acquisition of us or ThromboGenics, are permitted to research, develop, manufacture or commercialize any protein or peptide therapeutic that directly modulates one of the specified targets, except as otherwise provided in the agreement.

In connection with the agreement, we received an upfront, non-refundable payment of $1.75 million, and are entitled to receive payment for our performance of activities under the agreement at a set rate per full time annual equivalent personnel for research services pursuant to the agreement. We identified three deliverables in the arrangement: the research license, the research services and our participation on the joint research committee, or JRC deliverable, and concluded that there are two units of accounting: a combined research license and research services deliverable and the JRC deliverable. The estimated selling price for the JRC deliverable was *de minimis*, and thus we allocated the fixed arrangement consideration to the combined unit of accounting. We are recognizing revenue using the proportional performance method by which the amounts are recognized in proportion to the costs incurred based on full time equivalent efforts. In addition, we are eligible to receive up to an aggregate of $10.0 million if ThromboGenics achieves specified preclinical and clinical development milestones and up to an aggregate of $15.0 million if ThromboGenics achieves specified regulatory milestones. There are no commercialization or sales based milestones under the agreement. ThromboGenics is obligated to pay us a low single digit royalty on the sale of collaboration products. We recognized collaboration revenue of $244,000 in connection with this collaboration for the three months ended March 31, 2015 and $568,000 for the three months ended March 31, 2014. We expect that any revenue we generate from our collaboration with ThromboGenics will fluctuate from quarter to quarter as a result of the uncertain timing and amount of payments for research services, milestone payments and royalties.

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 preclinical 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 our product candidates 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;
- 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 EBI-005 or any other product candidate that we may develop 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 EBI-005 or any other product candidate that we may develop, 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 EBI-005 and EBI-031 product programs and other expenses by category. We did not allocate research and development expenses to any other specific product program during the periods presented:

	Three months ended March 31,	
	2015	2014
	(in thousands)	
Programs:		
EBI-005	$ 3,051	$ 4,031
EBI-031	428	—
Total program expenses	3,479	4,031
Personnel and other expenses:		
Employee and contractor-related expenses	1,268	1,027
Platform-related lab expenses	189	182
Facility expenses	109	104
Other expenses	193	475
Total personnel and other expenses	1,759	1,788
Total research and development expenses	$ 5,238	$ 5,819

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 and human resource functions. Other general and administrative expenses include facility-related costs and professional fees for legal, patent, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased accounting, audit, legal, regulatory, compliance, insurance and investor and public relations expenses associated with being a public company.

Other Income (Expense), Net

Other income and expense consists primarily of interest income earned on cash and cash equivalents, interest expense on outstanding debt and the gain or loss associated with the change in the fair value of our preferred stock warrant liability.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our audited financial statements appearing elsewhere in the 2014 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Codification, or ASC, 605, *Revenue Recognition*. Accordingly, we recognize revenue for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

We record as deferred revenue any amounts received prior to satisfying the revenue recognition criteria. We classify as deferred revenue, current any amounts expected to be recognized as revenue within the 12 months following the balance sheet date. We classify as deferred revenue, net of current portion any amounts not expected to be recognized as revenue within the 12 months following the balance sheet date.

We evaluate multiple-element arrangements based on the guidance in ASC Topic 605-25, *Revenue Recognition-Multiple-Element Arrangements*, or ASC 605-25. Pursuant to the guidance in ASC 605-25, we evaluate multiple-element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that the delivered item has value to the customer on a standalone basis, and if the arrangement includes a general right of return with respect to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can use any other deliverable for its intended purpose without the receipt of the remaining deliverable, whether the value of the deliverable is dependent on the undelivered item and whether there are other vendors that can provide the undelivered items. The consideration received under the arrangement that is fixed or determinable is then allocated among the separate units of accounting using the relative selling price method. We determine the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, we determine the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE nor TPE is available.

We recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. In the event that a deliverable does not represent a separate unit of accounting, we recognize revenue from the combined unit of accounting over our contractual or estimated performance period for the undelivered items, which is typically the term of our research and development obligations. If there is no discernible pattern of performance or objectively measurable performance measures do not exist, then we recognize revenue under the arrangement on a straight-line basis over the period we are expected to complete our performance obligations. Conversely, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then we recognize revenue under the arrangement using the proportional performance method. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method or proportional performance method, as applicable, as of the period ending date.

At the inception of an arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (1) the consideration is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item as a result of a specific outcome resulting from our performance to achieve the milestone; (2) the consideration relates solely to past performance; and (3) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone and the level of effort and investment required to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. We have concluded that certain of the preclinical and clinical development milestone payments pursuant to our collaboration and license arrangement with ThromboGenics are substantive. Accordingly, in accordance with ASC Topic 605-28, *Revenue Recognition-Milestone Method*, we will recognize revenue in its entirety upon successful accomplishment of these milestones, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are recognized as earned if there are no remaining performance obligations or over the remaining period of performance, assuming all other revenue recognition criteria are met.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotes and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to fees paid to CROs and other vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to CROs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepayment expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in our reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

Stock-Based Compensation

We account for all stock-based compensation payments to employees, directors and non-employees using an option pricing model for estimating fair value. Accordingly, stock-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line method. In accordance with authoritative guidance, we re-measure the fair value of non-employee stock-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

We apply the fair value recognition provisions of ASC Topic 718, *Compensation-Stock Compensation*, or ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. We recognize stock-based compensation expense for service-based awards ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions.

We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. As a new public company, we do not have sufficient history to estimate the volatility of our common stock price or the expected life of the options. We calculate expected volatility based on reported data for similar publicly traded companies for which historical information is available and will continue to do so until the historical volatility of our common stock is sufficient to measure expected volatility for future option grants. We utilize data from a representative group of public companies to estimate expected stock price volatility. We select companies from the biopharmaceutical industry with similar characteristics to us, including those at a similar stage of development and with a similar therapeutic focus.

We use the "simplified method" to estimate the expected term of stock option grants to employees. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term (ten years) and the vesting term (generally four years) of our stock options, taking into consideration multiple vesting tranches. We utilize this method due to lack of historical exercise data and the plain-vanilla nature of our share-based awards. We have never paid, and do not anticipate paying, any cash dividends in the foreseeable future, and therefore use an expected dividend yield of zero in the option-pricing model. The risk-free rate is based on the yield curve of U.S. Treasury securities with periods commensurate with the expected term of the options being valued. The fair value of each stock option granted to employees and directors is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions noted in the following table:

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	1.42-1.76%	1.80-2.02%
Expected dividend yield	—	—
Expected term (in years)	5.75-6	5.75-6
Expected volatility	73.07-74.11%	69.37-69.58%

We are also required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates are revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

Stock-based compensation expense was $664,000 for the three months ended March 31, 2015 and $636,000 for the three months ended March 31, 2014. As of March 31, 2015, we had $5.9 million of total unrecognized stock-based compensation expense related to service-based vesting awards, which we expect to recognize over a weighted-average remaining vesting period of approximately 3.03 years. In addition, as of March 31, 2015, we had unrecognized compensation expense related to performance-based awards of $1.7 million, which will be recorded when the vesting conditions become probable of achievement. Our stock-based compensation expense is expected to increase as a result of recognizing our existing unrecognized stock-based compensation for awards that will vest and as we issue additional stock-based awards to attract and retain our employees.

We allocated stock-based compensation expense as follows (in thousands):

	Three Months Ended March 31,	
	2015	2014
Research and development expense	$ 280	$ 355
General and administrative expense	384	281
Total stock-based compensation expense	$ 664	$ 636

Fair Value of Common Stock

Prior to the completion of our IPO, we were required to estimate the fair value of our common stock underlying our stock-based awards when performing the fair value calculations using the Black-Scholes option pricing model. The fair value of our common stock underlying our stock-based awards was determined on each grant date by our board of directors, with input from management. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date, we developed an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. We determined the fair value of stock options using

methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants, or AICPA, *Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation*, or the AICPA Practice Guide. In addition, we considered various objective and subjective factors, along with input from management and contemporaneous valuations, to determine the fair value of our common stock, including:

- external market conditions affecting the biotechnology industry;
- trends within the biotechnology industry;
- the prices at which we sold shares of preferred stock;
- the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- our results of operations and financial position;
- the status of our research and development efforts;
- our stage of development and business strategy;
- the lack of an active public market for our capital stock; and
- the likelihood of achieving a liquidity event, such as an IPO, or sale of our company in light of prevailing market conditions.

Results of Operations

Comparison of the Three Months Ended March 31, 2015 and 2014

	Three Months ended March 31,		
	2015	2014	Change
	(in thousands)		
Collaboration revenue	$ 244	$ 568	$ (324)
Operating expenses:			
Research and development	5,238	5,819	(581)
General and administrative	2,603	1,938	665
Total operating expenses	7,841	7,757	84
Loss from operations	(7,597)	(7,189)	(408)
Other income (expense), net	1,073	(33)	1,106
Net loss	$(6,524)	$(7,222)	$ 698

Revenue. Revenue was $244,000 for the three months ended March 31, 2015 compared to $568,000 for the three months ended March 31, 2014. The decrease of $324,000 was due to less revenue recognized pursuant to the ThromboGenics collaboration and license agreement. For the three months ended March 31, 2015 and 2014, revenue recognized related to the upfront payment received from Thrombogenics in 2013 was $133,000 and $234,000, respectively. For the three months ended March 31, 2015 and 2014, revenue recognized related to the performance activities was $111,000 and $334,000, respectively.

Research and development expenses. Research and development expenses were $5.2 million for the three months ended March 31, 2015 compared to $5.8 million for the three months ended March 31, 2014. The decrease of $581,000 was primarily due to a decrease of $980,000 of EBI-005 related development expenses. In 2014, we initiated and completed a Phase 2 clinical trial to evaluate the use of EBI-005 in patients with allergic conjunctivitis. These decreases were partially offset by increases in EBI-031 related development expenses of $428,000. In late 2014, we began undertaking the necessary CMC development work and nonclinical safety studies to support the submission of an IND to the FDA. In addition, stock-based compensation expense allocated to research and development expenses was $280,000 for the three months ended March 31, 2015 compared to $355,000 for the three months ended March 31, 2014.

General and administrative expenses. General and administrative expenses were $2.6 million for the three months ended March 31, 2015 compared to $1.9 million for the three months ended March 31, 2014. The increase of $665,000 was primarily due to increased operating costs as a result of our transition from a private company to a public company, including legal, accounting, insurance and investor relations expenses. In addition, stock-based compensation expense allocated to general and administrative expenses was $384,000 for the three months ended March 31, 2015 compared to $281,000 for the three months ended March 31, 2014.

Other income (expense), net. Other income (expense), net was $1.1 million for the three months ended March 31 2015 compared to $(33,000) for the three months ended March 31, 2014. The change of $1.1 million was primarily due to a decrease in the fair value of the Company's warrant liability.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred significant operating losses. All of our revenue to date has been collaboration revenue. To date, we have financed our operations primarily through private placements of our common stock, preferred stock and bridge notes convertible into our preferred stock, venture debt borrowings, our IPO, which we closed in February 2014, and, to a lesser extent, from a collaboration.

In May 2013, we entered into the collaboration and license agreement with ThromboGenics. Under this collaboration, ThromboGenics made a $1.75 million up-front, non-refundable cash payment to us and will fund the research services that we provide under the agreement.

Cash Flows

As of March 31, 2015, we had cash and cash equivalents of $45.5 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

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

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$(8,478)	$ (5,034)
Investing activities	(32)	(50)
Financing activities	—	51,106
Net (decrease) increase in cash and cash equivalents	$(8,510)	$46,022

Operating activities. Net cash used in operating activities was $8.5 million for the three months ended March 31, 2015, and consisted primarily of a net loss of $6.5 million adjusted for non-cash items, including stock-based compensation expense of $664,000, depreciation expense of $96,000, a net change of $1.3 million in the fair value of the warrant liability and a net change in operating assets and liabilities of $1.4 million.

Net cash used in operating activities was $5.0 million for the three months ended March 31, 2014, and consisted primarily of a net loss of $7.2 million adjusted for non-cash items, including stock-based compensation expense of $636,000, depreciation expense of $101,000 and a net change in operating assets and liabilities of $1.5 million.

Investing activities. Net cash used in investing activities consists of purchases of property and equipment. For the three months ended March 31, 2015 and March 31, 2014, we purchased $32,000 and $50,000 of property and equipment, respectively.

Financing activities. There was no net cash provided by financing activities for the three months ended March 31, 2015.

Net cash provided by financing activities for the three months ended March 31, 2014 was $51.1 million and consisted primarily of net proceeds from the initial public offering. We received aggregate net proceeds from our IPO of approximately $50.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us, of which $1.3 million were paid in 2013.

Funding Requirements

We anticipate that our expenses will increase substantially as compared to prior periods in connection with conducting our pivotal Phase 3 clinical program, consisting of two Phase 3 clinical trials evaluating the safety and efficacy of EBI-005, our most advanced product candidate, for the treatment of moderate to severe dry eye disease and a separate clinical trial evaluating the safety of treatment with EBI-005 for one year, and, if successful, seeking marketing approval for EBI-005 for this indication in the United States.

We received scientific advice from the European Medicine Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, that indicates that the requirements for European registration in dry eye disease will differ from the requirements for registration in the United States and our pivotal Phase 3 clinical program is not consistent with the advice of the CHMP. We will continue to evaluate the scientific advice received from the EMA and plan to further discuss with the EMA a registration plan for EBI-005 in moderate to severe dry eye disease for the European Union. We may be required to conduct additional clinical trials to support an application for marketing approval of EBI-005 in the European Union. We anticipate that our expenses will increase substantially if we pursue, alone or in collaboration with third parties, the development of and seek marketing approval for, EBI-005 for the treatment of moderate to severe dry eye disease in the European Union.

Furthermore, since the closing of our IPO, we have incurred additional costs associated with operating as a public company. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Our expenses will also increase if and as we:

- pursue the development of EBI-005 for the treatment of allergic conjunctivitis or additional indications or for use in other patient populations or, if it is approved, seek to broaden the label for EBI-005;
- continue the research and development of our other product candidates, including EBI-031 for the treatment of diabetic macular edema;
- seek to discover and develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies for the treatment of ophthalmic diseases;
- 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;
- hire additional clinical, quality control, scientific and management personnel;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and planned future commercialization efforts and our operations as a public company; and
- increase our insurance coverage as we expand our clinical trials and commence commercialization of EBI-005.

As of March 31, 2015, we had cash and cash equivalents of $45.5 million. We believe that our cash and cash equivalents as of March 31, 2015 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into 2016, without giving effect to any potential milestone payments we may receive under our collaboration and license agreement with ThromboGenics or draw down the remaining $5 million of our venture debt facility with SVB. 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 progress, costs and outcome of our pivotal Phase 3 clinical program for EBI-005 and of any clinical activities for regulatory review of EBI-005 outside of the United States;
- the costs and timing of process development and manufacturing scale up and validation activities associated with EBI-005;
- the costs, timing and outcome of regulatory review of EBI-005 in the United States, the European Union and in other jurisdictions;
- the costs and timing of commercialization activities for EBI-005 if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, the amount of revenue received from commercial sales of EBI-005;
- the progress, costs and outcome of developing EBI-005 for the treatment of additional indications or for use in other patient populations, including any clinical trials to assess the potential therapeutic benefit of EBI-005 for the treatment of allergic conjunctivitis in patients who do not respond adequately to antihistamines and mast cell stabilizers;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and, if we determine to proceed into clinical development, clinical trials of our other product candidates;
- the success of our collaboration with ThromboGenics;
- 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; and
- the extent to which we in-license or acquire rights to other products, product candidates or technologies for the treatment of ophthalmic diseases.

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 funding under our existing collaboration and license agreement with ThromboGenics in the form of research funding. Under this collaboration, we also may receive potential milestone payments upon the achievement of specified development, regulatory and other milestones and royalties with respect to future sales of collaboration products by ThromboGenics. ThromboGenics may terminate our existing collaboration for convenience on short notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of specified assets as collateral to secure our obligations under our loan and security agreement with our venture debt lender, Silicon Valley Bank, may limit our ability to obtain additional debt financing. 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

During the three months ended March 31, 2015, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in the 2014 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.

We are exposed to market risk related to changes in interest rates. As of December 31, 2014, we had cash and cash equivalents of $54.1 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. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the United States dollar are recorded based on exchange rates at the time such transactions arise. As of December 31, 2014, substantially all of our total liabilities were denominated in the United States dollar.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial and Business Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of March 31, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e)) under 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 the Company's disclosure controls and procedures as of March 31, 2015, the Company's Chief Executive Officer and Chief Financial and Business Officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is 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.

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $6.5 million for the three months ended March 31, 2015, $34.2 million for the year ended December 31, 2014, $18.0 million for the year ended December 31, 2013 and $19.7 million for the year ended December 31, 2012. As of March 31, 2015, we had an accumulated deficit of $98.3 million. To date, we have financed our operations primarily through private placements of our common stock and preferred stock and convertible bridge notes, venture debt borrowings and our initial public offering, or IPO, and, to a lesser extent, from a collaboration. All of our revenue to date has been collaboration revenue, which we first began to generate in 2013. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and, beginning in 2012, clinical trials. We are still in the early stages of development of our product candidates, and we have not completed development of any drugs. 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.

We anticipate that our expenses will increase substantially as compared to prior periods in connection with conducting our pivotal Phase 3 clinical program, consisting of two Phase 3 clinical trials evaluating the safety and efficacy of EBI-005, our most advanced product candidate, for the treatment of moderate to severe dry eye disease and a separate clinical trial evaluating the safety of treatment with EBI-005 for one year, and, if successful, seeking marketing approval for EBI-005 for this indication in the United States. We began randomizing and treating patients in our first Phase 3 trial in January 2014.

We received scientific advice from the European Medicine Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, that indicates that the requirements for European registration in dry eye disease will differ from the requirements for registration in the United States and our pivotal Phase 3 clinical program is not consistent with the advice of the CHMP. We plan to further discuss with the EMA a registration plan for EBI-005 in moderate to severe dry eye disease for the European Union. We may be required to conduct additional clinical trials to support an application for marketing approval of EBI-005 in the European Union. We anticipate that our expenses will increase substantially if we pursue, alone or in collaboration with third parties, the development of and seek marketing approval for EBI-005 for the treatment of moderate to severe dry eye disease in the European Union.

Our expenses will also increase if and as we:

- pursue the development of EBI-005 for the treatment of allergic conjunctivitis or additional indications or for use in other patient populations or, if it is approved, seek to broaden the label for EBI-005;
- continue the research and development of our other product candidates, including EBI-031 for the treatment of diabetic macular edema;
- seek to discover and develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies for the treatment of ophthalmic diseases;
- 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;
- hire additional clinical, quality control, scientific and management personnel;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and planned future commercialization efforts and our operations as a public company; and
- increase our insurance coverage as we expand our clinical trials and commence commercialization of EBI-005.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase substantially if:

- we are required by the United States Food and Drug Administration, or FDA, or EMA to perform studies in addition to those currently expected; or
- if there are any delays in enrollment of patients in, continuing or completing our clinical trials or the development of EBI-005 or any other product candidates that we may develop.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, EBI-005, which we do not expect will occur before 2017, if ever. This will require us to be successful in a range of challenging activities, including:

- completing and obtaining favorable results from our pivotal Phase 3 clinical program for EBI-005 for the treatment of moderate to severe dry eye disease;
- subject to obtaining favorable results from our pivotal Phase 3 clinical program for EBI-005, applying for and obtaining marketing approval for EBI-005 in the United States;
- establishing sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties, to effectively market and sell EBI-005 in the United States;
- initiating and obtaining favorable results from registration trials of EBI-005 for the treatment of moderate to severe dry eye disease in the European Union;
- subject to obtaining favorable results from registration trials for EBI-005 in the European Union, applying for and obtaining marketing approval for EBI-005 in the European Union;
- establishing collaboration, distribution or other marketing arrangements with third parties to commercialize EBI-005 in markets outside the United States;
- achieving an adequate level of market acceptance of EBI-005;
- protecting our rights to our intellectual property portfolio related to EBI-005; and
- ensuring the manufacture of commercial quantities of EBI-005.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly completing our pivotal Phase 3 clinical program evaluating EBI-005 for the treatment of moderate to severe dry eye disease and, if successful, seeking marketing approval for EBI-005. We expect to devote additional financial resources to the clinical development of EBI-005 as we initiate and conduct additional clinical trials of EBI-005 for the treatment of dry eye disease in the European Union and for the treatment of allergic conjunctivitis or other diseases and to functions associated with operating as a public company. We also expect to devote additional financial resources to conducting research and development, if we determine to proceed into clinical development, initiating clinical trials of, and seeking regulatory approval for, our other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we would need to devote substantial financial resources to commercialization efforts, including product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

- the progress, costs and outcome of our pivotal Phase 3 clinical program for EBI-005 and of any clinical activities for regulatory review of EBI-005 outside of the United States;
- the costs and timing of process development and manufacturing scale up and validation activities associated with EBI-005;

- the costs, timing and outcome of regulatory review of EBI-005 in the United States, the European Union and in other jurisdictions;
- the costs and timing of commercialization activities for EBI-005 if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;
- subject to receipt of marketing approval, the amount of revenue received from commercial sales of EBI-005;
- the progress, costs and outcome of developing EBI-005 for the treatment of additional indications or for use in other patient populations, including any clinical trials to assess the potential therapeutic benefit of EBI-005 for the treatment of allergic conjunctivitis;
- our ability to establish collaborations on favorable terms, if at all, particularly licensing, manufacturing, marketing and distribution arrangements for our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and, if we determine to proceed into clinical development, clinical trials of our other product candidates;
- the success of our collaboration with ThromboGenics;
- 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; and
- the extent to which we in-license or acquire rights to other products, product candidates or technologies for the treatment of ophthalmic diseases.

As of March 31, 2015, we had cash and cash equivalents of $45.5 million. We believe that our cash and cash equivalents as of March 31, 2015 will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into 2016, without giving effect to any potential milestone payments we may receive under our existing collaboration and license agreement with ThromboGenics. 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. We are planning to spend significant funds to complete our Phase 3 clinical program evaluating EBI-005 and to submit a Biologics License Application, or BLA, to the FDA seeking approval of EBI-005 for the treatment of dry eye disease in the United States by the end of 2016. We also are planning to spend significant funds on other development programs, including possible additional clinical trials of EBI-005 for the treatment of allergic conjunctivitis. At this time we cannot reasonably estimate the remaining costs necessary to prepare and submit the BLA seeking approval of EBI-005 and commercialize EBI-005 for the treatment of dry eye disease, including commercial manufacturing of EBI-005, or the nature, timing or costs of the efforts necessary to complete the development of EBI-005 for the treatment of allergic conjunctivitis or another disease or to complete the development of any other product candidate we may develop.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of EBI-005 or any other products that we successfully develop, none of which we expect to be commercially available for several years, if at all. In addition, if approved, EBI-005 or any other product candidate that we develop or any product that we in-license may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

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 funding under our existing collaboration and license agreement with ThromboGenics in the form of research funding. Under this collaboration, we also may receive potential milestone payments upon the achievement of specified development, regulatory and other milestones and royalties with respect to future sales of collaboration products by ThromboGenics. ThromboGenics may terminate our existing collaboration for convenience on short notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. For example, in December 2014, we issued and sold in a private placement an aggregate of 1,743,680 shares of our common stock, plus warrants to purchase a total of 871,840 additional shares of common stock, which resulted in dilution to our existing stockholders. And in April 2015, we issued and sold 1,251,784 shares of our common stock, which resulted in dilution to our existing stockholders.

Debt financing and preferred 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. Our pledge of specified assets as collateral to secure our obligations under our existing loan and security agreement with our venture debt lender, Silicon Valley Bank, may limit our ability to obtain additional debt financing.

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.

Our limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

We are an early-stage company. We were incorporated and commenced active operations in early 2008, and our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and, beginning in 2012, conducting clinical trials of EBI-005. All of our product candidates, other than EBI-005, are still in preclinical development. We have not yet demonstrated our ability to successfully complete a pivotal Phase 3 clinical trial, obtain marketing approvals, manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to the Discovery and Development of Our Product Candidates

We depend heavily on the success of EBI-005, our most advanced product candidate, which we are developing for the treatment of moderate to severe dry eye disease. If we are unable to successfully complete our pivotal Phase 3 clinical program and obtain marketing approvals for EBI-005, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize EBI-005, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of EBI-005 for the treatment of patients with moderate to severe dry eye disease and for other disease indications. There remains a significant risk that we will fail to successfully develop EBI-005. In 2013, we completed a Phase 1b/2a clinical trial to evaluate the safety, tolerability and biological activity of EBI-005 in patients with moderate to severe dry eye disease. In 2014, we completed a Phase 2 clinical trial to evaluate the safety, tolerability and biological activity of EBI-005 in patients with allergic conjunctivitis. Our pivotal Phase 3 clinical program in dry eye disease will consist of two Phase 3 clinical trials evaluating EBI-005 for the treatment of moderate to severe dry eye disease and a separate clinical trial evaluating the safety of treatment with EBI-005 for one year. We began randomizing and treating patients in our first Phase 3 trial in January 2014 and completed enrollment in October 2014. We do not expect to have initial, top-line data from our first Phase 3 trial available until the second quarter of 2015. The timing of the availability of such top-line data and the completion of our pivotal Phase 3 clinical program is dependent, in part, on our ability to locate and enroll a sufficient number of eligible patients in our pivotal Phase 3 clinical program on a timely basis. Even if the results of both of our Phase 3 clinical trials evaluating EBI-005 for the treatment of moderate to severe dry eye disease and our separate safety trial are favorable, we do not plan to submit a BLA to the FDA seeking approval of EBI-005 for the treatment of dry eye disease in the United States by the end of 2016. We cannot accurately predict when or if EBI-005 will prove effective or safe in humans or whether it will receive marketing approval. Our ability to generate product revenues, which we do not expect will occur before 2017, if ever, will depend heavily on our obtaining marketing approval for and commercializing EBI-005.

The success of EBI-005 will depend on several factors, including the following:

- completing and obtaining favorable results from our pivotal Phase 3 clinical program for EBI-005;
- initiating and obtaining favorable results from registration trials of EBI-005 for the treatment of moderate to severe dry eye disease in the European Union;
- applying for and receiving marketing approvals from applicable regulatory authorities for EBI-005;
- making arrangements with third-party manufacturers for commercial quantities of EBI-005 and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of EBI-005, if and when approved, whether alone or in collaboration with others;
- acceptance of EBI-005, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, including the existing standard of care;
- maintaining a continued acceptable safety profile of EBI-005 following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio related to EBI-005.

Successful development of EBI-005 for additional indications, such as allergic conjunctivitis, or for use in broader patient populations and our ability, if it is approved, to broaden the label for EBI-005 will depend on similar factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize EBI-005, which would materially harm our business.

If clinical trials of EBI-005 or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of EBI-005 or any other product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including EBI-005, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We will be required to demonstrate the safety of treatment with EBI-005 for one year in a separate safety trial in order to support marketing approval of EBI-005 for the treatment of dry eye disease in the United States. To meet this requirement, we initiated a safety trial with no fewer than 100 patients who will be treated with EBI-005 for one year. We cannot predict the results of this safety trial because we have no clinical data on the safety of EBI-005 when administered for a period longer than six weeks and only limited clinical safety data on the effects of EBI-005 when formulated with the vehicle being used in our pivotal Phase 3 clinical program.

In general, the FDA requires two adequate and well controlled clinical trials demonstrating effectiveness on two primary endpoints for marketing approval of a dry eye disease drug. One of these co-primary endpoints must be a sign of dry eye disease and the other must be a symptom of dry eye disease. We are not aware of any investigational dry eye disease drug in development that has met these criteria. Regulatory authorities outside the United States, in particular in the European Union, have not issued public guidance on the requirements for approval of a dry eye drug. We have received scientific advice from the CHMP regarding European registration requirements for EBI-005 for the treatment of moderate to severe dry eye disease. The scientific advice indicates that the requirements for registration in the European Union will differ from the requirements for registration in the United States and our pivotal Phase 3 clinical program is not consistent with the advice of the CHMP. Our pivotal Phase 3 clinical program also may not be sufficient to support an application for marketing approval in other jurisdictions outside the United States.

Our Phase 1b/2a trial evaluated EBI-005 for the treatment of moderate to severe dry eye disease. In our Phase 1b/2a trial, neither of the doses of EBI-005 tested achieved statistically significant superiority compared to vehicle control based on any primary or secondary efficacy endpoints, including those we intend to use for our Phase 3 clinical trials.

Retrospective subgroup analyses that we performed on the results of our Phase 1b/2a clinical trial may not be predictive of the results of our pivotal Phase 3 clinical program. We have based many elements of the design of the protocol for our Phase 3 clinical trials on retrospective subgroup analyses, including our expected use of improvement in pain and discomfort as measured by the painful or sore eyes question of the ocular surface disease index, or OSDI, as the co-primary endpoint measuring a patient symptom. In our Phase 1b/2a trial, we used total OSDI scores as a secondary efficacy endpoint. Although we believe that the retrospective analyses support our protocol design for our Phase 3 clinical trials and our proposed mechanism of action, retrospective analyses performed after unmasking trial results can result in the introduction of bias, may not be predictive of future study results and are given less weight by regulatory authorities than pre-specified analyses.

We may fail to achieve success in our pivotal Phase 3 clinical program evaluating EBI-005 for the treatment of moderate to severe dry eye disease for a variety of potential reasons.

- The efficacy endpoints in our Phase 1b/2a trial were measured six weeks after the first dose of EBI-005. The co-primary efficacy endpoints in our pivotal Phase 3 clinical program will be measured 12 weeks after the first dose of EBI-005. We have no clinical efficacy data on EBI-005 in any clinical trial longer than six weeks.
- We have made changes to the vehicle we use to formulate EBI-005 for topical, ophthalmic delivery in our Phase 3 clinical trials from the vehicle used in our Phase 1b/2a trial. The most significant change to the vehicle is the removal of carboxymethyl cellulose, or CMC. CMC is a common ingredient in artificial tears. We used our new formulation in our completed Phase 2 clinical trial of EBI-005 in patients with allergic conjunctivitis.
- We will restrict the use of rescue artificial tears by patients in our Phase 3 clinical trials. If the restriction on the use of artificial tears causes discomfort to patients and results in patients' discontinuing their participation in our Phase 3 clinical trials, such discontinuations would harm our ability to complete our Phase 3 clinical trials on a timely basis.

- We changed the eligibility criteria in our Phase 3 clinical trials from the criteria we used in our Phase 1b/2a trial with regard to patient scores on the OSDI. We cannot predict the impact these changes will have on the rate at which patients will be enrolled or randomized in our Phase 3 clinical trials. If these changes slow the rate at which patients are enrolled or randomized compared to the rate we anticipate, the availability of top-line clinical data from our first Phase 3 clinical trial and our completion of our pivotal Phase 3 clinical program will be delayed.
- We plan to conduct our Phase 3 clinical trials at many clinical centers that were not included in our Phase 1b/2a trial. The introduction of new centers, and the resulting involvement of new treating physicians, can introduce additional variability into the conduct of the trials in accordance with their protocols and may result in greater variability of patient outcomes, which could adversely affect our ability to detect statistically significant differences between patients treated with EBI-005 and vehicle control.

If, in our first Phase 3 clinical trial, we do not demonstrate a statistically significant improvement from baseline in the EBI-005 treatment group on a pre-specified co-primary endpoint, but we do demonstrate a statistically significant improvement from baseline in the EBI-005 treatment group on one of our secondary endpoints, we may decide to substitute that secondary endpoint for the co-primary endpoint in our second Phase 3 clinical trial prior to initiation of our second Phase 3 clinical trial. Whether this substitution and combination of results would be an acceptable means of meeting the FDA's requirement that we duplicate in two adequate and well controlled clinical trials a statistically significant improvement on a clinically relevant sign and symptom would be a review issue at the time of our application for marketing approval. If the FDA does not find this to be an acceptable means of meeting the requirements for marketing approval, we will not receive marketing approval for EBI-005, and we will have to conduct another Phase 3 clinical trial if we wish to seek marketing approval for EBI-005 in the future.

The protocols for our pivotal Phase 3 clinical program and other supporting information are subject to review by the FDA and regulatory authorities outside the United States. The FDA or other regulatory authorities may request additional information, require us to conduct additional non-clinical trials or require us to modify our pivotal Phase 3 clinical program, including its endpoints or patient enrollment criteria, to receive clearance to initiate such program or to continue such program once initiated.

In November 2013, we submitted to the FDA the protocol for our first pivotal Phase 3 clinical trial of EBI-005 and data supporting our change to a larger-scale manufacturing process for the production of EBI-005 to be used in this Phase 3 clinical trial. We submitted the protocol for our separate safety study to the FDA and intend to submit the protocol for our second pivotal Phase 3 clinical trial to the FDA prior to initiation of that trial. The FDA is not obligated to comment on our submissions within any specified time period or at all or to affirmatively clear or approve any clinical trial, and we are not obligated to wait for clearance or approval of the FDA to commence any clinical trial. We initiated our first pivotal Phase 3 clinical trial in the United States in January 2014 without waiting for comments from the FDA. On March 24, 2014, we received a letter from the FDA requesting additional information regarding the characterization of EBI-005 produced using our larger-scale manufacturing process based on the FDA's product quality review of our November 2013 submission. We have responded to the FDA with the information the FDA requested. If the FDA is not satisfied with our responses, the FDA may delay our continuation of our first Phase 3 clinical trial or our initiation of our second Phase 3 clinical trial. If our Phase 3 program is placed on clinical hold by the FDA, we may be significantly delayed and incur significantly greater expense in our proposed development program. For example, our Phase 1b/2a trial of EBI-005 was placed on clinical hold between September 6, 2012 and October 29, 2012 until we provided particular manufacturing stability information regarding the drug product lots intended to be used in our clinical studies.

We submitted to the EMA a draft protocol for our Phase 3 clinical program of EBI-005 for the treatment of moderate to severe dry eye disease and sought and received scientific advice from the CHMP regarding European registration requirements for EBI-005. The scientific advice received indicates that the requirements for European registration in dry eye disease will differ from the requirements for registration in the United States and our pivotal Phase 3 clinical program is not consistent with the advice of the CHMP. We plan to further discuss with the EMA a registration plan for EBI-005 in moderate to severe dry eye disease for the European Union. The EMA may require us to conduct other clinical trials, in addition to those included in our Phase 3 clinical program, in order to support an application for marketing approval of EBI-005.

We also are required to submit our plans for clinical trials to each national regulatory authority in the European Union having jurisdiction over a country in which we wish to conduct these clinical trials. These national regulatory authorities are not obligated to follow the scientific advice of the EMA and may impose additional requirements on our conduct of clinical trials of EBI-005 in order to initiate clinical trials and support our application for marketing approval of EBI-005. If we are required by the EMA or a national regulatory authority in the European Union to conduct other clinical trials, in addition to those included in our Phase 3 clinical program, our expenses will increase substantially, and we may experience delays in completing the development and commercialization of EBI-005 in the European Union.

We have not received guidance from other regulatory authorities outside the United States regarding the design of our pivotal Phase 3 clinical program. We may not receive clearance from the EMA or other national regulatory authorities in the European Union or other regulatory authorities outside the European Union to initiate our pivotal Phase 3 clinical trials on a timely basis, if at all. Our Phase 2 trial of EBI-005 for the treatment of allergic conjunctivitis was conducted in Canada. We have not submitted an investigational new drug application, or IND, to the FDA for the purpose of conducting clinical trials of EBI-005 for the treatment of allergic conjunctivitis. We must submit an IND to the FDA before commencing clinical trials of EBI-005 for the treatment of allergic conjunctivitis in the United States. Submission of the IND may not result in the FDA allowing clinical trials to commence.

In our Phase 2 clinical trial of EBI-005 in patients with allergic conjunctivitis, we designed the Phase 2 study to evaluate the safety and efficacy of EBI-005 compared to vehicle-control in two models of allergen challenge adapted to evaluate the late phase response of allergy. The two models were a modified environmental exposure chamber model, or EEC, and a modified direct conjunctival allergen challenge model, or CAPT. Neither the modified CAPT nor the modified EEC has been used as the basis for approval by the FDA of any other treatment for allergic conjunctivitis. We met with the FDA's Division of Transplant and Ophthalmology Products in February 2015 to discuss these results and our plans for a pivotal Phase 3 clinical program. Based in part on the discussions at that meeting and the scientific advice we received from the European Medicine Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, we now believe that the CAPT model alone is not an appropriate model for the conduct of our pivotal clinical trials. We intend to use a natural environmental study design for further clinical development of EBI-005 for the treatment of allergic conjunctivitis. We have no clinical efficacy data on EBI-005 in a natural environmental study.

We believe that our pivotal Phase 3 clinical program in allergic conjunctivitis will consist of two Phase 3 clinical trials evaluating EBI-005 for the treatment of moderate to severe allergic conjunctivitis and a separate clinical trial evaluating the safety of treatment with EBI-005. If we cannot use the results of our separate safety study of EBI-005 in our Phase 3 clinical program in dry eye disease to satisfy the requirement for a separate safety study of EBI-005 in allergic conjunctivitis, we could experience a delay in completing our Phase 3 clinical program in allergic conjunctivitis and we would incur additional costs to complete this Phase 3 clinical program.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize EBI-005 or any other product candidates that we may develop, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for EBI-005 or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as EBI-005, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of EBI-005 or any other product candidates that we may develop, we may need to abandon or limit our development of EBI-005 or such other product candidates.

If EBI-005 or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Although EBI-005 was generally well tolerated in our Phase 1b/2a dry eye trial and Phase 2 allergic conjunctivitis trial, we have no clinical safety data on exposure to EBI-005 for longer than six weeks. We have limited clinical safety data on patient exposure to EBI-005 formulated with the vehicle we are using in our Phase 3 dry eye clinical trials. Many compounds that initially showed promise in clinical or early stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound.

We may not be successful in our efforts to use our AMP-Rx platform to build a pipeline of product candidates.

A key element of our strategy is to use our proprietary AMP-Rx platform to rationally design, engineer and generate a pipeline of novel protein therapies and progress these therapies through clinical development for the treatment of a variety of ophthalmic diseases. Our research and development efforts to date have resulted in a pipeline of additional product candidates directed at the treatment of ophthalmic diseases. Other than EBI-005, our product candidates all are in early preclinical research and have not been tested in humans. These and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our technological approach, we will not be able to obtain product revenues in future periods.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Risks Related to the Commercialization of Our Product Candidates

Even if EBI-005 or any other product candidate that we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for EBI-005 may be smaller than we estimate.

If EBI-005 or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Current treatments that are used for moderate to severe dry eye disease include low cost artificial tears, Restasis and low cost, off-label use of corticosteroids. These treatments are well established in the medical community, and doctors may continue to rely on these treatments rather than EBI-005, if and when it is approved for marketing by the FDA. In addition, it is possible that the FDA may approve generic versions of Restasis in the foreseeable future. If generic versions of Restasis are approved for marketing by the FDA, they would likely be offered at a substantially lower price than EBI-005. As a result, healthcare professionals and third-party payors may choose to rely on such products rather than EBI-005. If EBI-005 does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of EBI-005 or any other product candidate that we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments, including the existing standard of care;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, particularly by Medicare in light of the prevalence of dry eye disease in persons over age 55;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Our assessment of the potential market opportunity for EBI-005 is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. If the actual market for EBI-005 is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing EBI-005 or any other product candidates that we may develop if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

In the future, we plan to build a focused sales and marketing infrastructure to market or co-promote EBI-005 and possibly other product candidates that we develop in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of EBI-005 or any other product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize EBI-005 or any other product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We expect to enter into arrangements with third parties to perform sales, marketing and distribution services in markets outside the United States. We may also enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States or if we determine that such third-party arrangements are otherwise beneficial. Our product revenues and our profitability, if any, under any such third-party sales, marketing or distribution arrangements are likely to be lower than if we were to market, sell and distribute EBI-005 or any other product candidates that we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute EBI-005 or any other product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market EBI-005 or our other product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing EBI-005 or any other product candidates that we may develop.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to EBI-005 and our other current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

The current standard of care for dry eye disease includes artificial tears and topical anti-inflammatory and immune-modulating drugs. The anti-inflammatory and immune-modulating drug market for the treatment of moderate to severe dry eye disease consists primarily of Restasis, which is approved for use in the United States, and off-label use of corticosteriods. Some patients with moderate to severe dry eye disease are effectively treated by the current standard of care therapies, some of which are available in generic form or offered at relatively low prices. There are also a number of products and therapies in preclinical research and clinical development by third parties to treat dry eye disease. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. These companies include pharmaceutical companies, biotechnology companies, and specialty pharmaceutical and generic drug companies of various sizes, such as Santen Pharmaceutical Co., Ltd. (Ikervis, received approval of Marketing Authorization Application (MAA) from the European Commission (EC) on March 25, 2015), Shire Plc (lifitegrast), Mimetogen Pharmaceuticals Inc. (MIM-D3), Allergan, Inc. (AGN-195263 and Restasis-X, a new formulation of Restasis), Alcon Research (LME-636), Kala Pharmaceuticals, Inc. (loteprednol mucous prenetrating particle (KPI-121)), RegeneRx Biopharmaceuticals, Inc. (RGN-259), Ocular Technologies SARL (OTX-101), Ocular Therapeutics, Inc. (OTX-DP), Herantis Pharma Plc (Cis-urocanic acid (Cis-UCA)), Mitotech SA (SkQ1), Winston Laboratories, Inc. (Civamide nasal spray), Xigen SA (XG-104) and Parion Sciences, Inc. (P-321).

In 2013, the peer-reviewed journal *JAMA Ophthalmology* published the results of an exploratory clinical trial in 75 patients conducted by one of our scientific co-founders, Dr. Reza Dana, at the Massachusetts Eye and Ear Infirmary using anakinra to treat patients with moderate to severe dry eye disease. Interleukin-1, or IL-1, is the therapeutic target of both anakinra and EBI-005, and the mechanisms of action of anakinra and EBI-005 are very similar. For this proof-of-concept study, the investigators compounded, or reformulated, anakinra in eye drops at two different concentrations for topical administration. The investigators reported positive results from this trial. We believe that the investigators continue to treat dry eye patients using reformulated anakinra. We would face competition with respect to EBI-005 if reformulated anakinra was available commercially through compounding pharmacies or if a third party successfully completed pivotal clinical trials of, and received marketing approval for, reformulated anakinra for the treatment of dry eye disease.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than EBI-005 or other product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. For example, in June 2013, the FDA's Office of Generic Drugs released guidance for the development of generic versions of Restasis. If EBI-005 or any other product candidate that we may develop achieves marketing approval, we expect that it will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize EBI-005 or any other product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize EBI-005 or any other product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for EBI-005 or any other product that we commercialize and, even if they are available, the level of reimbursement may not be satisfactory.

Inadequate reimbursement may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize EBI-005 or any other product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

There can be no assurance that our product candidates or any products that we may in-license, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage and an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our strategy of obtaining rights to product candidates and approved products for the treatment of a range of ophthalmic diseases through in-licenses and acquisitions may not be successful.

We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to other products, product candidates or technologies for the treatment of ophthalmic diseases. The future growth of our business may depend in part on our ability to in-license or acquire the rights to approved products, additional product candidates or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the rights to the relevant product, product candidate or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We face an inherent risk of product liability exposure related to the use of EBI-005 and any other product candidates that we develop in human clinical trials and will face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

We currently hold $5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage as we expand our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of EBI-005 or any other product candidate that receives marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We have entered into one collaboration and in the future may enter into collaborations with other third parties for the development or commercialization of our product candidates, including EBI-005. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

In May 2013, we entered into a collaboration and license agreement with ThromboGenics. Under the agreement, we and ThromboGenics are collaborating to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. This collaboration generally prohibits us, our affiliates and any entities which become affiliates of ours as a result of an acquisition of us by a third party, from researching, developing, manufacturing or commercializing any protein or peptide therapeutic that directly modulates one of the specified targets, except as otherwise provided in the agreement. This restriction may have the effect of preventing us from undertaking development and other efforts that may appear to be attractive to us.

We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to commercialize EBI-005 in markets outside the United States. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States or if we determine that such third-party arrangements are otherwise beneficial. We also may seek third-party collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our existing collaboration with ThromboGenics and any future collaborations that we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If our existing collaboration and license agreement with ThromboGenics, and any future collaborations that we enter into, do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have relied on third parties, such as CROs, to conduct our clinical trials of EBI-005 and do not plan to independently conduct clinical trials of EBI-005 or our other product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third parties for the manufacture of EBI-005 for clinical trials and expect to continue to do so in connection with the commercialization of EBI-005 and for clinical trials and commercialization of any other product candidates that we may develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of EBI-005 or any other of our product candidates. We rely, and expect to continue to rely, on third parties to manufacture clinical and commercial supplies of EBI-005, preclinical and clinical supplies of our other product candidates that we may develop and commercial supplies of products if and when any of our product candidates receives marketing approval. Our current and anticipated future dependence upon others for the manufacture of EBI-005 and any other product candidate or product that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We currently rely exclusively on one third-party manufacturer to supply us with EBI-005 drug substance on a purchase order basis. We also rely on another third-party manufacturer to conduct fill-finish services on a purchase order basis. We do not currently have any contractual commitments for commercial supply of bulk drug substance for EBI-005 or for fill-finish services. We also do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for EBI-005 or for fill-finish services. The prices at which we are able to obtain supplies of EBI-005 drug substance and fill-finish services may vary substantially over time and adversely affect our financial results.

If our third-party manufacturer for EBI-005 drug substance fails to fulfill our purchase orders or should become unavailable to us for any reason, we believe that there are a limited number of potential replacement manufacturers, and we likely would incur added costs and delays in identifying or qualifying such replacements. We could also incur additional costs and delays in identifying or qualifying a replacement manufacturer for fill-finish services if our existing third-party manufacturer should become unavailable for any reason. We may be unable to establish any agreements with such replacement manufacturers or to do so on acceptable terms. Even if we could transfer manufacturing to a different third party, the shift would likely be expensive and time consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before using or selling any products manufactured at that facility.

The FDA maintains strict requirements governing the manufacturing process for biologics. When a manufacturer seeks to modify or make even seemingly minor changes to that process, the FDA may require the applicant to conduct a comparability study that evaluates the potential differences in the product resulting from the change in the manufacturing process. The agency has issued several guidances on this point. In connection with our application for a license to market EBI-005 or other product candidates in the United States, we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth.

Reliance on third-party manufacturers entails additional risks, including:

- EBI-005 and any other product candidates that we may develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices, or cGMP, regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned or licensed patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

We are the exclusive licensee of patent applications owned by The Schepens Eye Research Institute, Inc., or Schepens, that cover methods of treating diseases of the eye using an inhibitor of the inflammatory cytokine IL-1. Even if these applications issue as patents, method-of-treatment patents are more difficult to enforce than composition-of-matter patents because of the risk of off-label sale or use of a drug for the subject method. In addition, European patent law generally makes the enforcement of patents that cover methods of treatment of the human body difficult. In the United States, the FDA does not prohibit physicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute. For example, anakinra is an IL-1 inhibitor that is approved for marketing in the United States and other countries for the treatment of rheumatoid arthritis and is formulated for subcutaneous administration. Anakinra can be re-formulated, or compounded, for topical ophthalmic application. Off-label sales of anakinra or other products comprising an IL-1 inhibitor could limit our ability to generate revenue from the sale of EBI-005.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that EBI-005 or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to a number of license agreements and a collaboration agreement that impose, and, for a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties or make specified milestone payments on net product sales of product candidates or related technologies to the extent they are covered by the agreement. We also are obligated under certain of our existing license agreements to pay maintenance and other fees. We also have diligence and development obligations under certain of those agreements that we are required to satisfy. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory and Marketing Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain required regulatory approvals, we will not be able to commercialize EBI-005 or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize EBI-005 or any other product candidate.

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates, including EBI-005. The failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. The activities associated with the development and commercialization of our product candidates, including EBI-005, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that EBI-005 or any other product candidate that we may develop is not safe, effective or pure, is only moderately effective or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Moreover, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

There are no drugs approved in the European Union and no drugs, other than Restasis, approved in the United States for the treatment of a sign or symptom of moderate to severe dry eye disease. The EMA has not issued any public guidance on the clinical trials that would be sufficient to support an application for marketing approval of a drug to treat dry eye disease. The lack of a defined regulatory pathway in the European Union, the different requirements of the EMA compared with the FDA and the lack of successful development of therapies to treat dry eye disease in both the United States and the European Union may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. If we experience delays in obtaining regulatory approvals, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

Our therapeutic product candidates for which we intend to seek approval as biological products may face competition sooner than expected.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, abbreviated pathways for approval of biosimilar and interchangeable biological products were created. The BPCIA establishes legal authority for the FDA to review and approve biosimilar biologics for marketing, as well as biosimilars that have been designated as “interchangeable” with a previously approved biologic, or reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a full BLA. This period of non-patent exclusivity runs concurrently with, but is independent of, periods of patent protection for the reference product.

We believe that any of our product candidates approved as a biological product under a full BLA should qualify for a 12-year period of exclusivity. However:

- the United States Congress could amend the BPCIA to significantly shorten this exclusivity period as has been previously proposed; and
- a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version.

The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could compromise the future commercial prospects for our biological products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing at both the federal and state levels of government.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market and sell EBI-005 and any other product candidate that we may develop in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we, or any collaborators we may have in the future, obtain marketing approvals for EBI-005 or our other product candidates, the terms of those approvals, ongoing regulations and post-marketing restrictions may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or they obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, if EBI-005 or any other product candidate that we may develop receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and potentially costly post-marketing studies or other clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to a strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates, including EBI-005, for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Recently enacted and future legislation may affect our ability to commercialize and the prices we obtain for any products that are approved in the United States or foreign jurisdictions.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate, including EBI-005, for which we obtain marketing approval or that we may in-license. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any approved products. While the MMA applies only to product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA or other healthcare reform measures may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively PPACA. Among the provisions of PPACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 50% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from afailure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Abbie Celniker, Ph.D., our President and Chief Executive Officer, Gregory D. Perry, our Chief Financial and Business Officer, Eric Furfine, Ph.D., our Chief Scientific Officer, and Karen L. Tubridy, our Chief Development Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval.

As of April 17, 2015, our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 73.5% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on The NASDAQ Global Market on February 6, 2014. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased their shares. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of EBI-005 or any other product candidate that we may develop;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;

- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of ophthalmic diseases, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against that company. We also may face securities class action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize EBI-005. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2014, we had federal net operating loss, or NOL, carryforwards of $84.9 million, state NOL carryforwards of $83.6 million and aggregate federal and state research and development tax credit carryforwards of $1.3 million available to reduce future taxable income. These federal and state NOL carryforwards and federal and state tax credit carryforwards expire at various dates beginning in 2029 through 2034, if not utilized. Utilization of these NOL and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. Under Section 382 of the Code and comparable provisions of state, local and foreign tax laws, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes, such as research and development tax credits, to reduce its post-change income may be limited. We have not completed a study to determine whether our IPO, our most recent private placements of our common stock and warrants to purchase shares of our common stock and other transactions that have occurred over the past three years may have triggered an ownership change limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change NOL and tax credits carryforwards to reduce U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liability to us.

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 April 17, 2015, we had outstanding 19,371,411 shares of common stock. Of these shares, 9,776,861 shares are restricted securities under Rule 144 under the Securities Act. Any of our remaining shares that are not restricted securities under Rule 144 under the Securities Act, including 2,615,520 shares that may be immediately sold pursuant to the registration statement on Form S-1 that we filed on December 19, 2014, or Resale S-1, and shares sold in our IPO, may be resold in the public market without restriction unless purchased by our affiliates.

Moreover, holders of an aggregate of 8,527,827 shares of our common stock 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. On April 9, 2014, we filed a registration statement registering all shares of common stock that we may issue under our equity compensation plans. As of April 17, 2015, we had outstanding options to purchase an aggregate of approximately 1,911,741 shares of our common stock, of which options to purchase approximately 685,476 shares were vested. These shares can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We took advantage of reduced reporting burdens in the 2014 10-K. In particular, the 2014 10-K did not include all of the executive compensation related information that would be required if we were not an emerging growth company. We expect to continue, in our public reporting, to take advantage of some or all of the reporting exemptions available to emerging growth companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to delay such adoption of new or revised accounting standards, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

We incur increased costs as a result of operating as a public company, and our management now is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described in the preceding risk factor. We may remain an emerging growth company until the end of the 2019 fiscal year, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our loan and security agreement with Silicon Valley Bank and any future debt agreements that we may enter into, may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain.

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 three months ended March 31, 2015.

Use of Proceeds

In February 2014, we completed our IPO pursuant to a registration statement on Form S-1 (File No. 333-193131), which the SEC declared effective on February 5, 2014. In the IPO, we issued and sold 5,750,000 shares of common stock (inclusive of 750,000 shares of common stock sold by us pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a public offering price of $10.00 per share, for aggregate offering proceeds of $57.5 million. The managing underwriters for the IPO were Citigroup Global Markets Inc., Cowen and Company, LLC and Leerink Partners LLC. The IPO commenced on February 6, 2014 and did not terminate until the sale of all of the shares offered.

The aggregate proceeds received by us from the IPO were approximately $50.2 million, net of underwriting discounts and commissions and estimated offering expenses payable by us. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

As of March 31, 2015, we have used approximately $37.9 million of the net proceeds from the initial public offering as follows:

- approximately $18.5 million to fund external research and development expenses for our pivotal Phase 3 clinical program for EBI-005 in patients with moderate to severe dry eye disease;
- approximately $2.2 million to fund external research and development expenses for our Phase 2 clinical trial of EBI-005 in patients with allergic conjunctivitis; and
- approximately $17.2 million for working capital and other general corporate purposes, which includes our internal research and development expenses for EBI-005, development of our preclinical product candidates and pursuit of other research and discovery efforts.

Purchase of Equity Securities

We did not purchase any of our registered equity securities 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.

None.

Item 6. Exhibits

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

SIGNATURES

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

ELEVEN BIOTHERAPEUTICS, INC.

By: /s/ Gregory D. Perry

Gregory D. Perry
Chief Financial and Business Officer (Principal Financial and Accounting Officer)

April 30, 2015

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated By-laws (Incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on April 16, 2015)
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.

Exhibit 31.1

Rule 13a-14(a) CERTIFICATION

I, Abbie C. Celniker, 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(s) 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/ Abbie C. Celniker

Abbie C. Celniker
President and Chief Executive Officer
(Principal Executive Officer)

Dated: April 30, 2015

Exhibit 31.2

Rule 13a-14(a) CERTIFICATION

I, Gregory D. Perry, 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(s) 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/ Gregory D. Perry

Gregory D. Perry
Chief Financial and Business Officer
(Principal Financial Officer)

Dated: April 30, 2015

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 March 31, 2015 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/ Abbie C. Celniker

Abbie C. Celniker
President and Chief Executive Officer
(Principal Executive Officer)

Dated: April 30, 2015

/s/ Gregory D. Perry

Gregory D. Perry
Chief Financial and Business Officer
(Principal Financial Officer)

Dated: April 30, 2015